Principal Investigator (Last, first, middle):

Research Supplement to Promote Diversity in Health-Related Research
Parent Project: Systems Analysis & Improvement to Optimize pMTCT: A Cluster Randomized Trial
Project 1: Lean Methodology & Simulation Tools to Reduce pMTCT Process Time Variation
Diversity Supplement Candidate:

1. ABSTRACT OF FUNDED PARENT RESEARCH

Despite significant increases in global health investment and the availability of low-cost, efficacious interventions designed to reduce mother to child HIV transmission in low and middle income countries with high HIV burden, the translation of these scientific advances into effective delivery strategies has been slow, uneven and incomplete. As a result, pediatric HIV infection remains largely uncontrolled. Enhancing the implementation of pMTCT interventions through contextually appropriate systems analysis and improvement approaches can potentially reduce drop-offs along the pMTCT cascade, leading to dramatic improvements in infant and maternal outcomes. The goal of funded research proposal is to develop a model for systematic assessment and improvement of pMTCT services in sub-Saharan Africa. In specific aim 1, we will identify health system factors and service delivery approaches associated with high and low performing pMTCT services in Côte d'Ivoire, Kenya and Mozambique. In specific aim 2 we will evaluate the feasibility and impact of a systems analysis tool and associated performance enhancement approach for pMTCT services in Côte d'Ivoire, Kenya and Mozambique. This systems analysis tool and associated performance enhancement approach is currently being developed and piloted for pMTCT services in Mozambique. The results of this implementation research are expected to generate knowledge of global health significance, and by disseminating the study results and intervention tools through the broad PEPFAR network, can rapidly impact pMTCT service delivery enhancements across the highest need countries.

2. RESEARCH PLAN

2.a. Specific Aims

The proposed research project will provide lean thinking and simulation tools that can be used during the parent research in order to identify pMTCT cascade inefficiencies and inform performance improvement pMTCT interventions. The proposed research will benefit the parent grant research by providing structured tools that have been used for the last 5 decades in the manufacturing industry[1] to identify causes of system inefficiencies and develop strategies to reduce inefficiencies to improve overall system performance. Our hypothesis is facilities with high pMTCT performance have less inefficiency in their pMTCT cascade and, consequently, have a decreased likelihood for pregnant women to not complete the pMTCT cascade in comparison to sub-optimal pMTCT performing facilities.

Lean thinking and simulation tools are qualitative and quantitative systems analysis tools used in industrial and systems engineering to identify and resolve process inefficiencies. In lean thinking, system inefficiencies are identified as *waste* or *non-value added* activities, which are activities that absorb resources but creates no value.[2] The goal of lean thinking is to eliminate all non-value added activities in the given system.[2] Simulation models are used to study systems to measure their performance, or improve operation or design.[3] The aims of the proposed project are to:

1) Develop lean methodology tools to identify pMTCT process time variation and inefficiencies
2) Develop current as-is and proposed to-be simulation model of the pMTCT cascade

The proposed research is highly novel since industrial and systems engineering approaches have not been used in this proposed manner to improve pMTCT performance in sub-Saharan Africa to date.

2.b Significance

Despite cost-effective, efficacious interventions to prevent pediatric HIV infection, as well as large investments to scale-up pMTCT services in countries with the highest burden of HIV, pediatric HIV infection remains largely uncontrolled.[4] Efforts to expand pMTCT have led to gains in the number of facilities with pMTCT services, reaching 78% of all clinics with ANC in Mozambique,[5] 44% in Côte d'Ivoire,[6] and 58% in Kenya.[7] Despite this expansion, gaps along the pMTCT cascade limit its effectiveness, with low coverage of HIV counseling and testing in the study countries (reaching between 47-72% of estimated HIV-infected women), and low maternal access to ART prophylaxis and triple-therapy for eligible women (44-72% of estimated HIV-infected pregnant women), as well as limited infant access to ART prophylaxis (reaching 33-59% of infants born to identified HIV-infected women in the study countries). Infant feeding practices, low post-partum use of family planning, weak linkages with HIV care, and sub-optimal integration with other effective ANC services further impede pMTCT effectiveness. As a result, pediatric HIV infection continues to be high, with estimated mother-to-child HIV transmission occurring in 24% of babies born to HIV-infected women in Kenya,[7] 29% in Côte d'Ivoire,[8] and, 27% in Mozambique.[9]

