

A. Title Preliminary evaluations of the accuracy, usability, and function of an automatic blood pressure monitor for use in the diagnosis and management of pre-eclampsia in low-resource hospitals

B. Investigators

Principal Investigator: Dr. Ronald Mataya, College of Medicine, Blantyre, Malawi

Co-Investigators:

Rebecca Richards-Kortum, PhD, Dept of Bioengineering, Rice University, Houston, TX USA

Maria Oden, PhD, Dept. of Bioengineering, Rice University, Houston, TX, USA

Kelley Maynard, MSE, Rice 360 Institute, Houston, TX, USA

Laura Causey, PhD, Rice 360 Institute, Houston, TX, USA

Investigators' CVs. Please see Appendix 1

C. Institutions under whose umbrella the research project will be conducted

College of Medicine, Blantyre, Malawi

Rice University, Houston, TX, USA

D. Executive Summary

Pre-eclampsia and eclampsia pose a significant threat to the health of mothers globally. The WHO estimates that 50,000 women worldwide die annually as a result of pre-eclampsia or eclampsia [1], with the majority in developing countries. The research team at Rice University has developed Sphygmo, an automatic blood pressure monitor to be used for the monitoring and diagnosis of pre-eclampsia in pregnant women, particularly in low-resource settings where current blood pressure monitoring is limited. This study aims to evaluate the clinical monitoring and diagnostic capabilities of the device in the setting for which it was designed - a low-resource hospital.

This is a **3- phase clinical community trial**. The first two phases are being completed by Rice University in Houston Texas. In phase 1, we will test the blood pressure monitor on healthy women followed by a secondary phase to test the monitor on pregnant women. Phase 3, in Malawi, the study will compare the Sphygmo device to a commercially available automatic blood pressure monitor that has been previously validated for accuracy in pre-eclamptic women and clinical auscultatory measurements taken by observers using a stethoscope and aneroid gauge [2, 3]. The main objective of this study is to determine whether the Sphygmo device correctly identifies instances where systolic and diastolic blood pressures meet the diagnostic criteria for mild or severe pre-eclampsia during monitoring of at-risk mothers.

Additionally, this study aims to understand the occurrence and type of any complications associated with the usability and function of Sphygmo in a resource-limited clinical setting.

The study will include 20 eligible and consenting women at QECH who are clinically identified as at-risk for pre-eclampsia or have already been diagnosed with pre-eclampsia. All participants will undergo the same protocol (monitoring with Sphygmo, the commercially available device, and using the auscultatory method). First, a nurse will fit a Sphygmo device cuff on one arm of the subject and the commercial cuff on the opposite arm. The nurse will program identical alarm thresholds and measurement intervals on the new device. A trained research assistant will be continuously on hand to assist the nurse in the device setup and record the blood pressure measurements and any alarm indications made by each device. Blood pressure measurements by Sphygmo and the commercial device will continue until monitoring is no longer clinically prescribed. All clinical decisions will be made according to the commercial device measurements. In addition, every hour an observer will take a blood pressure reading using the clinical auscultatory method to confirm that the readings of both the commercial device and Sphygmo are accurate.

The key results of the study will be the sensitivity and specificity of the Sphygmo device for identifying blood pressure levels corresponding to mild and severe pre-eclampsia. Additionally, a complication rate will be determined in regards to any user errors or device malfunction. These results will provide information on the performance, use, and usability of the device in its intended setting; this information will also alert the research team of any necessary design modifications for the device. The results of the study will be submitted for publication in a relevant research journal, such as the *American Journal of Obstetrics and Gynecology*.

E. Background/Introduction

Pre-eclampsia is characterized by hypertension and the presence of protein in urine of a pregnant woman and typically appears late in the pregnancy. Women with pre-eclampsia are at an elevated risk for stroke, organ dysfunction, blood clotting issues, pulmonary edema, and eclampsia [4]. Eclampsia is defined as the occurrence of seizures not attributed to other causes in women with pre-eclampsia [5].

The WHO estimates that 50,000 women worldwide die annually as a result of pre-eclampsia or eclampsia [1]. However, the vast majority of cases occur in developing countries where risk of dying from pre-eclampsia or eclampsia is 300 times higher than in the developed world [4].

One major obstacle to the reduction of maternal deaths from pre-eclampsia complications or eclampsia is the difficulty of diagnosis. While the diagnostic criteria for pre-eclampsia are clear in the literature [6, 7], early detection is unavailable in many clinical settings in the developing world. The diagnosis and monitoring of pre-eclampsia relies on measurements of blood pressure and proteinuria [8]. Unfortunately, the repeated use of mercury sphygmomanometry to monitor pre-eclampsia is too time-intensive for most resource-constrained clinical settings.

In the absence of regular measurements to observe the effects of treatment and the condition of the patient, a mother's safety may be compromised.

Further, automatic monitors appropriate for hospital use are prohibitively expensive for the low-resource settings where they are most needed. Standard commercial devices such as the Dinamap ProCare monitor (GE Healthcare) is the only known monitor with an accuracy for pre-eclamptic women that meets the standards of the British Hypertension Society (BHS) and is appropriate for hospital monitoring [2, 3]. Commercial hospital monitors are generally priced in the \$1000-\$2000 range.

F. Justification

Pregnancy-related hypertensive disorders cause 50,000 deaths annually, primarily in the developing world [1]. One major barrier to the diagnosis and management of pre-eclampsia is the time-intensive nature of conventional mercury sphygmomanometry, which is difficult in low-resource settings. There is a need for a blood pressure monitor that can independently monitor blood pressure and alarm if the pressure reaches the diagnostic criteria for mild or severe pre-eclampsia. This device must be shown to have a high level of accuracy and usability in low-resource settings.

G. Objectives of the study

Broad:

A team of engineers from Rice University has recently developed Sphygmo, an ambulatory blood pressure monitor which costs only \$50. This study aims to evaluate the ability of this device to monitor for the development of mild and severe pre-eclampsia in women in a resource-limited setting.

Specific:

- Primary Efficacy Objective: Determine whether the Sphygmo device correctly identifies instances where systolic and diastolic blood pressures meet the diagnostic criteria for mild or severe pre-eclampsia during monitoring of at-risk mothers.
- Primary Usability Objective: Understand the occurrence and type of any complications associated with the usability and function of Sphygmo in a resource-limited clinical setting.

H. Research Methodology/Materials and Methods

i. Study Type

This is a **3- phase clinical community trial**. The first two phases are being completed by Rice University in Houston Texas. In phase 1, we will test the blood pressure monitor on healthy women followed by a secondary phase to test the monitor on pregnant women. Phase 3, in

Malawi, the study will compare the Sphygmo device to a commercially available automatic blood pressure monitor on women who are at-risk for pre-eclampsia or have already been diagnosed with pre-eclampsia.

ii. Study Place

After two initial testing phases conducted in Houston, Texas, we will conduct the pilot study at Queen Elizabeth's Central Hospital in Blantyre, Malawi. Malawi represents an ideal location to conduct such a study as there are approximately 17,000 cases of pre-eclampsia annually.

iii. Study Population

The study will include 20 women in Malawi who are clinically identified as at-risk for pre-eclampsia or have already been diagnosed with pre-eclampsia. These women will either be pregnant or up to 48 hours postpartum. All participants in the study will undergo the same protocol (monitoring with Sphygmo, the commercial device, and using the auscultatory method). All eligible and consenting women will be enrolled in the study if a Sphygmo device and the commercial monitor are available at the time of clinical need for blood pressure monitoring.

iv. Study Period

We anticipate that the clinical assessment in Malawi will take 1-4 months to complete.

v. Sample Size

The Malawi study is a pilot study that is designed to provide data to be able to calculate the number of patients that would be needed in a full clinical trial to evaluate the efficacy of Sphygmo in diagnosing pre-eclampsia. As such, a sample of 10 participants would indicate how large of a sample would be required for the subsequent clinical trial. The sample size of 10 was suggested by collaborating clinical partners and feedback from statisticians. However, due to some patients potentially choosing to end study participation, the study team (researchers and clinical partners) will request a sample size of 20 to ensure the appropriate amount of data is collected.

The inclusion criteria for the clinical study in Malawi:

- Women who have been identified as at-risk for pre-eclampsia or have been diagnosed with pre-eclampsia during a visit to QECH.
- Women who have been clinically identified to benefit from continuous blood pressure monitoring.
- Women ages 18 or older.

The exclusion criteria for the clinical study in Malawi are as follows:

- Pregnant women who have already developed eclampsia.
- Women under age 18.

vi. Data Collection

Data will be collected on paper forms (Appendix 2) as is consistent with current clinical practice. Clinical and/or research personnel will record information, excluding personal identifiers, on a standardized patient monitoring form. After the patient's participation is completed, the research coordinator will collect and scan the form.

The following data points will be collected/processed:

- Patient history variables:
 - *Age*
 - *Gravidity*
 - *Estimated gestational age (or hours since delivery)*
 - *Mode of admission to hospital*
 - *Number of previous antenatal care visits*
- Threshold Accuracy:
 - *True positive (TP): Control device and Sphygmo cross alarm threshold*
 - *True negative (TN): Control device and Sphygmo do not cross alarm threshold*
 - *False positive (FP): Control device does not cross alarm threshold but Sphygmo does*
 - *False negative (FN): Control device crosses alarm threshold but Sphygmo does not*
 - *Sensitivity: $TP/(TP+FN)$ with confidence intervals*
 - *Specificity: $TN/(TN+FP)$ with confidence intervals*
- Usability:
 - *User error: dichotomous variable indicating incidence of nurse error (max 1 per device interaction)*
 - *Total number of Sphygmo device interactions by nurse*
 - *Percent of error-free device interactions by nurses*
- Device Function:
 - *Device malfunction: dichotomous variable indicating incidence of device malfunction (max 1 per device use)*
 - *Total number of device uses*
 - *Percent of malfunction-free device uses*

vii. Data Management and Analysis

Plan for Data Management: The data will be kept on a secure server accessible only to the study personnel. To ensure quality control of all data, we will strengthen the case managements audits that the program conducts to ensure completeness. A research team will be responsible for audits and completeness of the data. The research team will be conducting quarterly supportive supervision and meetings to validate the completeness and accuracy of

the data. For the purposes of our study, we also plan to compile scanned copies of the forms to perform intermittent checks on the accuracy of the database. No patient identifiers will be included when these forms are scanned.

