Paulina Eberts
**Graduation Year**: Junior
**College:** Engineering
**Major(s):** Chemical Engineering
**Minors(s):** N/A
**Scholar Group Membership:** N/A

**Did you received other funding for this project?:** N/A
**Could you have completed this project without CUSE funding?** No
**More details on CUSE funding assistance?**

**Project Title:** Detection of Substandard Pharmaceuticals in Kenya via High Performance Liquid Chromatography
**Project Location:** The Moi Teaching and Referral Hospital, Eldoret, Kenya
**ND Faculty Mentor:** Professor Marya Lieberman
**Project Type:** Service-Learning

**Why did you undertake this project/experience?** Deepen your knowledge of a topic or issue, Prepare for graduate school (MA or PhD), Prepare for national fellowships, Career discernment and/or preparation, Internationalize your Notre Dame experience

**Did your funded experience help you:**
**[Deepen your understanding of your coursework or field of study]:** Very Much
**[Discern your interests and post-bac goals]:** Very Much
**[Become confident in your ability to set and achieve your goals]:** Very Much
**[Gain a more nuanced view of local, national, or global communities]:** Very Much
**[Improve your written and verbal communications skills]**:Very Much

**Tell us about your experience.**
A fraction of pharmaceuticals procured within the developing world are of unacceptable quality and sometimes entirely fake. Each year substandard or counterfeit drugs kill more than 100,000 people in Africa (World Health Organization, 2015). This is especially a concern within Kenya where 25 percent of medicines could be substandard (Roxby, 2015).

At the University of Notre Dame, Associate Professor Marya Lieberman's team within the Department of Chemistry and Biochemistry at the University has developed cost effective, high tech paper that uses colorimetric chemistry to detect the presence of certain ingredients in pharmaceuticals, referred to as paper analytical devices (PADs). However, once a particular drug has been flagged, it is important to confirm its deceiving nature through the use of High Performance Liquid Chromatography (HPLC).

At the Moi Teaching and Referral Hospital (MTRH) in Eldoret, Kenya, Professor Lieberman has been working to set up a lab with HPLC capabilities for the purpose of conducting this type of pharmaceutical analysis. The lab currently has two donated Waters 2695 HPLC Systems.

However, prior to our trip to Eldoret, these machines were not in proper working condition. In addition, many potentially substandard pharmaceutical samples had been collected, but full analysis of them had not begun given the unavailability of result confirmation via HPLC. Further, the PADs are currently unable to detect clavulanic acid in the presence of amoxicillin. This posed additional difficulty in quick analysis of certain samples.

As this trip would serve as a training opportunity for those at the Moi Teaching and Referral Hospital, prior to leaving for Kenya I was tasked with preparing training materials for Thin Layer Chromatography (TLC). TLC pertains to many foundational concepts that serve as the basis for HPLC analysis. It is for this reason, that it is often desirable to train individuals on TLC prior to HPLC. This preparatory work involved developing a TLC assay for amoxicillin using the limited types of reagents that would be available in Eldoret as well as organizing and packing all of the relevant materials.

Upon initially arriving to the lab in Eldoret, much rearrangement and setup was required. A portion of the space was being used for pharmacy compounding. In the United States, this type of work is typically not conducted around other forms of analysis. Further, additional table space needed to be procured for running the PADs. Time was spent clearing out these spaces. Further, any unnecessary clutter was removed as it is good practice to keep working spaces sparse of extraneous objects. In conjunction with lab rearrangement, much of the first day was spent communicating with the individuals running the lab, in regard to what their most pressing challenges were. This way, time could be efficiently allocated to the highest priority tasks.

After establishing what could feasibly be accomplished in one week, Tabitha Healy (a fellow student) and myself, initially revisited the training materials that had been compiled. Isopropyl alcohol was not initially accessible and was needed for the paper chromatography. Therefore, we worked on performing the same experiment with other available reagents. Further, while the TLC assay for amoxicillin prepared in advanced was successful, it was desirable for us to create a similar assay for amoxicillin and clavulanic acid for use in this environment. This assay would potentially complement the PADs and enable more pharmaceutical samples to be analyzed. We were successful in resolving a distinction between the amoxicillin and clavulanic acid with the available reagents. Further work is required prior to its application and potential incorporation within future PADs.

The lab had received its first own pH meter. I calibrated the device so that it was performing properly and instructed others on how to do the same. I provided insight on regular upkeep and maintenance of the device.

