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The Automated Clinical Microbiology Laboratory: Fact or Fantasy?

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Automated chemistry laboratories dependent on robotic processes are the standard in both academic and large community hospital settings. Diagnostic microbiology manufacturers are betting that robotics will be used for specimen processing, plate reading, and organism identification in the near future. These systems are highly complex and have large footprints and hefty price tags. However, they are touted as being more efficient, rapid, and accurate than standard processes. Certain features, such as image collection, are highly innovative. Hospital administrators may be swayed to institute these new systems because of the promise of the need for fewer skilled workers, higher throughput, and greater efficiency. They also may be swayed by the fact that workers with the requisite clinical microbiology skills are becoming more difficult to find, and this technology should allow fewer skilled workers to handle larger numbers of cultures. In this Point-Counterpoint, Nate Ledebøer, Medical Director, Clinical Microbiology and Molecular Diagnostics, Dynacare Laboratories, and Froedtert Hospital, Milwaukee, WI, will explain why he believes that this approach will become widespread, while Steve Dallas of the University of Texas Health Science Center San Antonio explains why he thinks that this automation may not become widely used.

POINT

Automation as a benefit in clinical microbiology. Since inception, clinical microbiology has been dependent on a highly technical and skilled workforce to receive, process, and interpret results from a wide variety of clinical specimens with limited aid from automation. Clinical staff has complained of poor turnaround (TAT) while the laboratory inoculates appropriate media and awaits microbial growth. Ever-increasing specimen volumes and fewer available skilled workers have led laboratories to increasingly seek automated solutions for microbiology. Automation was introduced into the clinical microbiology laboratory in the 1960s as automated plating instruments but was initially met with limited success. Today, instruments are an integral part of many clinical laboratories and are used for specimen management, microbial detection, nucleic acid amplification, identification, and susceptibility testing.

In contrast to chemistry or hematology laboratories, which use standard collection tubes and a minimal diversity of specimens, microbiology laboratories must accept nearly any specimen type in any type of transport container. The absence of standardized collection devices and the lack of standardized transport media, complex specimen processing, and interpretation of cultures have left microbiology in the dark ages of automation. However, the advent of new technologies, such as mass spectrometry, liquid transport media, molecular techniques, and automated identification and susceptibility systems, has begun to simplify and allow for much greater standardization of the microbiology laboratory. This, combined with high-resolution digital imaging and robotics, has allowed microbiology to accomplish the impossible, i.e., to become automated.

Several factors have contributed to changing attitudes about automation in clinical microbiology, including declining reimbursement, an aging workforce, technological innovation, personnel shortages, demand for quality laboratory services, and demand for timely results.

Changing workforce. Medical laboratory professionals play a critical role in health care, with the majority of medical diagnoses being based on laboratory tests (1). Unfortunately, the United

States is facing a continuing shortage of qualified laboratory personnel, raising questions about the ability of laboratories to handle current and future testing demands. Much of the shortage in medical laboratory professionals is owed to an inability to train enough qualified practitioners to meet the demand for services, with 68.3% of vacancies requiring certification as a prerequisite (2). Moreover, there has been a steady decline in the number of medical laboratory training programs and in the number of students graduating from medical laboratory training programs (1). According to a 2003 study by the American Society for Clinical Pathology (ASCP), rural areas and areas served by smaller hospitals, in particular, are finding it increasingly difficult to recruit and retain qualified laboratory personnel (1). In its 2012 vacancy survey, the ASCP found the total vacancy rate for microbiology and specimen processing to be 5%, with 9% of microbiology department employees expected to retire in the next 2 years (2). As a result of the limited pool of qualified applicants, the survey also found that 50% of positions required 3 to 12 months to fill (2). In relation to new technology, the ASCP vacancy survey found nearly 75% of respondents indicating that new technologies did not cause changes in their staffing needs. However, those that were affected by new technologies found a decreased need for as large a staff (2).