Plan for data analysis: The research team from Rice University will be responsible for all data analysis. Data will be entered stored in a database that will export to a CSV file. We plan to analyze data using Excel and Matlab and associated statistics packages. As a result of this analysis, we hope to calculate accuracy, usability, and functionality of the device during use in a low-resource hospital. The data will be presented as means, sensitivity/specificity, rates, and proportions.

viii. Results Presentation

ix. Dissemination of the Results

The results of this study will be made available to the Ministry of Health, COMREC, the College of Medicine Library, the Department of Paediatrics, and other partners working in maternal health. Findings will be published in academic journals and conference proceedings in an effort to disseminate results to potential end-users. The research findings of this study will be critical in the evaluation of future interventions.

I. Ethical Considerations

Personal identifiers will be removed and confidentiality of the subjects will be strictly preserved. The data will be kept on a secure server accessible only to the study personnel. The study protocol will be approved by the University of Malawi COMREC and the Institutional Review Board of Rice University prior to initiation of the study. A data and safety monitoring plan will also be established under the leadership of the PI at the College of Medicine – University of Malawi. All investigators will be required to take the online *Protecting Human Research Participants* course provided by the NIH Office of Extramural Research. Any loss of patient data will be reported to the University of Malawi COMREC through the PI and to the Institutional Review Board at Rice University. Information will be de-identified to ensure patient confidentiality and data integrity.

Protection of Human Subjects:

All studies involving human subjects will be conducted in a manner that will minimize the risk to the individual, utilize all patient materials for scientifically meaningful purposes, and protect individual rights to confidentiality. The associated clinical protocols will be approved by the University of Malawi COMREC, Blantyre, Malawi and by the Institutional Review Board of Rice University, Houston, TX. All researchers will conform to the standards set forth by the National Institutes of Health regarding experiments involving human subjects.

Potential Benefits of the Proposed Research to Human Subjects and Others:

The primary benefit of this study is the information it will provide to aid in the development of an automatic blood pressure monitor for use in the developing world. Automated, periodic, long-term blood pressure measurement is essential for diagnosing hypertensive disorders such as eclampsia and pre-eclampsia in pregnant women. There is a great need for automatic monitors in very low resource settings to be able to perform this function given high patient volume and low hospital staff numbers. The subject will be simultaneously monitored with an FDA-approved automatic blood pressure monitor, which will inform all clinical decisions during the study.

Recruitment and Informed Consent:

The local PI will be the responsible investigator at the study site. The study protocol will be approved by the University of Malawi, College of Medicine, Research and Ethics Committee (COMREC) and the Institutional Review Board at Rice University prior to initiation of the study.

Our study will use de-identified data. Signed informed consents will be obtained from the subjects prior to the start of any study procedures.

Documentation of the consent process will include the following elements:

- Date and time of consent;
- Topics discussed with the subject (e.g. risk, benefits, etc.); and
- Confirmation that the consent was reviewed, that the subject's questions were answered, and that a signed copy of the consent was provided to the subject.

The consent form will be updated or revised whenever important new safety information is available, whenever the protocol is amended, or whenever any new information becomes available that may affect participation in the study. All consent forms will be kept in a locked cabinet for protection of confidentiality.

J. Possible Constraints

The risks and discomfort associated with participation in this study are no greater than those ordinarily encountered during routine blood pressure monitoring. This includes minor discomfort while the pressure cuff is being inflated.

There is the potential risk of the loss of confidentiality associated with participation in this study. No patient identifiers will be collected by the study. All patient data will be assigned a number to ensure subject confidentiality. All efforts will be made to maintain strict patient confidentiality.

K. Requirements

The study will require the following:

All supplies and equipment will be provided to QECH in Malawi. The commercial monitor will be available for permanent use at the hospital after the study is complete.

L. Budgetary Estimates

Salary Description	Cost
Study Coordinator	\$3,500
Nurse	\$2,000
Total	\$5,500
Direct Costs Total	\$ 5,500
COMREC Fee (10%)	\$550
Total	\$5,550

M. Justification of Budget

N. References

1. World Health Organization. Priority Life-Saving Medicines for Women and Children. 2012; Geneva: WHO.
2. Magee, L.A. et al. (2011). How to manage hypertension in pregnancy effectively. *Br. J. Clin. Pharmacol.* 2011; Vol. 72, Issue 3. 394-401.
3. De Greef, A., Ghosh, D., Anthony, J., & Shennan, A. Accuracy Assessment of the Dinamap ProCare 400 in Pregnancy and Preeclampsia. *Hypertens. Pregnancy* 2010; Vol. 29. 198-205.
4. EngenderHealth. Balancing the Scales: Expanding Treatment for Pregnant Women with Life-Threatening Hypertensive Conditions in Developing Countries. 2007; New York: EngenderHealth, 5.
5. World Health Organization. WHO Recommendations for Prevention and Treatment of Pre-Eclampsia and Eclampsia. 2011; Geneva: WHO.
6. Wagner, L.K. Diagnosis and Management of Preeclampsia. *Am. Fam. Phys.* 2004; Vol. 70, Issue 12. 2317-2324.
7. Turner, J.A. Diagnosis and Management of Pre-eclampsia: An Update. *Int. J. Wom. Health* 2010; Vol. 2. 327-337.
8. Dekker, G. & Sibai, B. Primary, secondary, and tertiary prevention of Pre-eclampsia. *Lancet* 2001; Vol. 357. 209-15.

Appendix 1. Investigator's CVs

Ronald H. Mataya, MD

CONTACT INFORMATION:

Home Address:

26235 Cresthaven Court,
Loma Linda,
CA, 92354
Phone: 909-799-7238

Work Address:

24951 North Circle Drive,
Loma Linda,
CA, 92350
Email: rmataya@llu.edu
Phone: 909-558-4902

Nationality: USA

Ron Mataya worked in Malawi as a clinician, teacher and manager in Obstetrics and Gynecology. As a clinician, he introduced laparoscopic tubal ligation in Malawi having been trained by the Johns Hopkins Program for International Education in Gynecology and Obstetrics (JHPIEGO). He was instrumental in training nurses in obstetrical ultrasonography in the country.

As a member of staff in the Department of Obstetrics and Gynecology at the University of Malawi College of Medicine, he was in the team that introduced community based antenatal care by fielding medical students to rural health units. As Medical Director of the Blantyre Adventist Hospital he led the staff in fund raising which resulted in the expansion of the hospital bed capacity from 25 to 50 beds making the hospital the first fully private tertiary care unit in the country. As the Chairman of the National Health Sciences Committee within the Ministry of Health, Dr Mataya participated in policy development for family planning, HIV/AIDS/STIs, EPI, Malaria, TB and other national health issues.

As Associate Director and then Director for Health Programs at the international head office of the Adventist Development and Relief Agency (ADRA) in the United States, Dr Mataya led in the institutionalization of reproductive health, family planning, maternal and child health and

HIV and AIDS programming in ADRA's programs world wide. He led a team of public health experts in managing, implementing, monitoring and evaluating health programs in 15 countries.

As Chair of the Department of Global Health (2005-2009) at Loma Linda University School of Public Health, Dr Mataya developed interdepartmental collaboration by establishing dual degrees in Global Epidemiology with the Department of Epidemiology and Biostatistics and Global Maternal and Child Health with the Department of Health Promotion and Education.

He has consulted with the Adventist Development and Relief Agency (ADRA) in Rwanda, Kenya, Zimbabwe Cambodia, Tanzania and Ghana, with the Academy for Educational Development (AED)/Africa 2010 Project in Liberia, with the Global Fund in Guyana and Nigeria, with Compassion International in the Philippines. He served as an external consultant on the Zimbabwe Maternal and Perinatal Mortality and Morbidity Study (2006-2009), the results of which were presented at the 2009 conference of the International Federation of Obstetrics and Gynecology.

He is Co-Principal Investigator on a five-year PEPFAR program in a consortium composed of the Johns Hopkins/University of Malawi Research Center, the University of North Carolina/Malawi Project and Loma Linda University School of Public Health "To Support the Scale-up of High Quality HIV Care and Treatment Programs in Malawi through a Strengthened Laboratory Infrastructure." The total funding for the consortium is \$12 million and Loma Linda University's portion is \$3.2 million. The program is managed by the Malawi College of Medicine.

He is Principal Investigator on a CDC-funded Public Health Evaluation to determine the effectiveness of the use of dry blood samples collected by needle prick to measure viral loads in patients on anti-retroviral therapy in Malawi. This is a two-year evaluation research funded at \$530,000 implemented in partnership with the University of North Carolina and the CDC.

He was a consultant with the Liverpool Associates for Tropical Health (LATH) supporting the development of health assessment tools and their application in a district-based HIV/TB Program in three distinct regions of Uganda (south/west, east central and eastern). This project was jointly implemented by Management Sciences for Health (MSH) and LATH. In South Sudan, he served as a consultant in the development of tools to assess primary health care services in the country. In Libya, he was a consultant in supporting the development of policies and services for voluntary counseling and testing and the prevention of mother-to-child transmission of HIV.

Loma Linda University seconded him to the University of Malawi College of Medicine where he currently serves as the head of the department of obstetrics and gynecology while providing support to the CDC/PEPFAR College of Medicine Laboratory Capacity Consortium.

EDUCATION

Hubert Humphrey Fellow in International Health
Policy, Planning and Management – Emory University Rollins
School of Public Health (non-degree)

**August 1996-
August 1997**

Specialized training in OBGYN
Taiwan Adventist Hospital
Taipei, Taiwan

**August, 1985 –
August 1988**

Medical Doctor
West Visayas State University
Iloilo City, Philippines

March, 1981

Bachelors of Science in Biology
Philippine Union College
Manila, Philippines

March, 1977

EMPLOYMENT

Loma Linda University School of Public Health, Loma Linda, California **July 1,
2009-to present**

Associate Professor, Global Health Department

Responsibilities: Teaching classes in maternal and child health, reproductive health, HIV and AIDS and women in development. Director of the Global Maternal and Child Health program in the Department of Global Health

Co-Principal Investigator Malawi College of Medicine Laboratory Capacity Consortium; a 5-year grant funded by PEPFAR through the CDC implemented in partnership with the University of North Carolina, the Johns Hopkins University Malawi Research Center and the Malawi College of Medicine

Senior Lecturer in Obstetrics and Gynecology, 2011 to present: under a special arrangement between the Loma Linda University and the University of Malawi College of Medicine

Responsibilities: teaching medical students, training registrars and conducting research

Head of the Department Obstetrics and Gynecology, February 2012:

Responsibilities: the same responsibilities as above with the addition of leading a team of 10 consultants, 50 nurse/midwives in a unit that delivers over 8,000 babies a year.

Loma Linda University School of Public Health, Loma Linda, California

Chair and Assistant Professor, Global Health Department

**September 2005
- June 30, 2009**

Responsibilities: Coordinating and leading in academic activities for both faculty and students, curriculum and course development, student advising, research, consultancies, class room teaching.

