Moving Latin American Laboratories Forward by Giving Back

Article:
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J Appl Lab Med 2016 (1) 2:234-236.
http://jalm.aaccjnls.org/content/1/2/234

Guests:
Dr. Laura Parnas, Director of Clinical Chemistry at Sutter Health Shared Laboratory in Livermore, California, and Dr. Veronica Luzzi, Director of Clinical Chemistry at Providence Regional Laboratories in Portland, Oregon.

Randye Kaye: Hello and welcome to this edition of "JALM Talk" from *The Journal of Applied Laboratory Medicine*, a publication of the American Association for Clinical Chemistry. My name is Randye Kaye and I'll be your host.

The Latin American Working Group was formed in 2012 with the mission of bringing educational programs to and improving the quality of general laboratory services throughout Latin America as part of AACC's Emerging Countries Program.

These missions are achieved by organization of interactive workshops taught entirely in Spanish in different Latin American countries through collaboration with local professional societies.

To date, workshops have reached over 1,000 Latin American colleagues in 10 countries, and have included topics such as best practices in quality control and method verification, while also allowing the exchange of ideas as to how to meet quality requirements with limited resources.

In the September 2016 issue of JALM, a Laboratory Reflections: Pay It Forward article entitled "Moving Latin America Laboratories Forward by Giving Back," discusses the experience of two members of the Latin American Working Group who are both from Argentina. They discussed the differences between Argentinean and U.S. clinical laboratories and what it meant to them to be able to give back to their home country through involvement in this initiative.

The authors of this article are Dr. Laura Parnas, Director of Clinical Chemistry at Sutter Health Shared Laboratory in Livermore, California, and Dr. Veronica Luzzi, Director of Clinical Chemistry at Providence Regional Laboratories in Portland, Oregon. Drs. Parnas and Luzzi are our guests for today's podcast.

Welcome, Doctors. Here's my first question. In the article, you described how, during your training in clinical chemistry in the U.S., you were constantly drawing parallels between your experiences in the clinical laboratory in Argentina and those in the American system. What are some of the most critical differences between both systems?

Dr. Veronica Luzzi: We can probably divide these critical differences on those related to regulatory compliance and those related to the pathologist role of the patient. So let me talk about the regulatory compliance first.

One of the most critical differences is that laboratories in the U.S. are regulated by a law signed by Congress. That law is the CLIA '88. In Latin America, we don't have a law that regulates laboratories, but instead, laboratories that want to pursue getting certified or want to develop a quality management program get certified by either ISO or accredited by ISO 17025 or 15189. And as an example, in Argentina, as of 2015, there are 46 labs that are ISO 9001 certified, 143 labs that are ISO 17025 accredited, and 8 labs that are 15189 accredited.

Most laboratorians do have a very good understanding of the importance of quality. However, they're working toward learning more. And I think that's one of the reasons why our workshops had been so successful, because the audience is thirsty for learning how countries like ours, United States of America, is providing laboratory services.

In regards to the role of the pathologist on the patients, this is quite different, and I'm going to base my response in what I know about Argentina, but my understanding is most Latin American countries have a similar model than the one that Argentina has, where the pathologist in general doesn't own or direct a clinical laboratory, but instead, the clinical biochemist does. That is a very interesting difference. The clinical biochemist, for example, is the person drawing the samples, so he does the phlebotomy. He also processes specimens, does the testing, and at the end, produces the results and acts as a clinical consultant to the ordering clinician. So very, very big difference what I would say.

On the other hand, I mentioned that the role of the patient is very different. What happens in the United States of America when a clinician orders a test, that test goes usually through an electronic ordering system and that order goes directly to the laboratory.

Instead in Argentina, the order gets printed in a piece of paper given to the patient. The patient then walks or goes to the lab of his or her preference, gets the testing done, the laboratory returns those results to the patient in usually

a written report, and then the patient goes back to the doctor, shows the results in that report that the laboratory gave directly to the patient. So the role of the patient is very important for the flow of information.

Randye Kaye: That is quite a difference. Thank you, Dr. Luzzi.

Dr. Parnas, the Latin America Workgroup workshops have been held in many countries throughout Latin America. So can you tell us about the audiences that are attending these workshops? What commonalities were you able to identify among the different countries?

Dr. Laura Parnas: So the people who attend the workshops are very diverse and many of them travel from different areas of the country and many of them are from rural areas as well, and they want to participate in the workshops that we offer. So people who attend range from clinical biochemistry college students to medical technologists, laboratory supervisors, managers, directors and also health care government officials that are involved in laboratory matters.

It's important to note that there's a wide variety of different types of laboratories in all countries in Latin America. In general, the main public hospitals or large hospitals are government run, and they also have large laboratories, but usually or often, these laboratories are short on resources and technology.

There are also on the other side of the spectrum very large private laboratories that have the latest technologies and operate at a high level. Like Veronica said, many of them are certified or accredited by international bodies such as the College of American Pathologists or ISO.

And to complicate things a little bit more, there are many small and medium size private laboratories that serve a small subset of patients and providers, and these laboratories range in resources and technology, and they are often not certified nor accredited. So there's a wide variety of different types of laboratories and people who work in different settings.

One of the commonalities that we hear from workshops, at least across the different countries we visited, is the difficulty for the public laboratories to obtain calibrators, reagents, and controls in a consistent manner as all these people in the government-run lab have very little control over the procurement process, which is often very bureaucratic and not aligned with the laboratory needs.