The current and future shortage of trained medical laboratory professionals is also the result of a reduction in medical laboratory science training programs. Since 1992, the number of medical laboratory science training programs has decreased by more than

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30% to fewer than 450 programs, nationwide. The lack of trained graduates and training programs is particularly problematic in rural areas, where recruiting certified technologists can be especially difficult.

With continued concern for vacancy and evaporating training programs, microbiology laboratories have been forced to address the acute labor shortage in a number of ways. Many laboratories have lowered prerequisites required to hire a medical laboratory professional, have begun to offer on-the-job training for nonlaboratory professionals, or have outsourced testing to reference laboratories as mechanisms of coping with labor shortage; others have turned to automation.

The benefit of automation in a labor shortage is to utilize the skills of medical laboratory professionals where they are most needed and to automate tasks that are repetitive and do not require the comprehensive skill set of a trained professional. As an example, a laboratory may elect to purchase an automated system for planting and streaking of urine samples and other liquid specimens while tasking a technologist to perform Gram stain review and processing of more-complex specimens, such as tissue. In this example, the laboratory utilizes automation to consistently plate urine samples, a mundane task for a laboratory professional, and utilizes the skilled professional for interpretation of critical specimens. By adopting a strategy of relegating a monotonous task to automation, while assigning interpretative or esoteric tasks to the technologist, the laboratory increases productivity per full time equivalent (FTE), increases reproducibility of the urine plating, and decreases monotonous responsibilities for laboratory professionals.

Technical innovation. Among the innovations leading to automation in clinical microbiology, the transition to liquid-based microbiology is among the most influential. Advantages of liquid-based microbiology include homogenization of specimens into a liquid phase (as opposed to receipt of specimens of various viscosities, such as stool and sputum, and receipt of specimens submitted on collection devices, including swabs), which enables more-consistent inoculation of medium. Elution of specimen from newer flocced-style swabs into liquid phase has demonstrated a significant increase in the release of viable organisms from the swab, which translates into increased sensitivity for detection of microorganisms in the specimen (3). While improvement in the sensitivity of culture is paramount, it is also important to note that the specimen is associated not with the swab but with the liquid phase of the transport device. The presence of the specimen in a liquid-based transport enables inoculation of the specimen and smear preparation with automated liquid-based specimen processors.

A second technical innovation that has driven laboratories to automation is matrix-assisted laser desorption ionization–time of flight (MALDI-TOF) mass spectrometry. MALDI-TOF mass spectrometry has revolutionized microbial identification by providing a cost-effective method that is standardized. The technology offers accurate, rapid, and inexpensive identification of microorganisms isolated from clinical specimens. MALDI-TOF procedures are highly amenable to automation because they are relatively simple, do not change based on organism, and are reproducible. Additionally, spotting of target plates and extraction of proteins can be standardized for most organisms, and when combined with automation, automated crude extraction using the

on-plate formic acid extraction method can be performed with minimal staffing.

Industry changes. Changes in the industry are multiple. Demand for laboratory testing is increasing. Overall testing volumes are expected to increase 10 to 15% per year for the next 20 years, due in part to an aging population that will require more health care (4, 5). Additional testing is also being driven by innovations in medicine that continue to expand life expectancy and manage ever-more-complex patients. For example, more patients are receiving indwelling devices which can become infected, increasing the demand for laboratory services. Infection control also continues to drive utilization of laboratory services through patient screening initiatives and increased vigilance to isolate patients colonized with multidrug-resistant pathogens and to prevent their spread within the health care environment. Each of these factors, while increasing the quality of health care, contributes to increased demand on the laboratory, despite continued labor shortages. Consolidation of laboratories, particularly for microbiology testing, also continues to increase due to cost reductions associated with economies of scale. Larger laboratories have a greater potential to benefit from lab automation than smaller laboratories. The 24-h, 7-day/week (24/7) microbiology laboratory is becoming much more common, and automation that can shorten TAT is being viewed more favorably. The 24/7 microbiology laboratory also allows cultures to be read following a specified incubation rather than waiting for the day shift, a scientifically unnecessary delay which can result in delays in turnaround times.