Adventist Development and Relief (ADRA) International, Silver Spring MD

Director for Health

**May 2002 -
September 2005**

Responsibilities: Worked with the health team in providing technical assistance to all USAID-funded projects and upon request to DFID and DANIDA funded projects as well. Worked with the

Planning Bureau and the health team in responding to requests for application (RFAs) released by USAID around the world. Worked with the health team in planning and implementing funded projects around the world. Made recommendations on policy to ADRA administration regarding ADRA's response to Reproductive Health, Family Planning, HIV/AIDS and Child Survival. Served on the Africa Advisory Board for HIV/AIDS response. Led the team in strategic planning for the health sector. Conducted field trainings and workshops in reproductive health and family planning. Successfully expanded the health portfolio's programs by being funded through the President's Emergency Plan for AIDS Relief (PEPFAR) in Kenya and Tanzania. The project was funded for \$10,000,000 and it became ADRA's largest single project.

Adventist Development and Relief (ADRA) International, Silver Spring MD

Associate Director for Reproductive Health

**January 1999-
May 2002**

Responsibilities: Under a USAID grant, developed policies and strategies for the integration of reproductive health and family planning into ADRA programs. Developed strategies for monitoring and evaluating on-going reproductive health and family planning programs with the aim of strengthening them and introducing new methodologies for implementation. Worked with the Reproductive Health Team, established a RH/FP learning group and a website for sharing with the ADRA Network the most recent information in the field. Continue to provide technical assistance to new RH/FP projects funded by USAID through the NGO Networks for Health in Ethiopia, Cambodia, Nicaragua, Malawi, Nepal and Guinea-Conakry.

**Blantyre Adventist Hospital, Malawi
OB/GYN Specialist and Medical Director**

**January 1989 -
July 1996**

Responsibilities: Specialty clinics in obstetrics and gynecology including out-patient and in-patient services such as antenatal care, deliveries, family planning and gynecological surgeries.

Selected achievements: Establishment of a baby friendly unit at the Blantyre Adventist Hospital and the male friendly labor ward in which husbands were allowed to accompany their wives during the process of labor and delivery.

**Hubert Humphrey Fellow in Health Policy, Planning and Management
Emory University Rollins School of Public Health**

**August 1996 -
July 1997**

Responsibilities: Studying Health Policy, Planning and Management in a non-degree program.

**College of Medicine, University of Malawi
Part-time Senior Lecturer**

**June, 1990-
present**

Responsibilities: Ran the OBGYN ultrasound clinic and teaching nurses to do ultrasound. Conducted teaching rounds as well as classroom tutorials.

Blantyre Adventist Hospital, Malawi

Clinical Practice and Medical Doctor

**January, 1989-
1996**

Responsibilities: As part of the clinical practice and medical director, performed general OB/GYN procedures and related services. Was responsible for overseeing a 50-bed general hospital with over 150 staff in all departments. In addition, carried out functions related to human resource planning, recruitment and placement as well as involved in public relations and fund raising.

Taiwan Adventist Hospital, Taiwan

Residence Program in OBGYN

August, 1985-1988

Responsibilities: As Chief Resident was responsible for preparing the residents' duty roster and operating room and emergency room coverage.

Blantyre Adventist Hospital, Malawi

General Practice

**January 1982-
August, 1985**

Responsibilities: Out-patient and in-patient clinical services.

Queen Elizabeth Central Hospital, Malawi

House Officer

**July 1981 to
December 1982**

Responsibilities: An eighteen-month rotation in all the departments at the hospital.

MEMBERSHIPS IN PROFESSIONAL ORGANIZATIONS:

1. Medical Association of Malawi
2. Registered in the Specialists' Registry of the Medical Council of Malawi
3. American Public Health Association
4. Christian Connections for International Health

LANGUAGES:

English as second language, Speaks Chinese, Shona (Zimbabwe) and Chichewa (Malawi)

COMMITTEES:

1. Chairman of the Malawi Health Sciences Research Committee, 1993-1996, continued as member up to 1998
2. Chairman of the National Cancer Society, 1994-1996
3. Member of the Rotary Club of Limbe, 1994-1997
4. Member of the International HIV and AIDS Committee of the General Conference of the Seventh-Day Adventist Church 2002 to present
5. Member of the Rank, Tenure and Promotion Committee at the Loma Linda University School of Public Health

INTERNATIONAL WORK EXPERIENCE:

As Director for Health Programs at ADRA International, supervised different health programs in the following countries: Indonesia (West Timor), Vietnam, Cambodia, Thailand, India, Nepal, Myanmar, Malawi, Kenya, Zambia, Zimbabwe, Uganda, South Africa, Ethiopia, Sudan, Somalia, Ghana, Guinea, Papua New Guinea, Madagascar, Azerbaijan, Armenia, Turkmenistan, Afghanistan, Honduras, Bolivia, Yemen, Peru and Nicaragua

INTERNATIONAL SHORT TERM CONSULTANCIES:

1. JSI Consultant, Mothercare Project Malawi, Uganda and Ghana 1994-1998
2. Malawi Task Force on Safe Motherhood Consultant 1994- 1996.
3. Malawi Task Force on Syndromic Diagnosis and Treatment of STIs
4. World Bank/KPMG Consultant, Cost Analysis of Health Services in Selected Private and Public Hospitals, Malawi, 1998
5. November 2005 – Consultant to ADRA Rwanda – assessing the health components of a Title II Food Security Program
6. Consultant to the Outdoor Therapy Program for post genocide young adults-ADRA Rwanda – November 2005
7. February 2006 – Consultant to ADRA Sweden, assessing a training of trainers program in HIV and AIDS counseling and community support in Kenya, Ghana and Zimbabwe
8. From February 1, 2007 to 2009; consultant for a DFID-funded project at the University of Zimbabwe, Study of maternal and perinatal morbidity and mortality. This was probably the largest study of maternal and perinatal mortality morbidity ever done anywhere in the world. The results of this study were presented at the FIGO conference in Cape Town in 2009.
9. March 1, 2007, ADRA Australia: curriculum development for training of health care workers in Papua New Guinea on both clinical and syndromic diagnosis and treatment of sexually transmitted infections
10. Member of the Academy for Education Development (AED) team to Liberia to assess health education and training institutions in the country. This was funded by USAID under the Africa 2010 project. (April 2007)
11. Member of the World Bank Monitoring and Evaluation Team for Health Facilities Assessment for Africa; 2007/2009
12. Member of the Monitoring Systems Strengthening Team of the Global Fund to Role Back TB, AIDS and Malaria (trained as facilitator of the Monitoring Systems Strengthening Tool (MESST) developed by MEASURE Evaluation for use by the Global Fund, the President's Malaria Initiative and the World Bank); 2007/2009
13. Facilitated MESST workshop in Guyana; January 2008

14. Facilitated MESST workshop in Nigeria; February 2008
15. Assessment of Compassion International's TB Program in the Philippines; July 2009
16. Development of health facilities assessment tools of a USAID/PEPFAR-funded, MSH-implemented project in Uganda; 2010
17. Development of health facilities assessment tools of a USAID-funded project, implemented by LATH in South Sudan; 2010
18. Team member on a USAID-commissioned review of the utilization of the health services provision assessment (HSPA) tools; 2010
19. Consultant to the Reproductive Health Unit of the Malawi Government Ministry of Health on the Maternal Death Review. This is a current assignment. January to October 2013.
20. Consultant to the MACRO-ICF International Health Services Delivery Assessment in Malawi: February to November 2013. This is a current assignment.

INTERNATIONAL TEACHING EXPERIENCE:

1. Taught reproductive health and safe motherhood courses in the Masters in International Development for ADRA's Professional Leadership Institute in Thailand, Costa Rica and Kenya (sponsored by Andrews University, Berrien Springs, Michigan)
2. Under the NGO Networks for Health partnership in Vietnam, worked with the Than Hoa Regional Hospital to develop protocols for infection control in obstetrical care
3. Taught reproductive health courses for the Loma Linda University School of Public Health off-campus program in Peru and Russia – 2007 and 2008
4. Volunteered at the Blantyre Adventist Hospital in Malawi every year (1999-2008)
5. Taught Integrated Community Development class; this is a Loma Linda University School of Public Health MPH class taught in the Philippines and Peru every summer (students and faculty travel to the Philippines) (2006-2009)

ACADEMIC REVIEWS:

1. Proposal reviewer at the NIH in the Fogarty Center for International Programs: under the supervision of Dr Jean McDermott: 2003
2. APHA International Health section reviewer of Reproductive Health, Family Planning and HIV and AIDS abstracts for presentation at the 2007 conference in Washington DC
3. October 2006 – Reviewed two chapters, 8 and 9 in CORE's Community Case Management manual (The CORE Group is a USAID-funded consortium of US-based international NGOs that provides technical assistance to programs in child survival and maternal health)
4. Systematic Review of the Effectiveness of Community-based Primary Health Care; commissioned by the Working Group on Community-based Primary Health Care, International Health Section, APHA: 2007
5. Guest reviewer for the Journal of Women's Issues published at the George Washington University
6. Guest reviewer for the Journal of Cell and Animal Biology
7. Guest reviewer for the Journal of AIDS and Education
8. Reviewer of the 2010 APHA abstracts in the Reproductive Health, Family Planning and HIV and AIDS section for presentation at the Denver Conference.
9. Reviewer of Naomi Baumslag's 1994 text book "International Maternal and Child Health" to prepare for a new edition in 2011
10. Guest reviewer of the Journal of Pediatric Infectious Diseases

11. Guest Reviewer of the BMC Public Health Journal “Prevalence and Correlates of School Truancy Among Pupils in Grades 7 to 10: Results from the 2004 Zambia Global School-based Health Survey”.
12. Guest Reviewer of the Malawi Medical Journal
13. Guest Reviewer of the SAHARA Journal

PRESENTATIONS:

1. Assessing the Impact of a Service Learning Program in an International Setting; by JC Belliard, A. Stromberg and **RH Mataya**; presented at the Service Learning Conference in Portland, Oregon, October 2006
2. The role of Schools of Public Health in Health and Development: presented at the Adventist International Institute of Advanced Studies (AIAS), Silang, Philippines, November 2006
3. Adventist Responses through Health and Development in Africa: paper presented at a Consultation on Adventist work in Africa at Andrews University; sponsored by the Institute of World Missions, October 21, 2007
4. HIV and AIDS prevention needs of Latinos and service providers in California; Stacy Morey, Rosalinda Cano-Hays, RN, Ann Fitzgerald, MPH, Ted C. Morrison, PhD, MPH, Enrique Gomez, MD, Thomas Donohoe BA, Joel Peisinger, Arturo Hernandez, MAS, Jaime Carillo, Allison Wolpoff, MPH, Blanca Lomeli, MD, **Ronald Mataya, MD** and Juan Carlos Belliard, PhD, MPH; presented at the 2008 APHA conference in San Diego, California
5. Maternal mortality in Zimbabwe; a comparison between clinicians’ interpretation of verbal autopsies and a computer generated probabilistic InterVA-M model. Presented at the FIGO conference in October, 2009, in Cape Town, South Africa
6. The role of Christian Health Associations in Health Care in African Countries: using Malawi as a case study. Presented at the Global Health Council in Washington DC on June 16, 2010.
7. Prevention of maternal mortality in a developing country; using Malawi as a case study: presented to physicians at the JFK Memorial Hospital in Indio on April 20, 2011.
8. Presentation at the Canadian Public Health Association Conference: The Malawi Laboratory Capacity Consortium; A Partnership of National and International Academic Institutions. June 21, 2011, Montreal, Canada.
9. A Systematic Assessment of Hospital-based Laboratories in Malawi: Poster presentation at the American Academy of Family Medicine, October 17, 2011, San Diego
10. Performance of laboratories on the 12 sections of the SLIPTA checklist in Malawi by Kundai Moyo, **Ronald Mataya**, Deborah Kamwendo, Hannaniah Moyo, Visopo Harawa, Reuben

Mwenda, Abdoulaye Sarr, Carol Porter, Henry Limula, Isaac Chauwa: Presented at the African Society of Laboratory Medicine Conference in Cape Town, South Africa, December 1 to 7, 2012

11. Lead Consultant on the Report on the Confidential Enquiry into Maternal Deaths in Malawi (2008-2012):presented to the Malawi Ministry of Health on October17, 2013 at the Ministry of Health Reproductive Health Unit

12. Long Term Outcomes for Women After Obstetric Fistula Repair in Malawi: a Qualitative Study by Laura Drew, Ronald Mataya, Jennifer Tang, Jeffrey Wilkinson; Poster presentation at the 5th Consortium of University for Global Health Conference, May 10-12, 2014, Washington DC.

PUBLICATIONS: (Peer reviewed)

1. Muula AS, Ngulube TJ, Siziya S, Makupe CM, Umar E, Prozesky HW, Wiysonge CS, Mataya RH. Gender distribution of adult patients on highly active antiretroviral therapy (HAART) in Southern Africa: a systematic review.

BMC Public Health. 2007 Apr 25;7(1):63 [Epub ahead of print]

PMID: 17459154 [PubMed - as supplied by publisher]

2. Muula AS, Prozesky HW, Mataya RH, Ikechebelu JI.

Prevalence of complications of male circumcision in Anglophone Africa: a systematic review.

BMC Urol. 2007 Mar 2;7:4. Review.

PMID: 17335574 [PubMed - indexed for MEDLINE]

3. Emmanuel Rudatsikira, **Ronald H. Mataya**, Seter Siziya, Adamson S. Muula

The association between bullying and physical fighting among Filipino adolescents: results from the Global School-based Health Survey

Indian Journal of Pediatrics; October 2007

4. Ronald Mataya

The Worth of Malawian Women: A literature review of safe motherhood in Malawi

Malawi Medical Journal; 19 (3): 116-117; September, 2007

5. Adamson Muula, Emmanuel Rudatsikira, **Ronald H. Mataya**, Seter Siziya, John Chipeta, Edward Kataika

Human resources requirements for highly active anti-retroviral therapy scale-up in Malawi

BMC Health Services Research 2007, 7:208

6. Adamson Muula, Emmanuel Rudatsikira, **Ronald H. Mataya**, Seter Siziya

Estimated financial and human resources requirements for the treatment of malaria in Malawi

Malaria Journal 2007, 6:168

7. Adamson Muula, Emmanuel Rudatsikira, **Ronald H. Mataya**, Seter Siziya, Kondwani Chalulu, Joseph I. Ichekebelu, Tharwat Sulaiman

An estimation of operative time requirements for the scaling-up of male circumcision in Malawi
The New Iraqi Journal of Medicine 2008 4 (1) : 40-48

8. Adamson Muula, Emmanuel Rudatsikira, Seter Siziya, **Ronald H. Mataya**

Correlates of cigarette smoking among school-going adolescents in Thailand: findings from the Thai Global Youth Tobacco Survey 2005.

International Archives of Medicine 2008, 1:8

9. Seter Siziya, Adamson S. Muula, Emmanuel Rudatsikira, **Ronald H. Mataya**

Correlates of HIV testing among women in Malawi: results from the Multiple Indicator Cluster Survey (MICS) Tropical Medicine and International Health, Volume 13, No. 11 pp 1-6

10. Jamison, B., Gaede, D., **Mataya, R.**, Belliard, J.

Reflections on Public Health and Service-Learning. (2008). *Academic Exchange Quarterly*. 12(3), 4134-4138.

11. Shalote Chipamaunga, **Ronald Mataya**, Adamson Muula

An assessment of sex work in Swaziland: barriers to and opportunities for HIV prevention among sex workers, *published in the Journal of Social Aspects of HIV/AIDS Research Alliance, Vol. 7 No. 3 October 2010*

12. Taha Taha, Johnston Kumwenda, **Ronald Mataya**, Faustin Matchere, Newton Kumwenda

Coverage of Highly Active Antiretroviral Therapy Among Postpartum Women in Malawi; *accepted for publication on February 28, 2011, in the International Journal of STD and AIDS as manuscript ID IJSA-10-359-R1*

13. T.L. Magwali, **R. Mataya**, S.P. Munjanja, M. Chirehwa

An Assessment of the Maternal Death Notification System in Zimbabwe-2006,
Central African Journal of Medicine 2011;57 (1/4)

14. **Ronald Mataya**, Don Mathanga, Jobiba Chinkhumba, Alinafe Chibwana, Kingsley Chikapupha, Jeanine Cardiello,

A Qualitative Study Exploring the Knowledge, Attitudes and Practices of HIV Positive Who Stopped Breastfeeding at 6 Months to Prevent HIV Transmission to Their Children; *submitted for publication in August 2012 to the Malawi Medical Journal: Accepted for publication in March 2013*

Non-peer reviewed publications:

1. A Ministry of Compassion: Adventist Review, December 2004

2. A Time to Heal: International Adventist World Magazine, March 2007

Funded Research and Service Grants:

1. A Qualitative Study to Explore Attitudes and Perceptions of HIV Positive Women Who Are Advised to Stop Breastfeeding at 6 months. Funded by the Loma Linda University School of Public Health Center for Health Research as a Seed Grant of \$5,000
2. Supporting the Scale-up of High Quality HIV Care and Treatment Programs in Malawi through a Strengthened Laboratory Infrastructure. Funding Opportunity Number CDC-RFA-PS09-969 under the US Health and Human Services and the Center for Disease Control and Prevention (PEPFAR). Project funded for \$12 million for five years to be implemented in a consortium made up of the Johns Hopkins/University of Malawi Research Center, the University of North Carolina/Malawi Project and the Loma Linda University School of Public Health. (35% time and effort)
3. Validation of new technologies in the use of dry blood samples (DBS) for monitoring viral loads in patients on antiretroviral treatment in Malawi. This is funded separately (Grant number 626110-3831) through the CDC's Public Health Evaluation Program for \$530,000 within the PEPFAR grant. (25% time and effort)
4. Currently funded for 15% effort by the University of Malawi College of Medicine as senior lecturer in the Department of Obstetrics and Gynecology in Blantyre Malawi. This is through an arrangement between LLUSPH and the University of Malawi College of Medicine.

Grant Proposals Submitted

1. Acceptability and Impact of Option B+ for the Prevention of Mother to Child Transmission of HIV in Malawi. This was in response to Funding Opportunity Announcement # RFA-GH-12-008. Principal Investigator; Dr Adamson Muula, Associate Professor of Epidemiology, University of Malawi College of Medicine, Department of Community Health, Co-PI; Ronald Mataya, Associate Professor, Loma Linda University School of Public Health, Global Health Department, Deborah Demster Kamwendo, Project Coordinator, University of North Carolina Malawi Project, Lilongwe Malawi. **(Submitted in 2012, was not successful)**
2. Long Term Safety, Durability and Effectiveness of Option B+ ART Use in Malawi: R01 application to NICHD/NIH in 2013: PI: Professor TahaTaha at the Bloomberg School of Public Health at Johns Hopkins University, Co-PIs: Ronald Mataya, Bonus Makanani, Frank Taalo. Received a score of 29; awaiting funding decision.

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Rebecca Richards-Kortum	POSITION TITLE Stanley C. Moore Professor of Bioengineering		
eRA COMMONS USER NAME rrrkortum			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	YEAR(s)	FIELD OF STUDY
University of Nebraska	BS	1985	Physics & Mathematics
Massachusetts Institute of Technology	MS	1987	Physics
Massachusetts Institute of Technology	PhD	1990	Medical Physics

A. Personal statement

Dr. Richards-Kortum has extensive experience developing point-of-care diagnostic tests for early detection of cancer and infectious diseases. In this project, she will participate as a training mentor to post graduate fellows receiving training in the development and assessment of point-of-care diagnostic tests for low-resource settings.

B. Positions and Honors

Current and Previous Academic Positions:

Rice University, Dept. of Bioengineering, Professor, July, 2005 – present
Rice University, Dept. of Bioengineering, Department Chair, July, 2005 – July, 2008
University of Texas at Austin, Dept. of Biomedical Engineering, Professor, September 2001 – July 2005
Cockrell Family Endowed Chair in Engineering #10, September 2003 – Date
Distinguished Teaching Professor, September 2001 - 2009
University of Texas at Austin, Dept. of Electrical & Computer Eng. & Biomedical Engineering, Professor, 1999-2001
University of Texas at Austin, Dept. of Electrical & Computer Engineering, Associate Professor, 1995–1999
University of Texas at Austin, Department of Electrical and Computer Engineering, Assistant Professor, 1990-1995

Professional Registration:

Licensed Professional Engineer, Texas SN89893

Selected Honors and Awards:

Presidential Young Investigator, National Science Foundation, 1991.
Presidential Faculty Fellow, National Science Foundation, 1992.
Becton Dickinson Career Achievement Award, Assoc. for Advancement of Medical Instrumentation, 1992.
Y.C. Fung Young Investigator Award, Bioengineering Division, Am. Soc. of Mechanical Engineers, 1999.
Fellow of the American Institute for Medical and Biological Engineering, 2000
El Paso Energy Foundation Faculty Achievement Award for Teaching Excellence, 2000
Chancellor's Council Outstanding Teaching Award, University of Texas, 2002.
Howard Hughes Medical Institute Professor, 2002, 2006
Piper Professor, Minnie Stevens Piper Foundation, May 2004.
ASEE Sharon Keillor Award for Women in Engineering Education, 2004.
Chester F. Carlson Award, American Society for Engineering Education, June, 2007
Member, National Academy of Engineering, 2008
Fellow of the American Association for the Advancement of Science (AAAS), 2008
IEEE Educational Activities Board Vice-President Recognition Award, 2008