In the meantime, the HPLC machines were ridden with a significant amount of air bubbles, which are severely problematic in order for the machines to run properly. This was due to the fact that the solvents feeding into the machine, particularly the methanol, had oxygen dissolved within in them. This was inevitable given that the reagents had been exposed to the air. Often labs mitigate this problem by storing solvents in the presence of an inert gas. This was not an available option, so we spent time remaking and filtering the solvents. This was sufficient to get

one of the machines functioning once more. However, the second machine had a faulty vacuum degasser. We worked to troubleshoot this machine error, but with limited resources on site, this predicament was placed on hold. Back at the University of Notre Dame, Tabitha Healy and I recently compiled an instructional video for replacing a vacuum degasser, as a replacement will be shipped to Eldoret shortly.

With the functioning HPLC machine, we were able to begin analysis on samples containing amoxicillin and amoxicillin in the presence of clavulanic acid. During this time, we provided individuals at the MTRH the opportunity to become acclimated with the use of the HPLC machine as well as the interpretation of results. This included promoting the efficient documentation of results. Given that there were over four-hundred samples that had been collected, a significant amount of time was put forth organizing the samples and pairing them with metadata delineating information such as the name of the chemist from which they were purchased. Once the samples were all in order, we were also able to begin analyzing them with the PADs. I assisted in communicating tips for best results.

We did not have sufficient time to perform the intended paper chromatography training. Therefore, we passed along the training materials to individuals at the MTRH and additionally modified a version of the procedure so that they would be able to perform a related activity with local children in the community.

Upon reflection of the various tasks that I performed, the key takeaway that I obtained was the importance of innovative practices when working in this type of environment. Being flexible in conducting the intended work was crucial as unanticipated problems developed and resultantly priorities changed. Further, improvisation was necessary in performing various tasks in the absence of certain materials.

**Describe the impact this project had, both on you as a student-scholar and on the people you worked with.**

“We all assume that the medicine we take will make us better. This is such a fundamental expectation that it is easy to take it for granted” - Dr. Jemina Kamano The Moi Teaching & Referral Hospital, Eldoret, Kenya

Residing in the United States, the presence of substandard pharmaceuticals for purchase is such a rare occurrence that for many, the concept does not seem plausible nor is it a household concern. However, in many developing regions, this is a very real problem that affects individuals seeking treatment for an array of conditions including malaria.

By engaging on this project I assisted in establishing and advancing the detection capabilities for substandard drugs on the market. I repaired equipment, passed along techniques, and evaluated new methods to potentially expand the list of pharmaceuticals that can be reliably evaluated. While no amount of work is sufficient to fully mitigate this public health concern, every step toward the elimination of substandard pharmaceuticals on the market is a positive

advance.

As a student scholar, I was able to witness the challenges and innovation associated with applying concepts in developing regions. One must be creative and exhibit great determination in order to translate and adopt common techniques for use in such environments. I will be able to carry forth this perspective in my future endeavors and will be more equipped to continue work pertaining to this form of technical application.

The benefits of this project generated both direct and indirect impact. The individuals at the Moi Teaching and Referral Hospital were able to learn new analytical techniques and gain skills pertaining to the use and troubleshooting of HPLC machines as well as the utilization of the PADs. Many of these techniques, particularly the use of the HPLC machines, have a milieu of potential opportunities for extended application in the general field of analytical chemistry. Further, with the improved functionality of the HPLC machines and continued progress in sample analysis, individuals at the MTRH will now be able to start pinpointing substandard pharmaceuticals and reporting them to the proper authority figures. In doing so, those purchasing medications will have an increased probability of obtaining the quality drugs, which they require.

**Describe how this experience is connected to your plans as a student or future professional.**

My educational plan is to obtain a PhD in bioengineering from a top research university. My career plan is to enter academia. This goal will enable me to translate basic research into application for improving public health. This project has presented me with the experience of procuring funding, developing analytical chemistry techniques, communicating and explaining various techniques and applying them in a taxing environment. That being said, it is my engagement in this impactful research opportunity that has solidified my intent to pursue academia within the field of bioengineering.

**What advice would you give other students who are planning to pursue similar projects?**

For students planning to pursue similar projects, I would urge them to step into the shoes of those with whom they are interacting. The more one fully understands the environment and reality of the situation in which he or she is working, the better equipped they are to generate sustainable and lasting effects.