Several studies have evaluated the clinical impact of rapid microbiology and its impact on antimicrobial stewardship. For example, Kerremans et al. (6) evaluated the effect of accelerated diagnostics on antibiotic use and patient outcomes using 1,498 patients with positive cultures from sterile body fluids. In the control arm ($n = 752$), routine microbiology was performed using broth subcultures and the Vitek Legacy system (bioMérieux, Marcy l'Etoile, France) to identify bacteria. In the study arm ($n = 746$), identification and susceptibility testing were performed directly on positive blood culture bottles using the Vitek 2 system (bioMérieux). The study found a mean reduction in TAT of 13 h for identification and 20 h for susceptibility results in the rapid arm compared to TATs in the control arm. The decreased TATs led to earlier modification of antibiotic therapy in the rapid arm and a reduction in defined daily doses of antibiotics used (6). In a recent review by Livermore and Wain (7), the authors determined that in the United Kingdom, management of only 3% of community-acquired respiratory infections and approximately 50% of cystitis cases is guided by laboratory results (7), in part due to the slowness of bacteriology. Further, it is critical in patients with pneumonia to receive appropriate antibiotics within the first hour for diagnosis. When empirical antibiotic therapy is not appropriate, mortality can increase each hour of delay (7–9).

Microbiological delays lead to empirical overtreatment of many patients who are not infected with resistant pathogens, which leads to increased antibiotic resistance. The increase in resistance can lead to increased acuity of patient presentation, which increases the length of stay and costs of health care (10). Many of these issues can in part be traced back to practices in the microbiology laboratory. Today, in most laboratories, plate reading is primarily a day shift activity. Total laboratory automation will facilitate reading plates as they are ready to be read without increases in

staffing, resulting in decreased turnaround times and more efficient decisions by the medical community.

Quality. The final driver of automation is our continually changing health care system. Laboratories of the future will no longer be paid based on the services that they perform but instead will be incentivized based on their contribution to delivery of quality care. In other words, health care in the future will be paid based upon keeping patients out of the hospital. This shift in reimbursement will mean that laboratories can no longer operate in a vacuum, concerned only about in-laboratory time and cost per test; instead, they will need to add value to patient care. Value from the laboratory will mean reducing the number of tests ordered for each patient, focusing on those tests that will actually aid in the diagnosis. Additionally, providing results at the time of care, rather than 2 to 5 days after care has been delivered, will be crucial. For microbiology, this will mean identifying novel technologies that will provide results in less time, determining when culture is appropriate and beneficial to the patient, and reducing turnaround times. While most microbiology laboratories do not have control over emerging technologies, they can control turnaround times through a variety of measures. Automation can help transform microbiology laboratories from a primarily day shift operation to a 24/7 laboratory. Reading cultures when they are ready to be read, instead of when the day shift arrives, can result in improved turnaround time, thus adding value to patient care.

Beyond changes in the delivery of health care, demand by clinicians for new tests continues to grow, not just in total numbers but also for the types of testing performed. The balance between molecular tests and culture-based assays will likely continue to shift toward molecular. Both the trend toward molecular testing and decreasingly shorter lengths of stay for hospital inpatients has led to increased demand for more-rapid turnaround times for infectious disease assays. This will mean that the current and future automation systems will need to incorporate both culture and molecular testing into a single specimen stream and manage both laboratory techniques. This will certainly add a level of complexity to automation systems, as the automation will need to (i) recognize the specimen type based on barcode, (ii) pipette the correct volume of liquid into various molecular systems, and (iii) manage data before transmitting them to the laboratory information system.

Traceability is another aspect of quality laboratory testing. Automated specimen processors and total laboratory automation solutions provide far greater traceability than when the same testing is performed manually. For example, during initial specimen management, labeling of plates, and transfer of a specimen from the transport vessel to plates, we rely on medical laboratory professionals to confirm multiple patient identifiers at multiple steps in the preanalytical process. If the professional omits confirmation of patient identification, wrong results can be inadvertently reported, potentially leading to inappropriate care. In the case of automation, the instrument is programmed to confirm the identification of each specimen by barcode each time the specimen is handled, a significant step in preventing medical errors.

