TLA in, volume up—micro labs take stock

Anne Paxton

May 2017—*Rise of the Robots. Disruption. Humans Need Not Apply.* "The Future of Work." A flood of books and articles in the past several months make the argument that service industries in the U.S. hover on the brink of total automation and humans will have to figure out how to adapt.

Forty-five years ago, when Michael R. Jacobs, MD, PhD, started in microbiology, people fantasized about microbiology reaching this stage. At that time, "the dream was that in a few decades there would be an instrument like an auto-analyzer that would take a specimen at one end and spit out a culture and result at the other end, without any action needed in the middle," says Dr. Jacobs, who is director of clinical microbiology at University Hospitals Cleveland Medical Center.

He doesn't think that's practical quite yet. However, the technology is available, and the total laboratory automation (TLA) or partial automation that's already in place in microbiology laboratories is doing a close imitation of what was pure fantasy in the 1970s. As microbiology directors at some of these labs explain, the return on investment from their TLA installation has been fairly reliable, but converting microbiology from its traditional semi-batch processing to a smooth, automated workflow continues to be tricky.

Dusich

"We first started looking at Kiestra Total Laboratory Automation in 2011, before it was bought by Becton Dickinson," says Irene K. Dusich, MT(ASCP)SM, microbiology manager for the NorthShore University HealthSystem in suburban Chicago. Shortly thereafter, a new chair of pathology came on at NorthShore who wanted a renovation of the laboratory; the retiring technologists and shortages of qualified new staff resulted in a "perfect storm," creating the conditions for TLA, Dusich says.

NorthShore, in fact, is the site of the first TLA system to be implemented in the United States. That had a downside, because there wasn't another laboratory they could emulate. "We weren't so sure about workflow and we didn't have others out there like us to tell us how to do it," says Dusich.

The laboratory's vision was to grow the four-hospital system's testing volume without needing more space. And, stoked by growth in outreach—now 52 percent of total test volume—the laboratory did achieve those goals. With its BD Kiestra TLA configuration, which includes three incubators, a conveyor, four online workstations, and four off-line workstations for reading plates, the lab now performs about 300,000 billable tests per year.

Unlike classical practice, where microbiologists might be assigned hundreds of urine cultures to read in a day and would perform identification and susceptibility testing at the bench until they were done, her laboratory's process has "readers" trained to read all types of cultures. They see what's ready and read it on a screen, and electronically mark it if colonies need to be worked up, noting which workup needs to be done. Other staff load specimens onto the TLA, pull positive blood cultures, make smears, and perform rapid PCR tests.

The staff have had three types of reactions to the transition to TLA, Dusich says. "Some people who were really ready to embrace new technology took to it like ducks to water; others needed a little gentle nudging and after a

few months they were okay with it, while others are still getting used to it, and we help them through it." The laboratory planned to cut six full-time equivalents and was able to achieve that—all by attrition.

The most common problem was microbiologists feeling that if they were strictly doing reading, they weren't doing their jobs. However, Dusich says the Kiestra does not determine whether a culture is positive or negative or what follow-up needs to be done. The technologist is still the decision-maker.

An early challenge arose with the laboratory's first BD Kiestra Inoqula, the specimen processor. "It didn't have a biological safety cabinet incorporated, so specimens that weren't truly liquid—like a viscous joint fluid or a tissue that must be ground—couldn't be put through the system because it uses a pipette and they would clog up the pipette. There is a semiautomated solution, but the laboratory preferred to wait until January 2016, when the Inoqula was upgraded to include the safety cabinet. Then we were able to put 100 percent of our bacteriology cultures on the TLA."

Another issue was that the culture swabs people were used to seeing don't come in a liquid. "We had to change to Eswabs, and the transition was a little more difficult than I envisioned it." Because of the number of players involved, the laboratory had to arrange a "search and seizure" operation at every site that used the old swabs and replace them, and nurses at four hospitals had to be educated around the E-swabs' use, "so it took longer than I thought it would," Dusich says.

Her laboratory takes credit for prompting a fix of a common trouble spot in processing: MacConkey plate lids getting stuck and causing errors or destruction of plates. "By February 2015 we had a fix for that. Now there are Teflon guides that keep plates in place, so when the instrument goes to pick up the lid, the bottom of the plate doesn't come with it. That completely solved the problem, and everyone who acquires the system now gets that automatically."

The NorthShore TLA installation, since it was the first, Dusich notes, cost less than a similar current installation, which would be about $3.5 million. But the laboratory initially thought its return on investment would take seven years. Instead, "because of the number of FTEs we were able to cut, our ROI should be three years just on labor savings," Dusich says. "That's not counting anything else you might be able to roll into it, like improving length of stay, antibiotic stewardship, and so on. Those are kind of intangible at this point and it's really hard to mine the data for that."