Fellow of the Biomedical Engineering Society, 2008

C. Selected Peer Reviewed Publications (from total of >230):

1. Thekkekk, N., T. Muldoon, A. D. Polydorides, D. M. Maru, N. Harpaz, M. T. Harris, W. Hofstetter, S. P. Hiotis, S. A. Kim, A. J. Ky, S. Anandasabapathy, R. Richards-Kortum. Vital-dye enhanced fluorescence imaging of gastrointestinal mucosa: Metaplasia, neoplasia, and inflammation. 2012. *Gastrointest Endosc.* **75**:4, 877-887. PMID: PMC3336371.
2. Vila PM, Park CW, Pierce MC, Goldstein GH, Levy L, Gurudutt VV, Polydorides AD, Godbold JH, Tenq MS, Genden EM, Miles BA, Anandasabapath S, Gillenwater AM, Richards-Kortum R, Sikora AG. Discrimination of benign and neoplastic mucosa with a high-resolution microendoscope (HRME) in Head and Neck Cancer. 2012. *Ann Surg Oncol*. Epub DOI: 10.1245/s10434-012-2351-1. PubMed- in process.
3. Hellebust A and Richards-Kortum R. Advances in molecular imaging: targeted optical contrast agents for cancer diagnostics. *Nanomedicine (Lond)*. Mar 2012; Vol 7(3): 429-45. PMID: PMC3327054.
4. Richards-Kortum R, Gray LV, Oden M. IBI*series winner. Engaging undergraduates in global health technology innovation, Apr 2012, *Science* 336(6080): 430-431. PMID: 22539712.
5. Pierce MC, Schwarz RA, Bhattar VS, Mondrik S, Williams MD, Lee JJ, Richards-Kortum R, Gillenwater AM. Accuracy of in vivo multi-modal optical imaging for detection of oral neoplasia. 2012. *Cancer Prevention Research*, 1 June 2012; Vol 5 (6):801-809. PMC in process.
6. Lee MH, Buterbaugh K, Richards-Kortum R, Anandasabapathy S. Advanced endoscopic imaging for Barrett's Esophagus: current options and future directions. *Curr Gastroenterol Rep*. June 2012; Vol 14 (3):216-225. PMID: 22453701.
7. Kelsey J. Rosbach, Michelle D. Williams, Ann M. Gillenwater, Rebecca R. Richards-Kortum; Optical Molecular Imaging of Multiple Biomarkers of Epithelial Neoplasia: EGFR Expression and Metabolic Activity in Oral Mucosa. *Translational Oncology*, June 2012; Vol 5 (3): 160-171. PMID: PMC3384270.
8. Brittany Rohrman and Rebecca Richards-Kortum; A Paper and Plastic Device for Performing Recombinase Polymerase Amplification of HIV DNA. *Lab on a Chip*, 2012. Vol 12 (17): 3082-3088. PubMed- in process.
9. Renu Regunathan, MD; Jenny Woo, MD; Mark C Pierce, PhD; Alexandros D Polydorides, MD, PhD; Mohammad Raoufi, MD; Sasan Roayaie, MD; Myron Schwartz, MD; Daniel Labow, MD; Dongsuk Shin, BS; Rei Suzuki, MD; Manoop S Bhutani, MD; Lezlee G Coghlan, DVM; Rebecca Richards-Kortum, PhD; Sharmila Anandasabapathy, MD; Michelle K Kim, MD; Feasibility and preliminary accuracy of high-resolution imaging of the liver and pancreas using FNA-compatible microendoscopy. *Gastrointest Endosc.*; August 2012, Vol 76(2):293-300. PubMed- in process.
10. Michael S. Cordray and Rebecca R. Richards-Kortum; Emerging nucleic acid based tests for the point-of-care detection of malaria. *American Journal of Tropical Medicine & Hygiene*; August 2012; Vol 87 (2):223-30. PMID: PMC3414556.
11. Lauren Levy, Peter Vila, Chan Park, Richard Schwarz, Alexandros Polydorides, Marita Teng, Vivek Gurudutt, Eric M. Genden, Brett A. Miles, Sharmila Anandasabapathy, Ann Gillenwater, R. R. Richards-Kortum and Andrew Sikora; High Resolution Optical Imaging of Benign and Malignant Mucosa in the Upper Aerodigestive Tract: An Atlas for Image-Guided Surgery; 2012. ISRN Minimally Invasive Surgery. (in press).
12. Mark C. Pierce, YaoYao Guan, Mary Kate Quinn, Xun Zhang, Wen-Hua Zhang, You-Lin Qiao, Philip Castle, Rebecca Richards-Kortum; A pilot study of low-cost, high-resolution microendoscopy as a tool for identifying women with cervical precancer. *Cancer Prevention Research*, Sept 2012. (Epub ahead of print). Pubmed in process.
13. Noah Bedard, Timothy Quang, Kathleen Schmeler, Rebecca Richards-Kortum, and Tomasz S. Tkaczyk; Real-time video mosaicing with a high-resolution microendoscope. *Biomedical Optics Express*, Sept 2012. Vol 3 (10): 2428-2435. PubMed- in process.
14. Brittany Rohrman, Veronica Leautaud, Elizabeth Molyneux, and Rebecca Richards-Kortum; A lateral flow assay for quantitative detection of amplified HIV-1 RNA. *PLOS One*, Sept 2012. Vol 7 (9): e45611. PubMed- in process.

15. Michael Cordray, Matthew Amdahl, and Rebecca Richards-Kortum; Gold nanoparticle aggregation for quantification of oligonucleotides: optimization and increased dynamic range. *Analytical Biochemistry*, Sept 2012. Pii: S0003-2697(12)00460-5, doi: 10.1016/j.ab.2012.09.013. PubMed – in process.

D. Research Support

Active

Title: Point of Care Diagnostics of Human Immunodeficiency Virus (HIV) Viral Loads Using Nano-based Reagents and Isothermal Amplification Studies

Agency: NIH

PI: Rebecca

Richards-Kortum

Dates: 04/13/2010-03/31/2012

We are developing an inexpensive, sensitive, and specific diagnostic test for determining type 1 HIV viral loads of seropositive patients in low-resource settings. The proposed assay combines: target isolation, isothermal amplification and oligonucleotide targeted gold nanoparticle detection assay for detection of viral nucleic acids. After initial optimization, it will be tested in a clinical pilot study at a low resource setting.

Title: Med Into Grad Award

Agency: HHMI 56006766

PI: Rebecca Richards-

Kortum

Dates: 4/01/2010-3/31/2014

Rice University and the M.D. Anderson Cancer Center will develop a PhD training program integrating: (1) courses in cancer biology, clinical medicine, bioengineering and translational research; (2) internships in clinical cancer care and translational research and (3) jointly mentored inter-disciplinary PhD projects.

Title: Low- Cost Respiratory Support: Reducing Early Neonatal Death in Rural Malawi

Agency: USAID

PI: Rebecca

Richards-Kortum

Dates: 9/30/2011-9/29/2012

In the developing world, oxygen therapy is often the only treatment option for babies who are suffering from respiratory distress. Through a partnership between bioengineers at Rice University, pediatricians at the University of Malawi and Baylor College of Medicine, and industrial design engineers from 3rd Stone Design we will: (1) design and rigorously test the efficacy of a novel, rugged bCPAP system which can be made at a unit cost of only \$160 at Queen Elizabeth Central Hospital in Blantyre, Malawi and refine it for use in rural district hospitals; (2) design a complementary training program for nurses and electromedical hospital staff; (3) engineer the bCPAP system for commercial manufacture; and (4) develop a country-wide plan to implement bCPAP at all district hospitals in Malawi.

Title: Integrated Bi-FOV Endoscope for Detection of Precancer

Agency: NIH RO1CA124319

PI: Tomasz Tkaczyk (R.

Richards-Kortum, co-PI)

Dates: 10/01/07 to 09/30/12

The major goal of this proposal is to build a dual FOV endoscope combining two: (1) high and (2) low resolution imaging systems. For the purpose of this proposal we call this instrument the “Bi-FOV Endoscope”. Using the Bi-FOV Endoscope will allow comprehensive study of molecular agents and streamline processes connected with (a) molecular drug development, (b) cancer screening and (c) and monitoring of guided drug therapy.

Title: Integrated Optical Needle (ION) for Cellular and Molecular Imaging of Cancer

Agency: NIH RO1EB007594

PI: R. Richards-Kortum

Dates: 7/01/08 to 06/30/12

The objective of this proposal is to develop and test a new optical imaging device for evaluation of neoplastic tumors. Here, we propose the development of a new class of optical imaging device – the integrated optical needle (ION) - which can be inserted into a small gauge needle, acquiring images with sub-cellular resolution at the distal tip in real-time.

Title: Multi-Modal Optical Imaging Systems for Early Detection of Oral Cancer

Agency: Cancer Prevention Research Institute of Texas **PI:** R. Richards-Kortum

Dates: 04/01/10 to 03/31/2013

The goal of this proposal is to develop, optimize and validate a Multi-Modal Optical Imaging System (MMIS) which combines the high sensitivity of autofluorescence imaging together with the high specificity of high resolution imaging. Image analysis algorithms will display processed images in real time, providing automated diagnostic criteria for community-based oral screeners..

Western Regional Center for Biodefense and Emerging Infectious Disease Research (WRCE)

Agency: NIH/NIAID 2 U54 A1057156-06 (Walker, DH)

Subproject: RP003.1

PI: A. Clinton White (R.

Richards-Kortum, co-PI)

Title: Point-of-Care Diagnostics Test for Intestinal Protozoa

Dates: 3/01/09 to 02/28/14

The specific aim of this project is to develop an inexpensive, sensitive and specific diagnostic test that can be used for point-of-care diagnosis of cryptosporidiosis. This is a major Research Project in the WRCE.

Title: Fluorescence Spectroscopy to Detect Oral Neoplasia

Agency: NCI/NIH 2R01 CA095604-05A2

PI: Ann Gillenwater (Richards-

Kortum,co-PI)

Dates: 07/01/2009 to 06/30/2014

The major goal of this proposal is to develop and test non-invasive diagnostic tools for oral dysplasia and early carcinoma of the oral cavity using the evolving technologies of fluorescence and reflectance spectroscopy.