Evidence-based medicine is the application of peer-reviewed literature to the art of patient care. One method of employing evidence-based medicine is through the use of clinical practice guidelines and standard techniques. The goal of these guidelines is the standardization of selected aspects of medical care to ensure both high quality and cost-effectiveness (11, 12). Standardization

of microbiology practices such as syndromic algorithms and standardized techniques in the laboratory can easily be achieved using laboratory automation and can increase safety within the laboratory. Laboratory staff frequently suffer ergonomic injuries as a result of repetitive tasks, such as urine inoculation and pipetting, which are avoided with automation. Repeat tasks also can be standardized using automation, minimizing variation between laboratory staff and minimizing costs associated with human error. Quality control (QC) may also be improved, owing to avoidance of human error. Standardization of nucleic acid extraction may even contribute to reduction in contamination or mislabeling errors (13).

Through standardization, laboratory errors, such as selecting the wrong plates for inoculation, mislabeling, and cross-contaminating specimens, can be greatly reduced by eliminating human errors. Further, significant delays occur in microbiology when colonies must be subcultured for isolation due to poor technique or insufficient isolation of colonies. When subculture is required, delays in results of up to 24 h is not uncommon. Through automation, variation in mixing and in selection of the specimen is minimized and transfer of a standardized volume is achieved. This has repeatedly been demonstrated to reduce the need for subculture, reducing laboratory turnaround times.

In quality, digital microbiology combined with inexpensive electronic data storage also offers the laboratory a nearly endless capacity to archive images. Images of Gram stains can be easily correlated with cultures and stored for future review. Additionally, images can be used for instruction of medical laboratory professionals and pathologists or sent electronically to an inquiring physician at the click of a mouse.

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COUNTERPOINT

Automated microbiology: not ready for prime time. Clinical microbiology laboratory automation lags behind its chemistry and hematology counterparts. This is obvious even to a non-laboratorian who tours the various sections of a full-service laboratory. Robotic tracks in the core lab can sort, centrifuge, and aliquot bar-coded specimens without human intervention. Automated instruments produce real-time results in minutes. In stark contrast, the microbiology lab harbors odiferous incubators. The tests are manual, and results are available in days instead of minutes. Even the automated blood culture systems and the identification and susceptibility systems are essentially modified incubators producing comparatively slow results. MALDI-TOF, the newest technology, still relies on incubation and isolated colonies. The most revolutionary technology in the clinical microbiology laboratory has been automated direct specimen real-time PCR, and even it has limitations.

Microbiology is primed for a breakthrough in automation. Ideally, this breakthrough should reduce labor costs and decrease the historically slow microbiology turnaround time (TAT). The reduction in TAT should lead to faster treatment of patients and better outcomes. Total laboratory automation (TLA) is touted as this breakthrough. TLA has been the topic of many recent journal articles (1–5). The instruments have been the centerpieces of the exhibit halls at scientific conferences, including the 2014 ASM meeting. The motions of the TLA platforms are instantly mesmerizing. A combination of robotic arms and fingers manipulates specimens and plates. Conveyors send the inoculated plates to smart incubators. Pipettes or loops make Gram stain slides. After incubation, the systems read and digitize colony growth and may even pick colonies for susceptibility testing or MALDI-TOF.

The makers of the BD Kiestra, the Copan WASP, and the bioMérieux FMLA (full microbiology lab automation) have wagered their fortunes on the premise that automated and digitized versions of traditional culture will be the primary technology of clinical microbiology well into the future. The sales forces of each company consistently note that good microbiologists are hard to find and that automation is the solution. Classic selling points are used to promote the TLA instruments: they are cheaper in the long run due to efficiency, superior result quality, and technical innovation. Each of these claims deserves a critical analysis.

