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Implementation of Universal HPLC Analysis for Counterfeit Medication: A Partnership of Purdue University and the Kilimanjaro School of Pharmacy

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Cover Page Footnote

The team would like to acknowledge appreciate for travel funding from the College of Pharmacy and the Department of Agricultural and Biological Engineering. We would like to thank the Office of Global Engineering Programs, the Purdue Study Abroad Office, and the staff at the Kilimanjaro School of Pharmacy for their support before and during travel. Finally, we would like to acknowledge our faculty mentors and thank them for their ongoing support.

IMPLEMENTATION OF UNIVERSAL HPLC ANALYSIS FOR COUNTERFEIT MEDICATION

A Partnership of Purdue University and the Kilimanjaro School of Pharmacy

Jordyn McCord, Michael Mavity, College of Engineering, and David Wintczak, College of Pharmacy

ABSTRACT

Jordyn McCord and Michael Mavity are 2016 graduates of both biological engineering and pharmaceutical sciences. David Wintczak is a third-year pharmacy doctoral candidate. Here, in their second article published in *PJSL*, they describe a weeklong study abroad course at the Kilimanjaro School of Pharmacy in Tanzania, designed to engage students in the implementation of methods for detecting counterfeit medications.

INTRODUCTION

Our Global Development Team, led by Drs. Stephen Byrn and Kari Clase (Purdue University three-credit course: GEP 40000), aims to develop methods for quantifying drug levels to assess for counterfeit medications in Moshi, Tanzania. The team works in partnership with Sister Zita Ekeocha of the Kilimanjaro School of Pharmacy (KSP). Formed in the fall of 2014, the team spent the first four semesters growing their knowledge on high-performance liquid chromatography (HPLC), choosing medications to focus on, and developing HPLC methods that are simplistic and universal for multiple drugs. In August 2015, three team members—Michael Mavity, Jordyn McCord, and David Wintczak—implemented the first phase of the project at KSP.

The course instructor delivered a complete Agilent 1100 Series HPLC unit to KSP in the spring of 2015; then we delivered a single column, four HPLC jars and some HPLC vials, in August 2015. The team intended to set up and begin running at least one HPLC, and potentially set up a second unit. The team planned to train a group

of students and faculty to use the instrument and complete drug testing using the methods developed by the team. From this training, they would determine whether or not there was need for a troubleshooting guide and if screenshots of software could be useful to the training documents. Through discussions and contact with Sister Zita, members of the School of Pharmacy, and possibly locals, the group intended to learn more about the current presence of counterfeit drugs not only in Kilimanjaro, but also throughout Tanzania and surrounding countries. The team also hoped to gather information about what other methods should be developed and how they should be prioritized.

Finally, the team hoped to use the time in Tanzania to solidify contact between the team and KSP and learn about Tanzanian culture. Visits to local pharmacies were aimed at providing details for further works, including assessment of which medications to prioritize for future testing. If possible, the group wanted to bring back pharmaceuticals from Tanzanian pharmacies to analyze using the developed methods.

DESCRIPTION

On our first day in Tanzania, Sister Zita gave us a tour of KSP and we met a few students in their classrooms. The students were preparing for their government-proctored exams given that week. Sister Zita introduced us to Ibraheem, a jack-of-all-trades. He could fix and build nearly anything. He showed us his machine shop where he built reverse osmosis water purifiers. She also took us through their good manufacturing practices (GMP) tablet manufacturing facility

used for teaching. We slipped on shoe covers to tour the facility. We saw material preparation, the mixing tank, the fluid bed dryer and granulator, the tablet press, and the tablet coater (see Figure 1). She also showed us various in-process check areas used to confirm material quality for loss on drying, compressibility, and weight during production. The German government donated most of the materials, which were old but still functional enough for teaching and producing various tablets. She then took us to the facility where glassware is cleaned and autoclaved. We finished our tour at the quality lab facility where Sister Zita's office is, and where we would be working with the HPLC units.

Figure 1. Micheal and Sister Zita with the tablet press.