Title: The Role of HER2 Signaling in Early Stage Breast Cancer Initiation & Resistance to Tamoxifen Prevention

Agency: Komen Research Program KG091020

PI: Dihua Yu (Richards-Kortum, Collaborator)

Dates: 09/25/2009-9/24/2014

We propose to (1) identify signaling pathways activated by HER2 during breast cancer initiation (2) determine the function of high HER2 expression and downstream signaling in transition from atypia to DCIS, and develop technology to image alterations *in vivo*, (3) test therapeutic strategies targeting HER2 and the PI3K/Akt pathway, and (4) investigate whether signaling alterations accompanying high HER2 expression can predict atypia progression and response to tamoxifen.

Title: Harnessing the power of light to see and treat breast cancer

Agency: DOD

PI: Nirmala

Ramanujam

Dates: 07/01/10 to 06/30/2014

Our objective is to exploit the wealth of physiological, metabolic, morphological and molecular sources of optical contrast to develop novel strategies that focus on two breast cancer applications: tumor margin assessment and prediction of response to neo-adjuvant therapy.

Title: Beyond Traditional Borders

Agency: HHMI

PI: R. Richards-

Kortum

Dates: 09/01/2010 to 08/31/2014

The goal of this project is to expand a unique, multidisciplinary educational program - Beyond Traditional Borders - which will train a new generation of students to reach beyond traditional disciplinary and geographic borders to understand, address and solve global health disparities.

Title: Academic-Industrial Partnership to Develop & Test Esophageal Cancer Imaging Tools

Agency: NIH

PI: R.

Richards-Kortum

Dates: 08/16/2010 to 05/31/2015

The goal of this proposal is to develop, optimize and validate novel multi-modal, multi-scale optical imaging

platforms for non-invasive, early detection of esophageal neoplasia based on optical imaging. We will collaborate with colleagues at Pentax, Inc. to design and test multi-modal endoscopic imaging systems for

early detection of neoplasia in Barrett's esophagus.

Title: Multimodal Optical Imaging for Cervical Cancer Screening in Developing Countries

Agency: NIH

PI: R.

Richards-Kortum

Dates: 04/01/11 - 03/31/14

The goal of this proposal is to integrate a series of collaborative studies to develop, test, and implement our optical imaging systems to improve cervical cancer screening in Botswana. A wide-field imaging system designed specifically to image the cervix will be constructed and tested. We will combine this system with a high-resolution microendoscope developed by Dr. Richards-Kortum under the parent NIH grant. Together, we will carry out a pilot clinical imaging study to test these systems in Botswana, collecting high-resolution and wide-field image data in reflectance and fluorescence modes.

Title: Low-cost, high-sensitivity, reconfigurable optical sensing components for POC diagnostics

Agency: Bill & Melinda Gates Foundation

PI: R. Richards-Kortum

Dates: 06/07/2011- 05/31/2014

The goal of this proposal is to reduce the expense of the optical sensing component of a POC system by developing a high-performance Readout & Signal Transduction (ROST) component for POC devices at completely new scales of physical size (e.g., palm size) and cost (below US\$10). Our proposed ROST consists of a universal fixture designed to attach to the surfaces of a sample platform and interrogate signal at multiple points, arranged in any pattern.

Title: Reagent-free, needle-free microscopy for malaria diagnosis

Agency: Bill & Melinda Gates Foundation

PI: R. Richards-Kortum

Dates: 09/11/2012- 09/30/2014

Our idea is to diagnose malaria by in vivo optical detection of the malaria parasite and its hemozoin crystal by-product. Our goal is to measure light scattered from infected red blood cells circulating in the superficial vasculature using a portable imaging device. This work will build upon the imaging techniques and instrumentation developed under Phase 1. Achieving this goal will provide a low cost, rapid diagnostic, free of biohazardous waste or the need for a trained technician, addressing key issues of conventional malaria diagnostics.

Title: High Resolution Microendoscopy for the Detection of Esophageal Neoplasia

Agency: NIH

PI: Sharmila

Anandasabapathy

Dates: 9/07/2011-8/31/2013

The goal of this proposal is to develop a low-cost, high resolution fiber-optic imaging system which can be combined with current white-light endoscopy. Within this project, a high-resolution microendoscope (HRME) system will be designed, assembled, and tested for use alongside the standard endoscope. We will train the clinical staff at the First University Hospital, Jilin, China in the use of the HRME, and in interpretation of the images acquired with the device.

Title: Competitive Renewal: Optical Systems for In Vivo Molecular Imaging of Cancer

Agency: NIH

PI: Rebecca

Richards-Kortum

Dates: 09/23/2011-07/31/2016

The goal of this proposal is to develop, optimize, and translate optical molecular imaging technologies to pilot clinical studies. Our team will carry out work to improve: (1) molecular screening, (2) early diagnosis, and (3) treatment of early disease. While this work has broad applicability for many types of cancers, we will develop and test systems for three organ sites, the oral cavity, esophagus, and lung, which together represent more than 25% of tumor mortality.

Completed

Title: Beyond Traditional Borders

Agency: HHMI 52005885

PI: Rebecca Richards-

Kortum

Dates: 9/01/06 to 08/30/10

The goal of this project is to create a unique, multidisciplinary educational program - Beyond Traditional Borders - which will train a new generation of students to reach beyond traditional disciplinary and geographic borders to understand, address and solve global health disparities.

Title: Reagent-free, needle-free microscopy for malaria diagnosis

Agency: Gates Foundation

PI: Rebecca Richards-Kortum

Dates: 11/01/09 to 10/31/2010

Our goal is to develop a functional prototype instrument for *in vivo* detection of the optical signals specific to the malaria parasite and its hemozoin crystal by-product; this novel, rapid, and painless diagnostic

does not require any consumable reagents, does not depend upon a trained operator, and does not generate any biohazardous waste.

Title: Image Guided Robotic Ablation of Oropharyngeal Cancer

Agency: Intuitive Surgical
Kortum

PI: Rebecca Richards-

Dates: 06/27/2010 to 06/30/2011

In this proposal, we will test the hypothesis that contrast-enhanced HRME, alone or in combination with wide-field reflectance imaging, can provide real-time discrimination between benign and malignant tissue during robotic tumor resection.

Title: Multidisciplinary Investigation of Cellular & Microenvironment Alterations in Breast Cancer Initiation & Progression

Agency: DOD BC074699P7
Kortum, Co-PI)

PI: Dihua Yu (R. Richards-

Dates: 05/01/08-09/21/2011

The goal of this proposal is to study the interactions between transformed breast epithelial cells and their surrounding microenvironment, and to identify those interactions important in the initiation and progression of breast cancer.

Title: Low-cost microscopy for diagnosis and drug-susceptibility testing of tuberculosis

Agency: Virginia and L.E. Simmons Family Foundation **PI:** Rebecca Richards-Kortum

Dates: 12/01/09 to 11/30/2011

The objective of this project is to design and fabricate a compact array microscope comprising 24 individual microscopes operating in parallel, enabling an entire sample to be simultaneously screened. The system will be tested with mycobacterial culture and clinical specimens. We will develop and apply image processing algorithms to automatically identify and quantify the presence of *M. tuberculosis*.

BIOGRAPHICAL SKETCH

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

NAME	POSITION TITLE		
Z. Maria Oden, Ph.D.	Professor in the Practice		
eRA COMMONS USER NAME			
MARIAODEN			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	YEAR(s)	FIELD OF STUDY
TulaneUniversity, New Orleans, LA	B.S.E.	1989	Biomedical Engineering
TulaneUniversity, New Orleans, LA	M.S.	1991	Biomedical Engineering
TulaneUniversity, New Orleans, LA	Ph.D.	1994	Biomedical Engineering
HarvardMedicalSchool, Boston, MA	Postdoctoral	1994-1997	Orthopedic Biomechanics

Positions

ACADEMIC APPOINTMENTS and EMPLOYMENT HISTORY:

10/08 – present	Professor in the Practice, Department of Bioengineering, RiceUniversity, Houston, TX
7/08 – present	Director, Oshman Engineering Design Kitchen, Brown School of Engineering, Rice University, Houston, TX
1/04 – 7/08	Lecturer and Laboratory Coordinator, Department of Bioengineering, RiceUniversity, Houston, TX
12/00 – 03/04	Senior Engineer, Sage-Crisp Engineering, Houston, TX
07/99 – 07/00	Visiting Assistant Professor, Department of Mechanical Engineering and Material Science, Rice University, Houston, TX
11/98 – 10/00	Assistant Professor of Orthopaedic Surgery, The University of Texas Medical School- Houston, Houston, TX
07/97 – 11/98	Instructor in Orthopedic Surgery, HarvardMedicalSchool, Boston, MA
07/97 – 11/98	Senior Research Associate, Department of Orthopedic Surgery, BethIsraelDeaconessMedicalCenter, Boston, MA
08/94 – 07/97	Research Fellow in Orthopedic Surgery, HarvardMedicalSchool, Boston, MA

LICENSURE & CERTIFICATION:

Engineer-in-Training

PROFESSIONAL ORGANIZATIONS:

1989-1992	Biomedical Engineering Society
1989-1992	American Society of Mechanical Engineers
1998-2001	Orthopedic Research Society
1990-2001	American Society of Biomechanics
2005-present	Biomedical Engineering Society
2006- present	American Society of Engineering Education

HONORS & AWARDS:

2008 Cain Award for Communication Instruction, RiceUniversity

- 1995 *New Investigator Recognition Award, Orthopaedic Research Society*
- 1995 *National Research Service Award (NRSA), National Institutes of Health*
- 1992 Student Paper Presentation Award, Twelfth Southern Biomedical Engineering Conference
- 1992 Alpha Eta Mu Beta
- 1991 Sigma Xi
- 1989 Student Paper Award, Louisiana Engineering Society
- 1989 Nissam Nathan Cohen Memorial Award for Contributions to the Class, to the School, and to the Profession of Biomedical Engineering, TulaneUniversity
- 1989 Dean James Marshall Robert Award for Leadership, Scholarship and Community Service, TulaneUniversity

MENTORSHIP OF AWARD WINNING DESIGN TEAMS:

- 2004-2005 **Team Cobra** (Austin Elam, Chris Gibson, ZeyadMetwalli, Roland Robb, Tom Rooney)
- *Revolutionary Aerospace Systems Concepts-Academic Linkage , Cape Canaveral, Florida May 2005, 1st place for Revolutionary Aerospace Systems Concepts Undergraduate Division*
 - *Texas Space Grant Consortium, Spring 2005, Best Project Model*
 - Patent Awarded, Fall 2007
- 2004-2005**Space Owls** (Allison Bean, Sriram Eleswarapu, Danika Hayman, Kim Hsu, Martin Kolnik)
- *Texas Space Grant Consortium, Spring Fall 2004, Best Project Model*
- 2006-2007 **HPN** (Elaine Chan, Cynthia Chang, Alex Gordon, Eric Vu, Peter Yang)
- *RiceUniversity Research Symposium, Spring 2006, 1st Place-Engineering Division*
 - *Texas Space Grant Consortium, Spring 2006, Best Poster Presentation, Best Project Model*
 - *Revolutionary Aerospace Systems Concepts-Academic Linkage , Cape Canaveral, Florida May 2006, 1st place for Revolutionary Aerospace Systems Concepts, Forum Favorite Award*
 - John L. McLucas Award for the study of space safety in recognition of outstanding work on the Osteonexus and efforts to provide for future Astronaut safety
 - Patent Application Filed, Fall 2006
- Thunderbirds** (Jimmy Barnes, NehaDatta, Vishal Gupta, Laura Higbie, Lei Ji)
- *Texas Space Grant Consortium, Fall 2005, Best Oral Presentation, Best Project Model*
- 2006-2007 **MDS** (Martin Bost, JennHowse, Ny-Ying Lam, ZavenSargsyan, Patrick Storer)
- *Texas Space Grant Consortium, Fall 2006, Best Oral Presentation*
- Team GQ** (Jesse Gill, Drew Bryant, Jon Martinez, Joe Valdez, Albert Yu)
- *Houston Society for Engineering in Medicine and Biology Student Design Competition, Spring2007, First Place*
- Team Mongoose** (Megan Jeans, Brian Schwab, Kim Bennett, Austin Ginnings)
- Patent Application Filed, Fall 2008, *Medicine Dosing Device*
- Team ICE** (Jon Ludwig, Christina Barry, Jonathan Hanson, Tim Josef, Mark Mendenhall)
- Provisional Patent Application Filed, Spring 2007, *Low Power Refrigeration for medicines in the developing world*
- 2007-2008 **Team Phoenix** (Shann Yu, Natalia Vasco, Eva Wang, Stacy Cheng, Kai Chu, Shuvro De)
- *Texas Space Grant Consortium, Optical immunoassay Device using Nanoshell Technology. Fall 2007, Best Oral Presentation, Best Paper, Best Poster, Best Overall Design Project*
 - *Texas Space Grant Consortium, Spring 2008, Best Oral Presentation, Best Poster, Best Paper, Best Overall Design Project*

- Team Three Minute Mile** (WafaSoofi, Allen Chen, Mariko Wei)
- *Houston Society for Engineering in Medicine and Biology*, February 2008, First Place Student Design Showcase.
- Team IV Drip** (NehaKamat, Ketan Shah, Aaron Cottle, Tyler Barth, Chris Vaucher)
- *Houston Society for Engineering in Medicine and Biology*, February 2008, Second Place Student Design Showcase.
 - *Department of Electrical Engineering*, May 2008, Top Undergraduate Design Project
- 2008-2009 **Team Taurus** (Charlie Foucar, Leslie Goldberg, Bodin Hon, Shannon Moore, Evan Williams)
- *Texas Space Grant Consortium, Bone Remodeling Monitor for Space Flight* Fall 2008, Spring 2009, Best Oral Presentation, Best Paper, Best Overall Design Project
 - *NASA 2009 Exploration Systems Mission Directorate Systems Engineering Paper Competition*, First Place, National Competition
- Team Heliotrope** (Jennifer Cieluch, CaterinaKaffes, Matthew Miller, Neel Shah, Steve Xu)
- *ASME iShow- Innovation Showcase*, June 2009, First Place, National Competition
 - RESNA Student Design Showcase, June 2009, One of five unranked finalists
 - Renamed to **OrthoIntrinsics**- finalist in 5 business plan competitions, earned 2nd place at University of Nebraska Business Plan Competition and 4th place overall at the Rice Business Plan Competition.
 - In Clinical Trials at present
- 2009-2010 **Team BabyBubbles** (Jocelyn Brown, Haruka Maruyama, Joseph Chang, Kathleen Schnelle, Michael Pandya with MBA students David Tipps, Will Pike, Cynthia Hu, Martha Vega)
- *Rice Business Plan Competition Social Ventures Category*, First Place

ACCOMPLISHMENTS:

- 2007-2009 Spearheaded the First and Second Houston Society for Engineering in Medicine and Biology- Student Design Showcase and Competition. This is an opportunity for student design teams from institutions from throughout Texas, Louisiana and other close states to demonstrate their student design to each other, industry and researchers. Secured funding from corporations to support this effort.
- 2007-2010 Started the Rice/TMC Design Technology Forum with Dr. David McStravick (MECH). This forum is a quarterly series where surgeons from the TMC come together with researchers and students from RiceUniversity to discuss medical problems that may have technologic solutions.
- 2007 BME Summit. Coordinated nations-wide survey and workshop on trends and best practices in bioengineering design education for this national meeting of biomedical engineering educators.

Selected publications

1. Andrew R Miller, Gregory L Davis, Z Maria Oden, Mohamad Reza Razavi, AbolfazlFateh, MortezaGhazanfari, FaridAbdolrahimi, ShahinPoorazar, FatemehSakhaie, Randall J Olsen, Ahmad Reza Bahrmand, Mark C Pierce, Edward A Graviss, Rebecca Richards-Kortum "Portable, Battery-Operated, Low-Cost, Bright Field and Fluorescence Microscope" PLoS ONE: 04 Aug

- 2010.
2. Oden, Maria, Mirabal, Yvette, Epstein, Marc, Richards-Kortum, Rebecca (2010) "Engaging Undergraduates to Solve Global Health Challenges: A New Approach Based on Bioengineering Design." *Annals of Biomedical Engineering*, Vol. 38, No. 9, pp. 3031–3041.
 3. Oden, Z. Maria, Jeans, M., Schwab, B, Ginnings, A, Bennett, K., Schutze, G. "Adjustable-volume liquid dispensing pump." Patent Application Filed, Feb, 8 2008.
 4. Oden, Z. Maria (2007) "Finding Ideal Projects for the Bioengineering Design Course: BME-IDEA.
 5. Oden, Z. Maria, Mirabal, Yvette, Richards-Kortum, Rebecca (2007). "Global Health Technology Woven into Many Levels of Design Courses" *Transactions of Biomedical Engineering Society*.
 6. Glauser CR, Oden ZM, Ambrose CG, Willits MB, Coupe KJ. (2003) Mechanical testing of small fracture implants for comparison of insertion and failure torques. *Arch Orthop Trauma Surg* Oct;123(8):388-91.
 7. Oden ZM, Selvitelli DM, Boussein ML. (1999) The effect of local density increases on the failure load of the proximal femur: a finite element study. *Journal of Orthopaedic Research*, 17(5):661-667, 1999.
 8. Oden ZM, Selvitelli DM, Wolf RM, Myers ER. (1997) The effect of anisotropy on DXA based predictions of bone failure. *Calcified Tissue International*, 63:67-73.
 9. Oden ZM, Hart RT. (1995) Correlation between mechanical parameters that represent bone's mechanical milieu and control functional adaptation, in *Bone Structure and Remodeling*, edited by A. Adgaard and H. Weinans, World Scientific Publishing, London, 127-137.
 10. Hart RT, Oden ZM, Parrish SW, Burr DB. (1992). Computational methods for bone mechanics studies, *The International Journal of Supercomputer Applications*, (6)2:164-174.

C. Research Support

Ongoing Research Support

2008- 2010	Brown Foundation Teaching Grant, Principal Investigator
2004- 2010	Texas Space Grant Consortium Undergraduate Design Initiative, Principal Investigator
2009-2010	NCIIA- eTeam Grant for OrthoIntrinsics, Principal Investigator
2009-2011	NCIIA – Course Development Grant, Co-PI
2006-2010	Beyond Traditional Borders USEP grant from Howard Hughes Medical Institute, co-PI
2010-2012	NCIIA- eTeam Grant for infantAir, Co-Principal Investigator

Completed Research Support

1989	Pittsburgh Supercomputing Center Summer Institute, National Science Foundation
1995-1997	Pittsburgh Supercomputing Center Grant for Cray Time, <i>Computational modeling proximal femur failure</i> , Principal Investigator
1995-1998	National Institutes of Health, <i>Predicting failure of human proximal femurs</i> , (NRSA) Principal Investigator
1997-1998	Genetics Institute, <i>The effect of local density increases on the failure load for the proximal femur</i> , Principal Investigator
1997-1998	National Institutes of Health, <i>Predicting hip fracture risk by QDR</i> , (PI: W.C. Hayes) Subcontract to Beth Israel Principal Investigator
1997-1998	National Space Biomedical Research Institute, <i>Bone loss team; DEXA analysis, geometry and structure, finite element analysis</i> , Co-Investigator with C. Ruff, T. Beck and D. Newman

1998-2001	Whitaker Foundation Biomedical Engineering Research Grant, <i>The influence of bisphosphonate therapy on the density distribution and structural capacity of the human femur</i> , Principal Investigator
1999-2000	Genetics Institute, <i>The effect of local density increases on the failure load for the proximal femur</i> , Principal Investigator
1998-2000	National Space Biomedical Research Institute Bone Team: <i>Skeletal structural consequences of bone loss</i> , Co-Investigator.
2005- 2007	Brown Foundation Teaching Grant, Principal Investigator
2005- 2008	CBEN Educational Initiative funding for Design Projects, Principal Investigator

KELLEY MAYNARD

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kmayn@rice.edu • (517)-474-4222

EDUCATION 2009-2011

UNIVERSITY OF MICHIGAN

Master of Science in Biomedical Engineering

Ann Arbor, MI

- GPA 7.97/9.00
- Biomechanics Concentration
- Graduate Design Program: performed complete biomedical product development process for a noninvasive device to detect internal bleeding after catheterizations
- Social Venture Program: developed mass manufacturing, distribution, and field testing strategies for male circumcision device on Gates Grand Challenges Explorations Grant
- Relevant Coursework: Global Health Design, Tissue Mechanics, Linear Programming, Applied Statistics, Biomedical Instrumentation

2005-2009

Bachelor of Science in Mechanical Engineering

Ann Arbor, MI

- GPA 3.90/4.00
- Engineering Global Leadership Honors Program
- Minor in Spanish Language and Literature
- Relevant Coursework: Design & Manufacturing I, II & III, Manufacturing System Design, Manufacturing and Supply Operations, Strategy at the Base of the Pyramid

Summer 2008

FACULTAD LATINOAMERICANA DE CIENCIAS SOCIALES

Public Health Program

Buenos Aires, Argentina

- Studied Public Health in Buenos Aires and engaged in a field placement in Mendoza to investigate community healthcare programs.

EXPERIENCE 2013-present

RICE 360: INSTITUTE FOR GLOBAL HEALTH TECHNOLOGIES

Director of Technology Development

Houston, Texas

- Lead development of maternal and neonatal healthcare technologies, including optimization of device designs and benchtop validation tests.
- Design and manage local and international clinical trials for maternal and neonatal healthcare technologies; communicate with regulatory boards concerning study and device approvals.