Good microbiologists are hard to find. The expansion of automation into microbiology appears to be a solution to staffing shortages. An alternate solution is to recruit more microbiologists. Recently, it has been difficult to find employees as experienced

microbiologists age and retire. In many labs, the average age of a microbiologist is over 50. The most recent ASCP vacancy survey of clinical laboratories in the United States shows that staff vacancy rates in microbiology are at 5% but that 9% of employees are expected to retire in the next two years. The overall number of medical laboratory science programs has decreased in recent years (6). However, there is some optimism ahead due to strong promotion of laboratory careers by the American Society for Clinical Laboratory Sciences and the American Society for Clinical Pathology. The recent weak economy has also helped steer college students toward careers in the health professions. Some of the remaining medical laboratory science schools are facing a record number of applicants and, rather than closing, are actually boosting enrollment. Based on an informal e-mail survey of medical laboratory science (MLS) programs in Texas ($n = 3$, October 2013), all programs have steadily increased enrollment over the last 3 years and have seen marked increases in applications. Medical laboratory technician (MLT) schools are opening in California to alleviate the shortage of licensed medical laboratory scientists (see the California Association for Medical Laboratory Technology website, <http://www.camlt.org/laboratory-profession#mlt>, accessed 4 March 2014).

Cheaper in the long run due to increased efficiency. Labor is the largest single cost in any business and usually the first line item that administrators attempt to cut. It is estimated that 24% of a microbiologist's time is spent in the inoculation of cultures (2). Therefore, any technology that promises reduced labor cost by automating the inoculation step must be given serious consideration. The Copan WASP walk-away specimen processor (Copan, Murrieta, CA) claims to replace 2 to 3 employees per day, yet it and the other TLA systems inoculate only one plate at a time. The BD InoqlA instrument inoculates one plate at a time but can streak five plates at a time (BD, Drachten, The Netherlands). Although the maximum-throughput claims for TLA systems range from 180 to 400 plates per hour (3), no scientific studies have compared the relative speeds of experienced microbiologists inoculating and streaking cultures head to head versus automated systems. It remains unclear whether the current TLA platforms decrease the total TAT of the entire departmental workflow, including sorting, accessioning, centrifuging, loading specimens, selecting plates, labeling, uncapping, inoculating, Gram staining a slide, recapping, streaking, discarding the loop, incubating, reading the Gram stain, and reading the cultures. One BD Kiestra TLA user with 18.4 total full-time equivalents (FTEs) reports that since implementation, five FTEs were reduced despite a 4% increase in workload (7). Since the current TLA systems still require plate reading by a microbiologist, on site or remotely, efficiency as determined by culture reading TAT is likely unchanged.

Since the current TLA systems culture only one specimen at a time, there is no solution for surge capacity. In a large laboratory, specimens are delivered in large batches by couriers. When a courier brings a bucket of 60 cultures to the laboratory all at once, microbiologists working together can temporarily repurpose and efficiently process the surge.

To achieve maximum return on investment, an instrument must run constantly. Thus, laboratories might consider the further consolidation of microbiology services to a single facility with a TLA system. Then, the claimed increased efficiency of TLA systems must make up the time lost in specimen transport to the consolidated laboratory, or true efficiency would be lost. Effi-

ciency may be enhanced by simply reconfiguring the lab to read plates more often, on the second and third shifts. Converting the lab to a 16/7 or 24/7 plate-reading operation will drastically decrease turnaround times.

Quality. There are very few studies comparing the quality of organism isolation and quantities of organisms recovered with TLA versus those of manual methods. Three recent studies compared the automated inoculation of specimens using liquid-based swabs with manual inoculation of cultures using routine fiber swabs (8-10). The studies all reported superior results with the automated platform. However, would the automated results still be superior if the manual cultures had also been collected using the liquid-based swabs? One study reports equivalency of Gram stains made manually and by the Copan WASP (11). None of the TLA systems to date can make a cytocentrifuged Gram stain, which is highly recommended for many body fluids, including cerebrospinal fluid (CSF).