There is a recognition that the most critical priority for improving the effectiveness of pMTCT services is to increase the number of women successfully passing through the multiple, sequential steps in the pMTCT cascade, which logically argues for approaches that focus on optimizing existing pMTCT system delivery and related HIV care services to lead to increased access to existing, efficacious interventions.[10] A number of novel systems analysis techniques that have recently been applied to health care settings have the potential to improve health outcomes by identifying and reducing system inefficiencies and improving program effectiveness in complex, multi-step health services, such as the pMTCT cascade.

These tools, such as process and value stream mapping, discrete event simulation, and continuous quality improvement, have been adapted from industrial and systems engineering and manufacturing improvement, and have been effective in leading to dramatic, rapid increases in program efficiency through simple, low cost, iterative adaptations in the service delivery design.[11,12] When these tools are applied to the healthcare industry, the process time and process steps to complete an activity are expected to fall, quality of care improve, and fewer mistakes made, with an accompanied overall cost of healthcare delivery.[2] A common element of systems analysis and improvement is to describe and understand the existing system, identify causes for inefficiencies as part of identifying current problems and risks, and work with frontline staff to generate, implement and assess solutions. Process and value stream mapping engages health managers and workers to describe the discrete, sequential steps in multi- step health service delivery strategies, which then serve as a basis for identifying contextually-appropriate systems innovations to improve system functioning.[13]

A hallmark of systems analysis and improvement approaches is encouraging the participation of frontline health workers in analyzing their system, as well as defining, implementing and evaluating improvement strategies using simple, locally accessible, and relevant data. Previous research, including research from resource limited settings, has found that engaging local health staff in health systems analysis and identification of adaptations for systems improvement leads to subsequent improvement strategies that are more appropriate, effective, and sustainable.[12] Through building a shared understanding of how work is carried out in reality, process mapping helps to build shared organizational values and goals, which has been found, along with the involvement of senior management champions, to be associated with improved health service delivery and patient-level outcomes at the facility level.[14,15]

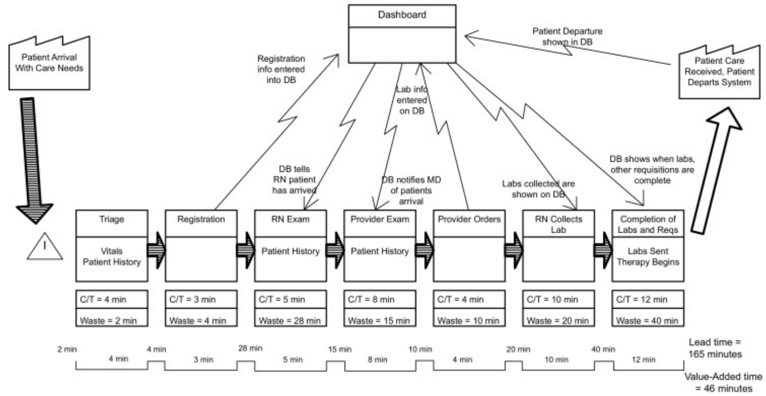
This research project is designed to build on the existing knowledge base and experience with applying systems analysis and improvement approaches to pMTCT programs. The application of simple, dynamic analysis tools by pMTCT staff and health facility managers provides local champions with a systems view of their pMTCT cascade, a process for identifying priority areas for intervention, and a method for jointly identifying program-specific adaptations that are likely have a large impact. Furthermore, the proposed project will combine the knowledge of program and research teams, which is especially important in scaling-up pilot successes that are often geographically confined, uneven or do not continue after the removal of inputs from the initial implementation period. **The development and use of generalizable lean thinking and simulation tools to identify and resolve non-value added activities within the pMTCT cascade in the Mozambique health care delivery system will provide an opportunity to inform application across other sub-Saharan African countries that are working to improve the effectiveness of scaled-up pMTCT programs nationally.**