A poster her lab presented at the American Society for Microbiology meeting last year illustrated how TLA, together with the MALDI-TOF mass spectrometer the lab installed in 2013, improved turnaround time variability on urine cultures significantly. The study showed this effect for both organisms identified by spot and conventional testing. Time to AST was also significantly reduced for both types of organisms. Dusich, who assisted in gathering data from the laboratory information system for the study, says the microbiology lab plans to continue data collection for possible future publication.

In contrast with many labs, PCL Alverno in Hammond, Ind., was not running out of space in 2011 when it devised a five-year plan that included laboratory automation. It was just planning for a large increase in test volume. "We had opportunities coming up, and we felt we needed either to expand our area of microbiology for manual workups or to start looking at the automation that was just coming on the market," says microbiology manager James Clark, BS, SM(ASCP).

"Automated incubators were just being developed, so, looking to the future, we wanted to have a system that would be compatible." At that point Alverno had automated only its identification and susceptibility testing, using MicroScan instruments.

Alverno, the core lab for 26 acute care hospitals in northwest Indiana and northeast Illinois, does about 4,000 cultures per day, and 30 percent of the test volume comes from outreach. With 10 MicroScans that handle 96 panels apiece, Clark thinks the laboratory is among one of the largest integrated delivery systems in the nation.

Partly to minimize the impact on employees, the laboratory sought to phase in its system by starting with automated processors for cultures, and it chose Copan's WASP, the front end of the WASP/WASPLab automated system. "We had extra floor space then. Within the lab we called it the dance floor. So it was easy for Copan to come in and move the power poles for the electrical supply and the CO2 lines to wherever they needed to be." The lab used a Lean design for the space, positioning the front end of the installation where the specimen receiving was, and managing to avoid some of the disruption that automation tracks can create with the laboratory workflow.

Currently the two WASPs, the setup instruments, which were installed in 2012, have 14-foot tracks leading straight back to two double incubators. But Clark says the system is versatile and nearly any configuration is possible, including right-angle turns. "One lab put a track through a wall in order to unload the plates from the canisters in a different room."

Half of the volume is off-line at the moment, with a single line being used to process urine cultures; tests processed by the second WASP come off the front of the instrument and go into manual incubation. The reason: The smart incubator system requires an interface with the LIS that had to be built from scratch, Clark explains. "We've just about finished the complete interface so we can go completely live with our positive urine cultures. That's the most complicated part of the interface, when you are dealing with the part of the culture that's going to have additional identification and susceptibility testing." The lab has a MALDI-TOF for identifications, which is in the process of being interfaced.

"Because of our capacity to grow, we anticipate adding another line within the next year with its own track and smart incubators, which will allow us to double our volume," Clark says. But Copan's system is suitable not just for large labs, he adds. "Copan has single incubators which are half the size of ours, so you could hook those up and have something that would handle a 400–500-bed hospital."

The need to move to a liquid collection system came up early after installation. "Historically in microbiology, it's very difficult to be sure you're keeping a sample refrigerated continuously until setup time to maintain sample integrity," Clark notes. "We've always had some issues with a level of contaminated growth due to collection systems, particularly in urine cultures."
When Becton Dickinson came up with collection tubes with preservatives, they were more expensive, and some hospital-based lab sites didn't use them for financial reasons. But Alverno decided that requiring its hospitals to use the preservative was appropriate as a matter of maintaining specimen quality, not as a matter of facilitating automation. "Since hospitals could be exposed to reimbursement cuts from the regulatory and reimbursement agencies that are starting to impose penalties for hospital-acquired urinary tract infections, specimen integrity and quality are important not only to patient outcomes but also for financial reasons."

Alverno approached the swab issue as it relates to automated processing the same way. "We had looked at the flocked swab in the past, which is typical for liquid-based swab specimens, but at the time they seemed cost-prohibitive. I think that automation and a growing demand for the swabs has been a factor in helping bring the price down." The primary reason to use the flock swabs, however, is still specimen quality—not to accommodate automation, he says.

Automation's impact on staff was kept to a minimum. "We really didn't lose FTEs. Not because the instruments didn't do their job. Rather, we were able to insource all the setups from the hospitals, which meant that each hospital could reduce, on average, by about one FTE. So at all 26 hospitals we were able to reorganize workflow, and at Alverno we only added two FTEs."