However, like Veronica said, clinical laboratory staff takes really great pride in their work, and they will do their best to

do the highest possible quality work with the resources they have. This is also, I think, a commonality we all share wherever in the world we're located.

Randye Kaye: I think that's probably quite true. Thank you for your answer. I want to know more. So, the program is meant to have a significant impact on the participating audiences. So maybe you can share with us some of the topics that have been taught during the workshops and why were these topics selected.

Dr. Laura Parnas: So when the Latin America Workgroup was originally formed back in 2012, several topics were identified and these were based on the general needs communicated to the AACC by the presence of the different Latin American clinical biochemistry societies. So the goal was to start the workshops with a topic that would have the highest impact in the practice of laboratory medicine in Latin America.

The first selected topic was quality control, so more specifically, adding value to patient care using quality control. The lectures we developed and shared with our Latin American colleagues included basic statistical calculations, definitions of error, selection of quality control materials, interpretation of Levey-Jennings charts, and best practices in quality control as well as how to investigate and troubleshoot issues and errors that occur in the laboratory.

A big emphasis was to make the workshops very interactive. So in the structure of the workshop, we usually devote a significant amount of time for interactive exercises where the attendees have an opportunity to apply what they just learned in a practical manner.

We have also improved the workshops overtime with feedback we obtained from the attendees both in a written manner and also through informal conversations that we have during our visits. I personally think that this topic has significant value for all the different types of laboratories that I discussed before.

Many of the attendees will learn many new practices. Some of them will learn new tricks, and then for the most advanced attendees, it will be a very thorough review.

Of course, our goal is that everybody can implement at least one best practice in their labs and spread the knowledge to their peers.

So the newest workshop topic that we developed has to do with verification of manufacturer claims using CLSI guidelines, as the laboratories in Latin America usually do not deal directly with instrument and reagent

manufacturers, but rather, they deal with distributors, the instruments are usually just delivered to laboratories with little to no guidelines as to how to verify the claims.

So due to variations in regulatory requirements of each country, verification protocols are widely variable across countries in different types of labs. So we decided that this topic group provides a baseline understanding of how easy it is to verify the claims with a limited number of experiments, a small budget, and strong statistics, which is something that everybody has access to in the countries that we visit. For this purpose, we decided to use a protocol from the CLSI and developed practical tools to explain and apply the protocols in a very easy to follow manner.

So far, we have presented eight quality control workshops and two method verification workshops throughout Latin America. In fact, next month, we're presenting the third method verification workshop in Córdoba, Argentina right before the start of the First International Congress in Clinical Biochemistry to be held in the city of Córdoba, which is very, very exciting for us.

Randye Kaye: Wow! That's wonderful. So it sounds like the participants learn a lot, but of course, the teacher always learns as well.

So finally, Dr. Luzzi, can you share your thoughts on how your participation in this group has impacted your current practice?

Dr. Veronica Luzzi: Yes, sure. Thank you for asking. I think one of the biggest uses of these workshops, or how this workshop has impacted my practice, is by learning how to teach, by being better at what I offer to the students, and to create better lectures that teach the topics to the technologist in my current practice.

I've been translating the presentations that we have from Spanish to English and sharing it with the supervisors and the managers in the health system where I work at Providence Health and Services. I realized that one of the things that we sometimes forget to do because we're so busy and running around is to share our experiences, to share what learned as we improve as professionals. And I think it is important to give the technologists the tools that they need to understand why they do the things that they do rather than tell them what to do. That is something that I'm going to be working on in the next few years.

In the next November, my colleague and I, here where I work, are going to start a series of lectures to our own technologists that are going to be focusing first on quality control, resolution of quality control issues, troubleshooting,

then we're going to move on into method evaluation. Very simple things as in, for example, how to deal with random errors, how to deal with systematic errors that we see every day in the laboratory, are sometimes not been taught in the medical technologist programs. I think we, as medical directors, are fundamental in helping the technologists to be better at what they do.

Another area that has been impacted by my current practice is how we monitor bias on the assays that we perform. One of the things that is interesting is that, we're always thinking as medical directors on how to meet the regulatory requirements that we have in the laboratories. But sometimes, we have to think beyond that. What else can go wrong? How else can I prevent something from happening? And teaching this course has made me think about my current practice. For example, one of the things that we're trying to do now is to analyze new lots of reagents to identify whether or not there is bias and monitor the cumulative bias after a few changes in the lot of reagent.

In addition, we also started to implement a check whenever we change, calibrate our lot numbers, because we have observed that not all the reagents lots recover equally with different calibrators. So without getting too technical in this answer, I think there's always room to learn, always room to teach others.

What the workshop has allowed us is also to open the doors to say, "How else can we do this better?" I hear from colleagues, not only from United States but from all other countries in Latin America. Thank you.

Randye Kaye: Thank you. Well, thank you both so much for paying it forward, and thank you both so much for joining me today on the podcast.

Dr. Laura Parnas: Thank you.

Randye Kaye: That was Dr. Laura Parnas from the Sutter Health Shared Laboratory and Dr. Veronica Luzzi from Providence Regional Laboratories, talking about the JALM Pay it Forward article, "Moving Latin America Laboratories Forward by Giving Back" for this podcast.

Thanks for tuning in for JALM Talk. I'm your host, Randye Kaye. See you next time, and don't forget to submit something for us to talk about.