Aim 1 – Develop lean methodology tools to identify pMTCT process time variation and inefficiencies

The parent project aims to use a systems analysis approach to develop pMTCT interventions processes. Aim 1 of the proposed research project will provide the parent project with lean thinking tools that can be used in systems analysis, primarily to the 'identify, define, and implement facility-specific workflow adaptations to eliminate modifiable bottlenecks' procedural step of the parent research. Lean thinking methods have been used to improve healthcare delivery systems in developed and developing countries.[25-26] The Flinders Medical Centre in Australia found the use of lean thinking tools to improve emergency department patient flows resulted in a significant decrease in both the total length of stay and number of patients who wait for ED services.[16] In 2012, a global emergency medicine study performed in Kumasi, Ghana found that using lean thinking tools helped to facilitate the partnership between researchers and local healthcare frontline staff towards solving healthcare system inefficiencies.[17] Although research will need to be completed in order to identify the specific lean thinking tools that will be developed and used in the proposed research project, value stream mapping and statistical process control charts will be used due to their usefulness in identifying non-value added processes that require attention and resolution.[18]

Value stream mapping is seen by lean practitioners a fundamental tool to identify waste, reduce process cycle times, and implement process improvement.[19] A value stream map illustrates how information and materials flow from the suppliers to the customer in a production or service system, and in the healthcare context, value stream mapping activities identify patient flow bottlenecks (Figure 1).[2] Value-stream mapping will be added to the process flow mapping in the parent project to assess the time variation and mean time around each process step in the pMTCT cascade. Identifying the process steps with the highest mean time and patient wait time variation will help the parent research team staff and frontline health workers discuss approaches to improve patient flow, as well as to assess the relationship between time variation and pMTCT system performance.

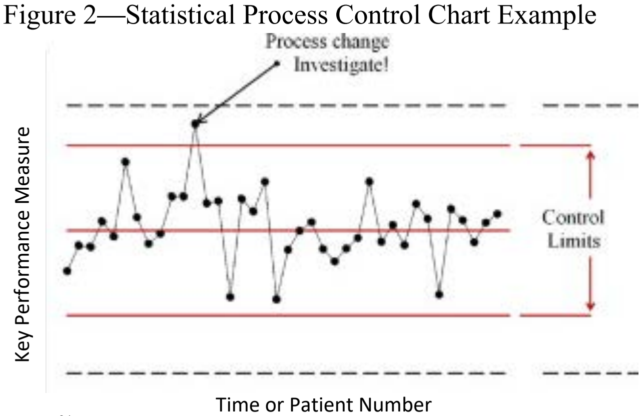
Figure 1—Value Stream Map Example



Source[23] : Dickson, E.W. et al. Application of Lean Manufacturing Techniques in the Emergency Department.

Statistical process control charts are used to monitor a production or service system performance over time and identify when special cause variation occurs (Figure 2).[20] Special cause variation is variation that results from system inefficiencies, such as process time variation that occurs during a shift change or on a certain day of the week. A special cause variation is indicated on the statistical process control chart when a data point exceeds 3σ from the expected value. When a data point exceeds 3 the process is considered to be out of statistical control, and investigation and an improvement strategy is required. An example of performance measures that could be featured in the pMTCT statistical process control chart are pMTCT process cycle time for each patient. The actual performance measure that will be featured on the statistical process control chart will be determined during the environmental assessment activities of the proposed research project. The statistical process control chart will be created before and after the parent research team facilitates the pMTCT process flow mapping and intervention activities so that the research team and facility frontline staff can observe the process time variation before and after the interventions have been implemented. In order for the frontline staff to continue to monitor the performance measure after the research project is complete, a measure system will be created with instructions for data collection and control chart maintenance.

Figure 2—Statistical Process Control Chart Example



Source[24] : Pawlicki, T. et al. The Systematic Application of Quality Measures and Process Control in Clinical Radiation Oncology.

