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Q & A: Automation in the Clinical Microbiology Laboratory

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The clinical microbiology laboratory has historically been considered “low-tech”, especially when compared to 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, identification of microorganisms, susceptibility testing, and extraction and detection of nucleic acids in 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. We have asked four experts in this field, from clinical microbiology laboratories in the United States and Europe, as well as from industry, to comment on the feasibility and impact of automation in the clinical microbiology laboratory.

Are you currently using or do you anticipate using an automation platform in your microbiology laboratory? If yes, which sections of your laboratory are automated?

Robin Patel: Mayo Clinic’s clinical microbiology laboratory has been performing testing since 1911. Although select tests today resemble those performed a century ago, we have many examples of automated, state-of-the-art tests. These include blood cultures, infectious diseases serologic platforms and nucleic acid and proteomic diagnostics, to name a few. For over two decades, microbiology laboratories have been using automated blood culture instruments that “sense” microbial growth in blood culture bottles and “flag” positive bottles for immediate attention by laboratory technologists. Prior to the availability of such systems (in the not-so-distant past), laboratory technologists manually

evaluated *each* blood culture bottle on *multiple* occasions. Technologists today could not fathom returning to the manual approach used a mere three decades ago. As with many chemistry tests, a myriad of infectious diseases serologic tests are performed on automated platforms. Nucleic acid diagnostics, which have been used in our laboratory for over two decades, are evolving to automated, "black-box"-type formats. We use a core nucleic acid extraction facility preparatory to downstream molecular microbiology testing. And, several of our nucleic acid amplification platforms are fully automated. Finally, matrix assisted laser desorption ionization time of flight mass spectrometry has revolutionized identification of bacteria and fungi in our laboratory. The success of this automated platform lies in advances in mass spectrometry and bioinformatics. With its implementation, we have been able to not only to reduce turn-around-times but also the associated cost of identification of organisms.

Susan M. Novak: I direct a high volume laboratory servicing 14 hospitals and >100 clinics in the southwestern United States where automation is a necessity. Our integrated health care system services members in a broad geographic area relying on a centralized reference laboratory for processing and work up of approximately 4000 microbiology specimens per day. Our microbiology laboratory has been automated since 2002 with semi-automated and automated plating instrumentation. Greater than 80% of the microbiology specimens arrive at the central laboratory for processing and plating. Based on the high specimen volume the decision was made years ago to capitalize on the economies of scale and allow centralized plating. This improved the plating quality and mitigated ergonomic injuries by automating repetitive manual functions. Specimen processing delay in the medical centers was another reason our health care system chose to centralize and automate microbiology plating. Our laboratory is anticipated to expand over the next several years. This expansion and increased testing volume will continue to put us in the position to incorporate additional

automation into the laboratory setting to continue to meet the goal of cost effective quality laboratory testing.

Gilbert Greub: Given the current shortage of financial resources and the concomitant increase in activity of our clinical diagnostic microbiology laboratory of about 4 to 12% per year, we decided to move towards a fully automated bacteriology laboratory. We also considered automation a priority for our serological and molecular diagnostic laboratories. Given the ease to automatically handle samples received in a liquid format, automation of serological laboratories is relatively straightforward. The same is true regarding molecular diagnostic laboratories, as soon as the first steps of DNA extraction have been done. Thus, in our molecular diagnostic laboratory, we now use automation for most DNA extraction and PCRs. Automation of PCR was associated with (i) reduced technician workload, (ii) reduced rate of PCR contamination (< 1%), and (iii) reduced time to results (< 24h).

In our bacteriology laboratory, since fall 2011, we are using an automated inoculation system which was selected among all systems available at that time based on various criteria including number and diversity of samples daily received in our laboratory. This system considerably reduces the technician workload by automatically inoculating and spreading each sample, labeling and sorting inoculated agar plates and preparing smears for Gram staining. For microbial identification we currently use two stand-alone automated systems. In 2015, we will move to a fully automated laboratory, by adding the missing pieces to the puzzle, i.e. smart incubators, high quality digital imaging, automated colony picking system and all required transport belts in-between.

Which features or criteria are/would be most important to you when selecting a laboratory automation system?

Susan M. Novak: Based on our experiences there are several equally important features that need to be considered when selecting laboratory automation. Specimen volume, mix and timing of specimen arrival in the laboratory will drive the size of instrumentation, throughput requirements and type of automation. Throughput is a very important metric that must be assessed carefully. The laboratory automation capacity must parallel and support the overall specimen volume of each individual laboratory. In addition to throughput, reliability (mean time to failure) of the automation is extremely important. If adjustments to staffing are based on the implementation of automation it is extremely important to have robust instrumentation that has little down time and negative impact on the day to day work flow. Excessive down time impacts staffing (i.e. overtime) in addition to turn-around-time and even the morale of the staff. Implementation of automation in the laboratory is a complex decision and the negative effect of a poor decision cannot be stressed enough. It is important that vendors realize that they must become partners in helping laboratories work through change management with the staff as automation is integrated into the laboratory setting. Employee "buy in" is critical to the success of a new test or piece of automation. Other criteria are important and it is advisable for laboratories considering automation to get input from colleagues that have prior experience.

Robin Patel: Several issues bear consideration. Cost is paramount – will the system result in increased or decreased operating costs? Increased costs are associated with instrumentation, reagents and/or disposables. Automated systems should be green; in other words, reagents and disposables should be minimal. Decreased costs would primarily be expected to be personnel-related. Laboratory safety is an important consideration as there may be hazards to laboratory personnel associated with automation, either as a result of exposure to hazardous microorganisms or dangerous equipment. As bizarre as the latter may seem, we have had instruments harm laboratory personnel! Space must also be considered – is there space to accommodate automation (and how much remodeling will be needed)? Automation

can “solve” problems in the laboratory. Our technologists and laboratory assistants suffered ergonomic injuries (e.g., as a result of repeat pipetting), which are avoided with automation. Quality control *may* be improved, due to avoidance of human error. The possibility of nucleic acid contamination of molecular diagnostic assays deserves careful consideration, even in the era of automation. Systems must interface with electronic medical records for test ordering and result reporting. Volume throughput must be taken into consideration. