Clinical Chemistry

Automation in the Clinical Microbiology Laboratory

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Guest:
Dr. Carey-Ann Burnham is Assistant Professor of Pathology and Immunology at the Washington University School of Medicine in St. Louis, and Medical Director of Clinical Microbiology for Barnes-Jewish Hospital.

Bob Barrett: This is the podcast from *Clinical Chemistry*. I am Bob Barrett.

The clinical microbiology laboratory is sometimes considered low-tech, particularly when compared to the high degree of automation found in the clinical chemistry laboratory. However, systems are emerging for the clinical microbiology laboratory with the potential to automate almost all areas of testing, including inoculation of primary culture plates, detection of growth on culture media, susceptibility testing, and extraction and detection of nucleic acids from clinical specimens.

As a result, the workflow in the microbiology laboratory is changing at a rapid pace, and microbiologists have the challenge of selecting the most appropriate, clinically useful, and cost-effective automation for their laboratories.

The December 2013 issue of *Clinical Chemistry* included a question-and-answer feature addressing the impact of automation in the clinical microbiology laboratory. Dr. Carey-Ann Burnham served as moderator of that feature, and she is our guest in today's podcast.

Dr. Burnham is an Assistant Professor of Pathology and Immunology at the Washington University School of Medicine in St. Louis, and the Medical Director of Clinical Microbiology for Barnes-Jewish Hospital.

Doctor, what is the typical workflow for processing and analysis of bacteriology cultures in the clinical microbiology laboratory?

Dr. Carey-Ann Burnham: Well, microbiology laboratories look for the growth of pathogenic organisms in many different specimen types. These could include things such as blood,

urine, respiratory specimens, even tissues or throat swabs. As you might imagine, these different specimen types are very heterogeneous and laboratories may look for different organisms depending on the type of specimen.

So, what happens is the specimens are received in the laboratory, they are accessioned, and they're put on to different types of growth medium depending on the culture type. In addition to the different types of media, the way in which the specimen is put on to the media varies depending upon the specimen type. Cultures are then incubated which can be for from one day up to eight weeks depending on the type of specimen, and the culture plates are then reviewed by the laboratory technologist and the organisms or pathogens that are recovered are worked up according to the laboratory standard operating procedure.

This is a very manual and subjective process that really hasn't changed a lot in many decades. Once the pathogens are identified, they would be reported back to the physician using the laboratory information system.

Bob Barrett: What are some of the challenges or limitations to this approach?

Dr. Carey-Ann Burnham: Well, one of the major challenges that we face is that there can be quite a bit of inter-operator variability. So, for example, on the initial plating step, if isolated colonies are not achieved, additional subcultures may be needed before work on the culture can begin. This adds both to the cost of working up the culture and also to the turnaround time. In addition, one of the largest challenges is that this approach really requires a lot of hands-on time, a lot of personnel time.

Bob Barrett: Well this does sound like a fairly manual process. Many of the other areas in the clinical labs such as chemistry and hematology have been highly automated for quite some time. What have been some of the major roadblocks to automation of microbiology?

Dr. Carey-Ann Burnham: Well, this is a great question. So, while automation has been common place for many of our colleagues in hematology and chemistry for many years, microbiology laboratories have been largely excluded from this trend. Now, there are number of reasons for this.

One of the biggest reasons is that in hematology and chemistry, the tests that they do are typically very high volume. Now, while these tests are very high-volume, they are primarily performed using one specimen type, mostly blood specimens that are in a very consistent type of tube.

In microbiology, the story is a little bit different. We have a lot of variability in the specimen types that we receive as I mentioned earlier everything from tissues to stools to respiratory specimens, and all these different specimen types arrive in the laboratory in different types of containers, and transport devices.

So, there is not really a one-size-fits-all in terms of automation that can accommodate all of these different specimen types as well as their containers. In addition, we have different sample processing protocols such as potentially centrifugation, or a homogenization, that may be applied to these different specimen types and then they're plated on to different types of media. So historically, this just has not been very amenable to automation.

Another major impediment has been cost. Automation is often very expensive and outside of the budget of many microbiology laboratories. In addition in microbiology we've long had a culture--no pun intended--of having a laboratory that is very manual, and the human element is very important. So, there's some thought that it's just too complex and it would be too difficult to automate. And until recently, there have truly been a lack of automation options in clinical microbiology. However, at the present time, this is a rapidly changing area.

Bob Barrett: Well, what types of automation options are emerging for clinical microbiology labs?

Dr. Carey-Ann Burnham: This is also a very interesting and exciting question. A variety of options are beginning to emerge. They range from very simple front end automation to what's called total laboratory automation.

So, front end automation could be something like a plate streaker where once a specimen is added to a plate, it's put on an instrument that will streak it in a very consistent reproducible fashion. There are also a number of instrumentation options that would decap your sample, apply it directly to the media, and streak it for you.

Now, this runs all the way up to what I mentioned full laboratory automation, which would have your plate streaker or front end processing options coupled to a variety of downstream elements. One of these elements may be something like a smart incubator where the culture plates are sent to an incubator, which would pull the plates out at user-defined intervals and image them using high-resolution cameras.