We selected and prepared methods for the medications amoxicillin, quinine, mefloquine, and Coratem (artemether and lumefantrine) prior to our arrival at KSP (Figure 2). Our rationale for selecting these medications was that they each treat a variety of disease states and are common throughout the world. In the afternoon, we went to Moshi Town to exchange money and buy these medications for testing. We visited a small but busy pharmacy where Sister Zita purchased amoxicillin, quinine, mefloquine, and Coratem (Figure 3). It was interesting to learn that people go into the pharmacy and tell the pharmacist what they need medicine for, and they will give you enough to make you better. Sister Zita had someone pick up another set of the medications on our list from the Kilimanjaro Christian Medical Centre (KCMC) university hospital for additional testing.

We spent the rest of our first day setting up the HPLC unit and learning the new version of the Agilent software (Figure 4). We created a 50:50 acetonitrile and water mixture and put all four stones in the jar. We opened the bypass valve and found no pressure running through the lines, so we successfully primed each line. We then created a basic set-up method and sequence and operated the instrument under a predetermined protocol.

Figure 2. View of Kilimanjaro from KSP (quality lab on the right).

The column leaked, causing the instrument to auto-shutdown, so we rebooted the computer. When we tried to turn the computer back on, it showed an alert that the operating system was gone from the laptop. Once we removed a flash drive, the computer booted back up; however, when we opened the Agilent software, the computer no longer recognized the instrument and thought that the unit was offline. We spent the rest of the day troubleshooting the instrument. We took screenshots of the software and instructions for the use of the HPLC and for the methods that we brought from Purdue. We also prepared method and sequence files on the software from the methods we brought from Purdue so that students could run our methods quickly and easily when the instrument began to work.

By day two, our new goal was simply to get the instrument functional again. We consulted with students and spoke with Dan Smith, the postdoctoral lab manager at Purdue. We finished the pictorial guide of general HPLC procedures and added a brief section on safety and good documentation procedures in the lab. We were able to fix the connection between the computer and the instrument early that evening. From this knowledge, we developed a troubleshooting guide for various issues, including leak detection and solutions, low pressure, and communication problems between the computer and instrument. We believe this guide will give students the confidence to try to fix problems, rather than leave the instrument

nonfunctional, as has been done in the past. We then ran the 50:50 acetonitrile-water mix through the instrument in our set-up method as both a blank and as a standard. There were no peaks on these results, indicating that using a blank was a suitable method despite potential impurities in the available mobile phase. The data also indicated that the pumps and the column were clean. We then created a solution of amoxicillin using United States Pharmacopeia (USP) standards and methods we brought from Purdue. These results were good and showed a single large peak around 5.6 minutes. During dinner that evening, we spoke with Sister Zita about commonly used medications that we could consider for further counterfeited analysis. These included metformin, glimepiride, atenolol, Imodium, Aleve, and ibuprofen.

On day three, our instrument was functional and we made the decision to focus on testing amoxicillin and on training (Figure 5). We had intended to test as many of our drugs as possible, and to confirm system suitability using all of the USP compounds that we brought from Purdue. Unfortunately, this was not feasible, so we decided to bring the compounds back to Purdue for complete testing instead. We focused on teaching during our final day on-site. We tested an amoxicillin capsule made in Tanzania, which eluted around 4.2 minutes with one

Figure 4. The team with set-up HPLC. Courtesy of Sister Zita.

large peak. This was interesting compared to the USP that we tested the day before, which eluted at 5.6 minutes. We decided we would need to investigate when we got back to Purdue. We had a few additional issues arise the third day. We added more information to our troubleshooting guide about making sure the method agreed with the sequence, and updated the software on the level of solvent in the HPLC jars. We also added notes to the general guide about being careful not to dry our columns or stones. These instructions were completed, printed, and added to a training binder.

We planned to train for the entirety of the third afternoon, but we experienced a column leak. After lunch, we trained Nsabo, Goodluck, and Wensaa—KSP students and faculty. They created a demo method and sequence to help learn the software. Nsabo fixed the column leak, and they created an amoxicillin extraction with a capsule made in China obtained from the KCMC hospital. They then set up their own method and sequence for amoxicillin, and ran the test. They commented that they liked the simplicity of the method. Nsabo asked that we create a system suitability method that used more readily available chemicals than USP standards. We left the USP

Figure 3. Sister Zita at a local pharmacy.

Figure 5. David training at KSP.

standards for them to do testing with, but that was not a sustainable solution.

Our team and KSP students also put together the second HPLC unit during the third day, and were able to get it running with the new software and laptop. We used this instrument to teach the students how to prepare and purge an instrument and were able to get all of the lines running.

During the final evening at KSP, we visited with the students and learned that their goal is for KSP to have an HPLC lab hub for testing drugs. They hoped this would be both a contract facility and a training facility.

On our fourth day, Emmason picked us up for our safari. After he dropped off Sister Zita with her sisters in Arusha, we traveled to Tarangire National Park, where we saw elephants, zebras, giraffes, monkeys, and many more animals. We then drove to “mosquito town” and stayed at the Karatu Hotel before spending our final day on a safari in the beautiful Ngorongoro Crater (Figure 6). There we saw many animals including lions and hippos, and saw a few Masai men walking their goats and cows. We learned a lot about the animals and the natives, and saw some incredible sights.

IMPACTS

Purdue University fosters an environment rich in diversity. Purdue students come from many different ethnicities, religions, backgrounds, and cultures. Much of

our coursework aims to encourage collaboration, exemplified through group projects, presentations, papers, and other assignments. Our experience in Tanzania reinforced these processes—we worked as a group in order to achieve our project goals. Communication and collaboration among team members and those at KSP was essential to developing, testing, and implementing our methods and processes. Additionally, traveling to and working in a different culture promoted professional and personal development. Having an understanding of other cultures is important when interacting with others at our diverse university and beyond.

The goals of this project were to develop methods for universal analysis of drugs via HPLC, provide a means for the individuals at KSP to utilize these methods, and expose students to a unique culture. In these regards, the project was a success. We developed methods for several different drugs that were replicable and utilizable. Additionally, we successfully set up two HPLC units and ensured that they were both in working order. After the training session, the individuals from KSP demonstrated that they could successfully utilize the instruments and methods. We were also exposed to Tanzanian culture. We visited local pharmacies, had opportunities to converse with and learn from some of the locals, and participated in a two-day safari.

During our time at KSP, we were able to implement the usage of the HPLC units and train the students to run the methods provided. While we did not test samples on-site due to lack of time, we prioritized and completed

Figure 6. Michael, David, Jordyn on our Ngorongoro Safari.

the testing of the medications. The students at KSP are now able to obtain and test samples of medications they purchase from the local pharmacy.

However, we have not yet completed our ultimate long-term goal of being able to utilize the methods developed to analyze any drug. Our group and future members of the team must continue to achieve short-term goals (e.g., more methods for more drugs, future collaboration) in order to achieve the broader project goal.

We were well prepared in terms of having developed methods, instrument training, and an ability to train others. Our knowledge and understanding of the region and culture was not as well prepared. Having some background knowledge would have been a good starting point when conversing with locals. A brief orientation could include geographic information, the current state of the country's political affairs, cultural beliefs and ideologies, and important historical events.

The largest shortcoming of the trip was having only three days to spend on research and setting up instruments, and two days for the safari. Two to three weeks would have allowed us the time to conduct more experiments, ensure that the instruments continued to function properly, and learn more about the culture and participate in more excursions. This was an approximate 50-hour round-trip, which would have been more cost-effective by having more time to work and learn.

CONCLUSION

In today's globalized world, everyday job functions require interactions with individuals from other cultures. Not only did we develop a strategy to meet the

needs of our international partners, but we also received hands-on experience utilizing an HPLC unit and gained an understanding of how to successfully navigate broad complexities. We learned how to interact in a new culture to overcome a lack of resources, and experienced differences in viewpoints due to contrasting societal norms. This experience will be vital in our futures.

Additionally, we learned that it is possible to make an impact in the world no matter who you are. In addition to continuing and expanding our own project, we hope to inspire other projects similar in nature. If a handful of college students from the Midwest can complete a project that may improve the quality of life in a country halfway around the world, then with the right determination and opportunity, many others can do the same.

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