Clark

Unfortunately, Clark says, not enough manufacturers are amenable to the concept of open systems that can link to other companies' instruments. "Some major companies feel they can put their own products out there and stay a closed system. But we try being involved with manufacturers that have systems that are open and can have others linked to them, particularly in the case of TLA." With the technology changing so fast, he says, "systems are just going to have to open up, as far as we see it."

Even within two weeks of installation, the technologists and technicians were commenting on how uniform and standardized the streaking was, Clark says, which reduced the number of subcultures the lab needed to perform. However, as a microbiologist who had streaked thousands of his own cultures, Clark was interested in demanding that automated instruments have a flexible style of streaking.

When Alverno acquired its WASPs, Copan had 12 or 16 patterns to choose from but offered to program modifications if the laboratory wished. "About eight months into using their patterns, we wanted to modify slightly one of the streaks so it would go only two-thirds of the way down the plate instead of all the way down." Once that modified pattern was produced, Copan added it to the stock of patterns available to new customers.

From his perspective, one of the major benefits of Alverno's automation has been the smart incubators. "You don't take plates in and out of the incubator to put on your counter and sort through; they stay in the incubator. And it's been proven that with continuous incubation, you actually get colony formation faster. So instead of taking 18 to 24 hours, we actually read our first urines at 14 hours. About 60 to 70 percent of the positive cultures can be worked up at that time."

Reducing turnaround time was particularly important for his lab because of the centralization of setups, which has added to the time lost in transport. "But we make up at least six hours per culture just because of the automation," Clark says.

Return on investment is always a concern. "Our front end has more than paid for itself, so depending on your volume, you are probably looking at three years for ROI," Clark says. The cost of the system varies from lab to lab, but "for the smart incubator side of the system with servers and workstations, I would say somewhere around $1 million for a single incubator system would be pretty common. The front-end processors run around $300,000 each."

Next on the lab's automation agenda is adding another line to take care of the remainder of the cultures it is working with. "We're working with Copan to improve the programming of software to make the system more capable of handling multiple-day/multiple-read cultures," Clark says. In the meantime, BD and Copan are racing to see which will come out with software that will have colony recognition and the ability to read the cultures, instead of having a technologist read them, he adds.

Clark considers workflow to be pivotal in taking advantage of all that automation can offer. "Historically, microbiology is what we would call a semi-batch process. You go to the incubators, get all the plates out on the day shift, or maybe two shifts, look at them, decide what you're doing, set some stuff up, put them back in the incubator, wait, and then get them out to batch again." A set of plates might be 12 hours old or 30 hours old under current professional standards.

To maximize throughput and minimize turnaround time, "you need to have a constant flow," he emphasizes. "And the only way to do that without having a ton of incubator space is to have a computerized incubator that can produce images effectively and generate a worklist based on them that techs can scan through quickly and

continuously, 24/7."

This kind of process will allow for every plate, when it is ready to be read, to be imaged, and for that image to be available on a screen, with a dashboard listing how many plates are to be read at 2:00 and 4:00 and 6:00 and 8:00, Clark says. "That will minimize turnaround time and maximize efficiency, which will reduce some of the workforce needs, or free people up to do more manual things."

Like NorthShore's laboratory, the microbiology lab at University Hospitals Cleveland Medical Center had been looking into automation for a long time because of its volume increases, says Dr. Jacobs. "Our workload has gone up enormously in the last decade as University Hospitals have developed a system from the central campus that incorporates community hospitals, lots of physician offices, patient care centers, and outpatient labs," Dr. Jacobs says. "Over the last seven years, we consolidated all microbiology from the community hospitals into the central hospital."

In 2010, his laboratory was the first in the country to get automated specimen plating using the Copan WASP system. Also that year, Dr. Jacobs witnessed the Kiestra TLA—then available only in Europe—in action, and was impressed. When Becton Dickinson bought Kiestra two years later, University Hospitals made the jump to BD Kiestra TLA.

The Kiestra system arrived at University Hospitals' microbiology lab in early 2016, making the laboratory the second hospital in the U.S. to acquire a Kiestra system and, when it was installed, the largest Kiestra TLA to that date. "It took two months to install; then we went live with urine specimens and did that for a year while we went through the whole process of getting staff trained and getting all the tests validated. Now all our specimens are being tested on the system." The specifications called for the automation system, which cost $3.5 million, to be able to absorb up to 40 percent more volume; since installation, the lab has already increased its volume by 15 percent, Dr. Jacobs says.