Aim 2 – Develop current as-is and proposed to-be simulation model of the pMTCT cascade

A discrete event simulation tool allows decision makers to model a current system made up of time-based process steps to study and gain a deeper understanding about how system inputs, such as patient volume and process step time, affect outputs, such as resource utilization and average wait time[3]. Examples of pMTCT inputs and outputs are featured in Table 1. Simulation applied to healthcare setting is well-suited to tackle problems where resources are scarce and patients arrive at irregular times, as is typical in pMTCT services.[21,22] The proposed study will develop a generalizable simulation model that can be used to identify and understand current pMTCT inputs causing process bottlenecks. The term “as-is” is used to indicate the

Table 1—Simulation Input & Output Examples

Simulation Model Inputs	Simulation Model Outputs
ANC patient volume	Average patient wait time per process step
ANC patient flow logic	Total patient wait time in pMTCT system
Process step time distribution	Total time patient spends in pMTCT system
pMTCT staff volume	Staff utilization rates
pMTCT staff schedule	

current process before performance improvement interventions are implemented, while the term “to-be” indicates the proposed process after interventions are implemented. The results and findings from the as-is simulation model can inform pMTCT discussion. Once frontline staff identify interventions, the simulation tool can then be used to develop a to-be simulation model in order to test how the interventions improved output measures in comparison to the as-is model. The results from the to-be simulation model will inform pMTCT cascade performance improvement strategies.

2.c. Methods

Study Overview

Lean methodology tools most appropriate for pMTCT intervention identification will be researched and developed in the proposed study and used by the parent research team to identify and eliminate causes for process inefficiencies. The proposed simulation tool will be used as part of the process of testing and assessing the impacts of pMTCT process time improvement interventions. The proposed lean methodology and simulation tools will be first piloted at test facilities in Mozambique to test feasibility and applicability to pMTCT processes. These final tools will have a generalizable design so they can be used at multiple facilities with pMTCT services in different countries. In order to test the feasibility and applicability of the lean methodology and simulation tools, the proposed research project will be a pilot study to take place at test sites in Mozambique, and the results from the test will inform the development of generalizable tools for sites in Mozambique, Cote d’Ivoire, and Kenya.

The proposed research project consists of two specific aims. The tasks listed under each aim will be piloted in Mozambique, and the lessons learned will be used to finalize the generalizable lean methodology and simulation tools. In aim 1, the candidate will research and develop generalizable lean methodology tools that have been used and proven effective in healthcare and manufacturing industries to identify and help reduce process time variation, including but not limited to value stream mapping and statistical process control charts. To complete the value stream map of aim 1 and the simulation model of aim 2, the process and wait time data will be collected. The candidate will develop a data collection tool that will be used to collect pMTCT process and patient wait times. To conclude aim 1, the candidate will compile and analyze the data and use it to complete the value stream map. During aim 2, the candidate will use pMTCT process time data and patient flow and employee workflow logic as inputs into the pMTCT discrete event simulation model.

Procedures

Aim 1: Develop a generalizable, standardized lean methodology toolset

As part of study aim 1, existing research lean methodology, measurement system, and process time data collection tools that are appropriate for identifying pMTCT cascade process inefficiencies will be gathered from the literature. Tool appropriateness will be assessed based on applicability and ease of use for those unfamiliar with lean methodology tools and their usages, and barriers and lessons learned from previous lean thinking applications in healthcare will inform the application of these tools to improve the pMTCT cascade.

After reviewing existing literature, an environmental assessment will be carried out using process flow mapping to identify the main steps in the pMTCT system that will be elaborated in the value stream map. To complete the environmental assessment, the research candidate will shadow and interview the staff during and after the completion of pMTCT services to collect data on pMTCT service staff scheduling and volume, which will serve as the inputs into the as-is simulation model.

After the environmental assessment, lean methodology, measurement system, and process time data collection tools will be developed to incorporate the pMTCT process steps and the types of health workers who provide pMTCT services for the given process step. The research candidate will work with the parent research team to identify the tools to be pilot tested during this phase and to develop standardized work instructions. Subsequently, these tools and work instructions will be piloted at pMTCT services in five health facilities in Mozambique, intentionally selected to represent varying levels of the health system in terms of size and rural/urban location, as well as to be separate from facilities that may be included in the parent cluster randomized trial. During this piloting, the research team will explain the tools requiring to the staff, have the staff perform data collection activities using the tools and standard work instructions, and interview staff while they are using the tools on ways that the tool and standard work instructions can be improved for use. The tools and work instructions will be finalized based on feedback from the pilot application, and translated into English, Portuguese, and French for incorporation into the intervention to be tested as part of the parent project.