A microbiology laboratory, in addition to being judged for the enhanced quality of its well-streaked plates, may be judged internally (did it make a correct interpretation and workup of significant organisms?) or externally (did the results help contribute to a positive outcome and reduce patient stay?). Further automation is not a guarantee of better overall quality. Automated blood culture instruments have revolutionized the detection of bacteremia, and yet microbiologists still struggle with the preanalytical quality problems of sensitivity (short draws) and specificity (contaminated bottles). Automated blood cultures are monitored 24/7, and yet many laboratories struggle with the postanalytical quality problem of finding the person to receive a positive culture report after day shift hours. Despite these problems, there are studies that show that rapid reporting of blood culture Gram stains positively affect patient outcomes (12). To date, there are no published studies documenting improved patient outcome quality by investing in a TLA system.

The quality of the TLA systems in terms of overall reliability and mean time to failure is unknown. If labs have only one TLA instrument, then the microbiology staff will have to retain the ability to process cultures manually during downtime.

Centralizing microbiology to maximize TLA efficiency may lead to quality problems. Specimen transport delays are a common occurrence when microbiology laboratories consolidate. Lastly, centralized labs also become a quality issue when microbiology laboratory leadership is not on site to consult with clinicians (13).

Technical innovation. Many laboratorians view coming trends with simultaneous dread and excitement. The trend toward the broader use of flocked swabs with liquid-based transport media is a true innovation in microbiology. This technology enhances sensitivity while ensuring uniform inoculum with or without TLA. The problem is that not all specimens are best collected on swabs. Since the microbiology laboratory can test any specimen, a hair for fungi, a needle biopsy specimen for acid-fast bacilli, a 500-gram prosthetic knee joint for methicillin-resistant *Staphylococcus aureus* (MRSA), or a liter of pleural fluid for *Streptococcus pneumoniae*, the best TLA instrument will be a partial solution. The TLA vendor websites state clearly that nonliquid specimens require manual intervention (Copan WASP walk-away specimen processor; BD Inoqula instrument). The current TLA offerings offer between 5 and 12 culture medium types held in silos, so depending on the lab's complexity, not all culture types can be

plated (3). Parasitology and virology are not included in TLA because of the different methods, and tuberculosis (TB) cultures cannot be included due to safety concerns. TLA systems essentially force standardization of containers, culture media, and processes, essentially relegating TLA to routine cultures for routine microorganisms from routine body sites in routine volume containers.

Further automation of the clinical microbiology laboratory is needed, but the current instruments on the market are not what many would have expected or envisioned. The instrument footprints are large (see the sizes of the Copan WASP walk-away specimen processor, BD Inoqula instrument, and Previ Isola [BioMérieux]). It may be difficult to place TLA in many laboratories without significant remodeling. Moving parts will break, and the TLA systems have many moving parts. The current TLA offerings are not the breakthrough that will revolutionize the profession. Designed by robotics engineers, they are innovative by nature of their complexity but not by nature of the central technology used. Essentially, the current TLA instrument vendors have automated the 20th century.

If the automation of classic culture is the future, then smaller, faster, and cheaper benchtop versions of TLA are needed. The instruments should process more than one culture at a time and fit into a laboratory without requiring remodeling. Like continually monitoring blood culture systems, TLA systems should monitor all culture plates at the same time, discard negatives, and flag positives.

Additional concerns. (i) Biosafety. Historically, the majority of microbiology specimens have been processed under a class II biological safety cabinet (BSC), preventing spills and aerosolization. A study showing no cross-contamination between cultures (14) processed by TLA instruments is published. To date, no studies prove or disprove the safety of TLA platforms compared to that of working under a BSC for the potential of aerosolization of pathogens.

(ii) The business case for TLA. The microbiology laboratory director must justify major capital expenses to administration while competing for resources with the other laboratory departments. Ideally, capital expenses should generate revenue or reduce costs. Multiplex viral respiratory PCR instrumentation is an example of revenue generation through new current procedural terminology (CPT) codes, also known as billables. A TLA instrument will simply automate what the microbiology laboratory is already doing. No new revenue will be generated. Thus, TLA must be justified based on claims of reduced cost in the form of less labor. The reduced cost must be estimated in the form of a return on investment (ROI) calculation.