His laboratory has found that the continuous processing Kiestra permits brings major improvements in turnaround time. Whereas a partial automation system would automate specimen processing and then put out the plates, having laboratory workers carry on manually from there, Kiestra eliminates the manual step, Dr. Jacobs says. "It puts the plates into an incubator, which we set for 16 hours, then it takes images of the plates to be reviewed as images on a screen. If there's no growth, then you don't have to handle plates; the culture is flagged as negative and then it throws the plate away. Since 80 percent of urine cultures are negative, that's a big time savings."

Dr. Jacobs

This automation makes the whole process more efficient. "If a urine specimen came in at 4 PM, we would put it in the morning basket to read at 8 AM, which would be 16 hours later. First thing in the morning, we read all plates that are 16 hours old, then at 10:00 we get the next batch, and eventually we'll be able, 24 hours a day, to read each plate as it reaches 16 hours. This puts you on continuous processing, where you're reading plates at the right spot, not between 16 and 30 hours, which is what we would do before."

"Even for outpatient specimens, the continuous processing can reduce your average turnaround time by a day once your system is installed," Dr. Jacobs says. That estimate confirms studies by Kiestra, which has found that its European installations reduce the average turnaround time for all microbiology specimens by 24 hours.

The laboratory has probably doubled its specimen volumes since 2010, Dr. Jacobs says. Now it receives about 750

specimens a day, 300 of them urine and 150 to 200 blood. The footprint of the system that handles all this volume is smaller than the manual setup it replaced. “But it’s still a pretty big footprint, because we have two inoculating stations, five reading stations, and five incubators.”

Although the laboratory hasn’t yet recalculated turnaround time, he knows it is shortened. “We’ve definitely had ID physicians contact us and say they’re aware they are getting results faster.”

The laboratory has used its MALDI-TOF to help speed up the system processing of positive blood cultures. “We put a plate in the system, have it incubate for four hours, then send the plate on to the workstation. At that point, within the next 30 to 60 minutes, we do the MALDI, and on at least two-thirds of blood cultures, we have enough growth to get good identification.” With this process, Dr. Jacobs says, “we’re also getting better susceptibility results because there are more antibiotics in the tray.”

Within a couple of months, the lab will convert completely to MALDI identifications as it is phasing out the MicroScan combo plates. “We’re working on ways of speeding up the susceptibility part of the four-hour blood culture testing. We hope to have that in play by the end of the year.”

The laboratory adopted a different strategy to address initial issues with the MacConkey plates. They can be very wet and sometimes get stuck, Dr. Jacobs says. So tweaks in the process were necessary to ensure the plates are dry before they are put into the system: “Instead of taking plates directly from refrigeration, we wait until they are at room temperature before putting them in the loading stations.”

Dr. Jacobs says his laboratory justified the installation of the Kiestra system by arguing it would be able to get 40 percent more work done without an increase in staffing. That prediction has been borne out, he says, and the laboratory is finding the number of FTEs needed to run the laboratory “keeps on going down.”

“It’s really difficult to get microbiology technologists, a lot of our people are reaching retirement age, and we have people coming in who are less qualified with less experience. So we needed to simplify the processes as much as possible, and we’ve achieved a lot of those goals,” he says. There’s been a quick learning curve for staff, and the new workflow creates a more efficient division of labor. “You can have experienced people reading a lot of plates, and less experienced doing the workups, as opposed to having everyone at the bench for the whole process.”

Dr. Jacobs’ team originally calculated that the decreasing length of stay for patients with bacteremia, plus the benefits reported in the literature of getting faster definitive results on blood cultures, are sufficiently substantial that the system could pay for itself in one year.

As it turns out, it’s only been in the past three months that turnaround time has reached the speed in those calculations, he cautions. “So it’s probably going to take us two years to get to that period. But thereafter, we’re going to get the same returns every year.”

In addition to shorter hospital stays, the savings from reducing the amount of unneeded treatment will also contribute to a quick return on investment, Dr. Jacobs believes. “When you go to a physician with a urinary tract infection, you get put on treatment before the culture results come back. If the cultures are negative, and the physician finds out 24 hours sooner, then you’ve saved the cost of extra antibiotic treatment.” In fact, he says, “I think there are going to be small savings on almost every specimen we touch.”

As microbiologists make the adjustment to the era of automation, Dr. Jacobs cautions, they shouldn’t get too comfortable. “Genetic methods are going to take over everything we’re doing; it’s just a question of when that becomes affordable. And I think it will be sooner rather than later.” He estimates that the automated system his lab now has will be practical for about 10 years. “Then it will be all genetic and molecular testing.” In the meantime, he is optimistic that other microbiology labs, if they are large enough, will find they can benefit from installing TLA. □n
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