In completing the value stream map, a data collection tool will be used by frontline staff/healthcare workers to collect process time data. Process step mean and variation time will be calculated from the collected data, and facility level results will be developed to use as part of the systems analysis approach.

Aim 2: Develop a pMTCT as-is and to-be discrete-event simulation model

After completing the data collection tool in Aim 1, the tool will be used to collect quantitative data on pMTCT process and wait time. The research candidate will work the parent grant research team to determine an appropriate sample size for the process time data collection activities. The process time data will be used as the input into the as-is simulation model and used to determine the process time mean and variation for each step in the pMTCT cascade for the value stream map. The wait time will be used to determine the wait time mean and variation for each step in the pMTCT cascade for the value stream map; the simulation model will calculate wait time based on the inputs. The parent research team will collect data on the percent of patients lost at each step and pMTCT performance. Once the percent of patients lost at each step of the pMTCT cascade, process and wait time have been collected at a Mozambique antenatal care (ANC) facility, linear regression analysis will be used to assess the relationship between pMTCT performance (dependent variable) and process time variation, process time duration, and percent of ANC patients lost at each stage (independent variables). The process steps with the highest mean time and/or variation will be identified, and a summary of the value stream map findings will be drafted. Subsequently, process time data and environmental assessment information will be used to build an as-is pMTCT simulation model. ARENA ® simulation software will be used to model the as-is and to-be pMTCT process. This as well as the steps listed above will be completed before the research team begins facilitating the pMTCT intervention / improvement discussion so that the data analysis and as-is simulation output results can be shared with frontline staff and the results can be used to better inform the development of improvement interventions.

After the research team and frontline staff develop interventions and create the to-be process flow map, the next step is to translate the to-be process flow map into to-be simulation model. The simulation model output results will be shared with frontline health workers to demonstrate how their proposed improvements could impact pMTCT process time, in order to further guide discussions on where to intervene and which solutions to implement.

Analysis

Linear regression analysis will be used to assess the relationship between pMTCT performance and process step time variation, process step time duration, and percent of ANC patient lost at each step. The results from this study will provide frontline staff as well as future pMTCT researchers with information about factors that impact pMTCT performance.

The Output Analyzer function in the ARENA ® Software Package will be used to test whether the alternative as-is and to-be simulation model output measures, such as total patient wait time and total patient time in the pMTCT cascade, are statistically different. Output analyzer performs a paired-t test comparison on the means of the selected simulation output measures.

3. Career Development & Mentorship Plan

**3.a How proposed activities will expand and foster the research capabilities of the candidate **

aims to use the knowledge and experience gained from this research to establish herself as an industrial engineer and pMTCT researcher in global health. The proposed research will improve her ability to write a grant, conduct a study, publish her findings in a peer-reviewed journal, and present her work at conferences, which will ultimately introduce her to the global health research community. Working in collaboration with well-established global health researchers will prepare her for future work in developing and implementing performance improvement interventions.