The estimated cost of an automated specimen processor is \$125,000 to \$350,000. The cost of a complete TLA system is estimated to be into the millions of dollars (3). An expenditure of this magnitude will require very complicated ROIs using calculations such as an economic justification index (EJI) and strategic justification index (SJI) (3). Since these calculations often involve estimates and assigning subjective values to "change factors," the true ROI may not be completely clear until sometime after the investment is already made. Therefore, TLA may be a hard sell to administration.

(iii) Unintended consequences. The consolidation of microbiology services continues, with many laboratories offering minimal services. An unintended labor-cutting consequence of TLA is potential outsourcing as health care embraces cloud computing

(15). In anatomic pathology, the revolutionary technology of whole-slide imaging and cloud computing allows virtual microscope slide reading from any computer. Similarly, with TLA, slides and plates can potentially reside in one lab but be read and reported by an outsourced microbiologist anywhere in the world. This may seem like a good idea to some but will be very unsettling to others.

Conclusions. Good microbiologists are indeed hard to find, but positive efforts are being made to train them. Automation is not the only solution for staffing shortages in microbiology. Efficiency can be enhanced without further automation by simply reading cultures more often throughout the day, requiring no increase in capital outlay. Technical innovation should move away from culture-based approaches toward rapid, non-culture-dependent microbiology. For example, automated multiplex PCR instruments now allow rapid testing from positive blood cultures and directly from CSF, genital, stool, and respiratory specimens. These instruments are within the reach of most clinical microbiology laboratories due to their small size and relative ease of use. They allow smaller labs to be early adopters of efficient technologies, to improve patient care, and to increase revenue without large investments.

The current TLA instruments are simply too large, too expensive, and unnecessarily complicated, and they have too many shortcomings to be a sound investment for most medium- to small-size laboratories. Most of their claimed advantages remain poorly substantiated to date. In summary, the current TLA systems have essentially automated 20th century classic microbiology. Similarly to the way cell phones allowed some underdeveloped countries to bypass telephone poles and go straight to cell towers, TLA should involve some sort of transformative, disruptive, truly revolutionary technology that we have not yet imagined.

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SUMMARY

Points of agreement

- As the population ages in the industrialized world, the number of microbiology tests that will be done will increase. At the same time, the number of trained clinical laboratory scientists available to perform these is declining as a generation of skilled microbiologists retires and a new generation has not been identified to take their place.
- Microbiology has been difficult to automate because of the wide variety of specimen types and collection/transport devices. Culture-based systems must ensure organism viability.
- Laboratory automation of microbiology specimen processing will relieve clinical laboratory scientists from performing repetitive, mundane tasks, such as plate streaking, so that they can concentrate on specimens of higher complexity.
- Liquid-based microbiology, where specimens can be eluted from flocced swabs or other semisolid or viscous specimens that can be liquefied, should enhance both the sensitivity and the reproducibility of culture. It will also ensure more-uniform plate streaking.
- The ability to store digital culture images will allow the easy comparison of sequential cultures from patients with chronic infections, which may enhance the care of these patients. It will also allow remote “plate rounds” in satellite teaching hospitals that are remote from increasingly centralized microbiology laboratories.
- The footprint of the current systems are large, and the throughput is somewhat limited.

Points requiring further considerations

- There are no data thus far that show that automation of microbiologic culture processes improves patient outcomes. How the ability to store and compare culture images will be parlayed into improved patient outcomes needs to be determined.
- One of the promises of automation of specimen processing is reduction in costs. Cost analysis of another new diagnostic microbiology technology, matrix-assisted laser desorption ionization–time of flight (MALDI-TOF) mass spectroscopy has shown impressive savings. Similar studies are needed to justify the use of this technology.
- A major shortcoming of culture-based microbiology is turnaround times, which are much longer than those of chemistry and hematology testing. It is not clear how automating culture processing will improve turnaround times.
- The automation of microbiology specimen processing has not addressed the growing importance of molecularly based microbiologic testing. Will automated specimen processing for culture, which requires a significant capital outlay, become outmoded as diagnostic microbiology shifts more and more to molecular testing, which is amenable to automation and has much reduced hands-on and turnaround times?

Peter H. Gilligan, Point-Counterpoint Editor, *Journal of Clinical Microbiology*