2011-2012

MEDICAL TECHNOLOGY TRANSFER AND SERVICES

Biomedical Engineer, Whitaker International Fellow

Hanoi, Vietnam

- Led design of patient breathing circuit and parameter control system for infant continuous positive air pressure device for use in low-resource hospitals in Asia.
- Managed technical aspects of 3-phase clinical trial of phototherapy device for the treatment of neonatal jaundice.
- Developed and tested closed-loop temperature control system for infant warmer device.

2007-2011

UNIVERSITY OF MICHIGAN BIOMECHANICS RESEARCH LAB

Research Assistant, Advisor: James Ashton-Miller, Ph.D.

Ann Arbor, MI

- Investigated the energy expenditure in childbirth by facilitating a human labor simulation study and building a 3-D computer model of muscles used in labor.
- Performed dissection and biaxial material testing on pelvic floor tissues to determine the effects of pregnancy on the viscoelastic properties of these tissues.

2009-2010

UNIVERSITY OF MICHIGAN COLLEGE OF ENGINEERING

Graduate Student Instructor

Ann Arbor, MI

- Led help sessions, prepared homework, wrote exams, and graded exams (Mechanical

Behavior of Materials, Fall 2009 & Fall 2010).

- Taught laboratory classes, led help sessions, wrote projects, and graded exams (Introduction to Computer Programming, Winter 2010).

Summer 2010

CARDINAL HEALTH, INC.

Tauber Institute Team Project Intern

Romulus, MI

- Developed service metrics to improve upon current metrics in capturing the true customer experience; validated metrics with interviews and electronic data analysis.
- Uncovered inefficiencies and provided process improvement recommendations through collaboration on-site with a customer hospital.
- Initiated strategic change in a multinational corporation through qualitative and quantitative reasoning; presented recommendations to Cardinal Health CEO.

Summer 2009

UNIVERSITY OF MICHIGAN DEPARTMENT OF COMPLEX SYSTEMS

Research Leadership Team Intern

La Union, Honduras

- Developed procedure, protocol and content for network analysis research; trained 20 student researchers and 30 Honduran translators in research process; partnered with research team to collect network data for over 4000 subjects in over 30 villages.
- Contributed to the development of partnerships and investments for the establishment of a rural microfinance institution.

AWARDS

- First Place, NCIIA BMEidea National Competition, \$10K award (2011)
- First Place, University of Michigan Biomedical Engineering Design Competition (2011)
- Top Project, Innovative Design for Global Health (2010)
- University of Michigan Alumnae Council Scholarship (2009, 2010)
- Tauber Institute Academic Scholarship (2008, 2010)
- Thomas M. Iden Scholarship (2009)
- James B. Angell Scholar (2008)

PRESENTATIONS

- Evaluation & Implementation of a Bubble Continuous Positive Airway Pressure System for Newborns, Second WHO Global Forum on Medical Devices (2013)
- Infant Healthcare Technology Development in Southeast Asia, Whitaker Enrichment Seminar (2012)
- Metric Development in Healthcare Operations, Tauber Spotlight Competition (2010)
- SolarFocus Reflection System, University of Michigan Design Expo (2009)
- Pneumatic Cycling Model, University of Michigan Design Expo (2007)

PUBLICATIONS

- Maynard K, Brincat C, DeLancey J, Ashton-Miller J. On the energetics of volitional pushing during a simulated second stage of labor. *In preparation*.
- Sarvestani AS, Perosky J, Maynard K, Weist M, Jiang C, Sienko KH. Development of a Database for Global Health Medical Devices. *Journal of Medical Devices* 2011; 5(2):27532.
- Contributor; Compendium of Medical Devices. *World Health Organization* 2011.

SKILLS

- Software: Unigraphics, Solidworks, Adams/View, 3DS Max, 3D Slicer, Mimics, Maple, MATLAB, LabVIEW, C/C++ programming, SPSS, R Statistics
- Prototyping: mill, lathe, drill press, band saw, CNC, electronics assembly
- Laboratory: small animal dissections, biaxial tissue testing
- Lean Six Sigma (MoreStream Yellow Belt training at Cardinal Health)

LANGUAGES

- Professional working proficiency in written and spoken Spanish
- Elementary proficiency in written and spoken Vietnamese

ACTIVITIES

- Blue Dragon Mentorship Program – English Tutor (2011-2012)
- UM Center for Global Health, Technology Team – Member (2010-2011)

- Kiva Microfinance – Spanish Translator (2009-2011)
- Michigan Health Engineered for All Lives – Member (2006-2011), Team Leader (2009)
- Short-term field experience in Mexico (2005), Haiti (2007), Nicaragua (2010), India (2012), Philippines (2012), Myanmar (2012), Tanzania (2013), Malawi (2014)

Laura Causey Sandoval

1615 Hermann Drive Apt 1315, Houston, TX 77004 704.287.5514 laura.causey@gmail.com

EDUCATION

Doctorate of Philosophy in Biomedical Engineering, December 2013

The City College of New York, New York, NY

Advisors: Distinguished Professors Sheldon Weinbaum, Ph.D. and Stephen Cowin, Ph.D.

NASA Advisor: Beth Lewandowski, Ph.D.

Masters of Science in Biomedical Engineering, May 2008

Florida International University, Miami, FL

Advisor: Anthony McGoron, Ph.D.

Bachelors of Science in Chemical Engineering, May 2005

University of Oklahoma, Norman, OK

Minor in Spanish

Study Abroad Program, Universidad Privada de Santa Cruz, Bolivia. Fall 2002

EXPERIENCE

Rice University, Program Associate, Houston, TX, January 2014-Present

- Research and development of a low-cost ambulatory pressure cuff designed to monitor pre-eclampsia in pregnant women living in developing countries
- Design will be tested in clinical trials in a hospital in Houston, TX as well as The Queen Elizabeth Central Hospital in Blantyre, Malawi

The City College of New York, Research Assistant, New York, NY. August 2008-December 2013

- Theoretical applications of the lymphatics system, muscle compressibility, and Starling's Principle
- Predicted the pressure generated in skeletal muscle using theoretical calculations and simulations in MATLAB

United Nations Headquarters, Supporting Officer, New York, NY. September 2013-November 2013

- Assisted with the first United Nations High Level Meeting on Disability and Development
- Managed social media (Facebook, Twitter, Thunderclap)
- Author of UN Enable Newsletter (September 2013 edition)
- Drafted the Secretary General Report, speeches, and letters to diplomats, including the former Vice President of Ecuador, Lenin Moreno

NASA Glenn Research Center, Fellow, Cleveland, OH. August 2010-August 2013

- Mathematical modeling of the effects of microgravity and hypoxia on skeletal muscle of astronauts using MATLAB
- Presented work to scientists of various disciplines from Johnson Space Center and Glenn Research Center on a regular basis
- Worked at NASA Glenn for 10 weeks each year while supplementing the work of the "Digital Astronaut" project

Florida International University, Research Assistant, Miami, FL. August 2006-May 2008

- Modified membranes using vapor and solution graft polymerization
- Investigated potential applications of membranes, including possible treatment of acute respiratory distress syndrome

Cardinal Engineering, Inc., Project Manager, Oklahoma City, OK. August 2005-August 2006

- Drafted regulatory plans for brick and material companies and power plants in OK, TX, KS, and GA
- Soil vapor extraction and ground-water remediation

PUBLICATIONS

L. Causey, B.E. Lewandowski, and W. Weinbaum. *A mathematical model of oxygen transport in skeletal muscle during hindlimb unloading*. NASA Technical Memorandum NASA/TM—2014-216631, March 2014.

L. Causey. *Quantitative Model for Predicting Intramuscular Fluid Pressure and Skeletal Muscle Compressibility During Contraction and Stretch with Oxygen Transport Correlations*. Ph.D. dissertation. The City College of New York, New York, 2013.

L. Causey, S.C. Cowin, and W. Weinbaum. *Quantitative model for predicting lymph formation and muscle compressibility in skeletal muscle during contraction and stretch*. PNAS, 109.23: 9185-9190, June 2012.

L. Causey. *Intravenous Oxygenator: Enhancement of Surface Properties to Minimize Bubble Size*. M.S. thesis. Florida International University, Miami, 2008.

CERTIFICATIONS AND SKILLS

- Engineer Intern Certification #13161, Oklahoma State Board of Registration for Professional Engineers and Land Surveyors, 2005
- Skilled in most major computer applications (expert in Microsoft Office, MATLAB, Abaqus FEA, SolidWorks, Adobe Photoshop and Illustrator, Code Composer Studio, Multisim, Ultiboard)

GRANTS AND SCHOLARSHIPS

- NASA Graduate Student Research Fellowship (GSRP) – Independently submitted a research proposal that led to the support of stipend and research expenses for 3 years, 2010-2013
- National Science Foundation Scholar – 7th International Summer School on Biocomplexity from System to Gene in Istanbul, 2008
- Laurance Reid Gas Conditioning Conference Scholarship Recipient, 2003

ACTIVITIES AND HONORS

- P. Marathon Finisher – ING NYC Marathon, 2013
- Q. Distinguished student speaker – The 3rd US-Turkey Advanced Institute, Antalya, Turkey, 2012
- R. New York Junior League Advocate for Public Policy Committee, 2010-2012
 - S. City Advocacy Co-coordinator – met with legislators to discuss Elder Evictions Legislation Int 0475-2011; organized volunteer training leadership courses to educate league members on local and state politics; met with legislators in Albany to discuss Domestic Survivors Justice Act
- T. Award for Outstanding Leadership – NIH Undergraduate Minority Mentor for CCNY Program, 2009-2011
- U. Volunteer Tutor – Harlem Boys and Girls Club, 2009-2011
- V. Third place winner of the First Regional South Florida Technical Presentation, 2007
- W. Volunteer Tutor for Little Brother, Big Brothers/Big Sisters, 2007

Appendix 2. Study Data Collection Form

Subject number: _____
Age: _____
Gravidity: _____
If pregnant, estimated gestational age: _____
If postpartum, hours since delivery: _____
Systolic alarm limits set: high: _____ low: _____
Diastolic alarm limits set: high: _____ low: _____
Time interval set: _____
Test device ID: _____
Nurse ID: _____
Time monitoring starts: _____
Time monitoring ends: _____

Blood Pressure Measurements

Measurement #	Time	Control Systolic / Diastolic (mmHg)	Test Device Systolic / Diastolic (mmHg)
1			
2			
3			
4			
5			
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7			
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Alarm Indications

Time	Device (control/test)	Alarm type

Errors/Questions by Nurses

Time	Nurse ID	Description of Error/Resolution

Device Malfunctions

Time	Device ID	Description of Malfunction/Resolution