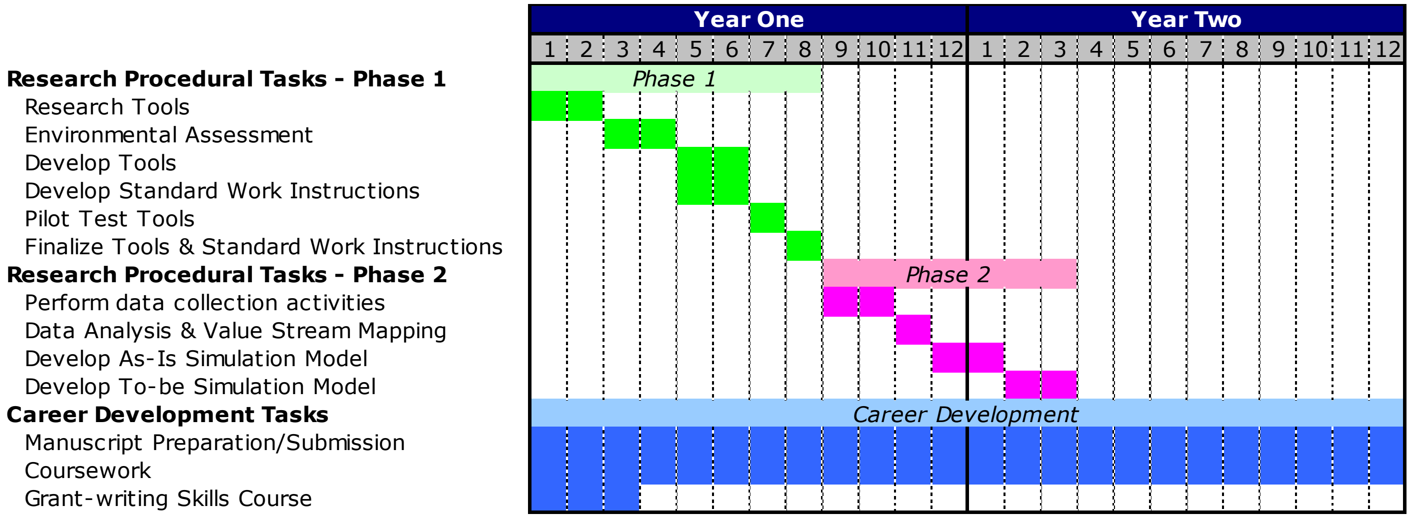
3.b Description of the Mentor Team

is an Assistant Professor in Global Health at the University of Washington, with adjunct appointments in the Department of Industrial & Systems Engineering and Epidemiology.

Chair of the Industrial & Systems Engineering Department at the University of Washington. As PI of the parent project, Dr. will serve as the primary mentor to ensure that Ms. is well integrated into project activities. Dr. Storch will provide mentorship on the development and application of Industrial & Systems Engineering methodologies. Drs. will meet semi-monthly with Ms. in person or via phone to discuss progress and support Ms. research and coursework.

3.c Course work in Global Health

Table 2—Research & Career Development Timeline



In addition to obtaining her PhD in industrial & Systems Engineering, Ms. has begun taking core courses from the School of Public Health at the University of Washington's. The candidate aims to pursue a Masters in Public Health, with an emphasis in Global Health, and will attend courses on epidemiologic methods, biostatistics, implementation science, management and leadership. The proposed research work will serve as the basis for Ms. thesis.

3.d Career development activities

Presentations: Ms. plans to present her research at both industrial and systems engineering and global health conferences, such as Institute for Industrial Engineering Annual conference, International AIDS Society meeting, and NIH Dissemination and Implementation scientific meeting.

Manuscript Development: Ms. plans to publish at least one manuscript based on her work in a high impact, peer reviewed journal that houses similar implementation oriented material with readership from both the global health and industrial and svstems engineering fields.

Collaborative Meetings: Ms. will be integrated into ongoing implementation science meetings and workshops at the University of Washington, including those of the Department of Global Health (including the Center for AIDS Research, Health Alliance International, the International Training and Education Center for Health, and the Institute for Health Metrics and Evaluation). These meetings offer opportunities for faculty, staff and students to share activities and discuss methodological aspects in implementation science, as well as foster synergies.

Grant Writing Skills: will attend Grant Writing Workshops offered at the University of Washington. She will also receive expert career development and grant writing guidance from her mentors in applying for career development grants.

4. CONTRIBUTIONS TO THE PARENT PROJECT

The proposed supplementary research project will contribute to the parent research project by providing relevant tools (such as lean methodology and simulation tools) that will help identify causes for process variation, which can help navigate the discussion with frontline health workers to identify intervention areas and process improvements that will improve the pMTCT system performance. The tools will also be useful for frontline health workers to continually monitor performance, which can be used by the frontline staff and healthcare management at the intervention facilities to continue to improve pMTCT performance after the project has ended.

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