These cameras have the ability to detect plates that are growing bacteria and can alert the user that the culture is growing. In contrast, it could send cultures that are not growing anything directly to the garbage, and report them to lab automation system without any human intervention being required.

A number of systems also have monitors that display the high-resolution images, and laboratory technologists can look at these monitors, decide what may need additional workup or testing, ask for this directly on the monitor, and even send it to other automated colony pickers that can lead to doing MALDI-TOF Mass Spec on the colonies, or even automated susceptibility testing.

One of the major factors that has allowed for the shift in testing is that the types of specimens we are receiving in the lab are hugely shifting to liquid microbiology, especially with something called the eSwab, which is a liquid transport media that allows pipetting directly on to the system so that the entire specimen can be processed using this automated procedure.

Bob Barrett: Other than the obvious manual versus automated advantage, what are the other advantages of this automation?

Dr. Carey-Ann Burnham: Well, the biggest number one advantage is consistency in plating. So, the same specimen will be plated using the same inoculation technique for isolation of colonies every time. This will result in more rapid work-up because you will have isolation more rapidly.

It would also result in more rapid reporting of negative culture. So, if no human intervention is needed, if the system detects that the culture is not growing at a user-defined interval, it can automatically be reported as negative. You would not have to wait until a shift change or a specific time in

the day that a manual human intervention would be required to report that culture as negative.

This also forays into as potentially being able to read cultures and report results around the clock, whereas historically in many microbiology laboratories, this type of analysis was only done during the day shift.

We could also ask for early alerts for critical specimen types such as cerebrospinal fluid that's used to diagnose meningitis. So, for example, we could ask the automation to look at that plate every hour, or every couple of hours and alert us for this critical specimen type as soon as microbial growth is detected.

In addition, the automation will reduce our need for personnel or allow us to process more specimens or do more work with the existing personnel. And this is becoming an increasingly important issue for microbiology labs especially in the era of centralization and consolidation of microbiology services in many health systems.

Bob Barrett: Doctor, in past podcasts, we've talked about the emerging problem of a shortage of laboratory technologist, would this technology help address that shortage?

Dr. Carey-Ann Burnham: Well, I certainly hope so. This is a very important question, because we have more skilled technologists leaving the workforce than entering it, and this is mostly due to the fact that we have more people retiring than are entering the pipeline. So really, we need to focus on having skilled personnel use their skills where their expertise is most needed.

So, automation would allow us to take the human element out of things where a human isn't needed and save that expertise for when specific expert intervention is required. Ideally, this would allow us to work smarter, not harder, and address personnel shortages while maintaining a very high quality work product for our patients.

Bob Barrett: What are the major considerations for a microbiology lab approaching implementing automation?

Dr. Carey-Ann Burnham: Well, as automation is a whole new world for microbiology, there's a lot of discussion surrounding this topic. Honestly, for most labs, cost is still a major consideration. What will be the return on investment and is the automation affordable?

But, there are many other practical concerns. For example, the size of the equipment; will it fit in the existing laboratory space? Laboratories will also have to look at their sample volume and sample mix. So, how much automation would they need to accommodate their sample volume? And do the samples all come in at one time, throughout the day, or in a continuous flow throughout the day? And will all samples be able to be processed using the automation, or will a large number of offline processing be necessary? All of this would factor in to the accessibility and the practicality of automating microbiology.

Another important issue is will the automation interface with the existing laboratory information system? If the automation cannot tell the laboratory information system the data that it needs to do its analysis, then the automation will essentially not be effective. And of course, a large issue is connectivity of different instrumentations.

So, laboratories may have some pieces of existing automation or other technology that may be from different vendors. So, it's a very important consideration if these different pieces of technology will talk to one another to all be able to work together on one automated line.

Bob Barrett: So, do you think that a full lab automation system is appropriate for all clinical labs?

Dr. Carey-Ann Burnham: This is a very difficult and interesting question, especially considering the cost associated with some of these automation platforms. I think that nearly all laboratories large and small can benefit from some form of automation. But, it will definitely depend on the type of testing performed by the lab, the personnel they have available, the budget of the lab, and the laboratory goals. But, even most small labs could highly benefit from the consistency and savings in tech time of an automated plating system.

Bob Barrett: Well, finally Dr. Burnham, let's take this to the other end of the pipeline. How will automation in microbiology impact patient care and outcomes?

Dr. Carey-Ann Burnham: This is a very important area with great potential. We truly hope that it will improve patient care in multiple ways including expediting reporting of both positive and negative culture results, the potential to reduce human error. Our goal would be to produce high-

quality results that are reproducible, traceable with improved turnaround time.

So, our goal is obviously to produce results faster. However, we're going to have to interface very closely with our clinical colleagues to make sure if we're reporting results, they're being reported in a timeframe and in a way that they are rapidly usable.

So, while we hope that the end product will be improved patient care, truthfully, at the present time we are lacking in outcome studies to demonstrate this. These studies are critically needed to show us how automation will truly benefit patient care and will be important to help laboratories justify the cost of purchasing and implementing this equipment in the future.

Bob Barrett: That was Dr. Carey-Ann Burnham of the Washington University School of Medicine in St. Louis. She has been our guest in today's podcast from *Clinical Chemistry,* examining automation in the clinical microbiology laboratory.

I am Bob Barrett. Thanks for listening!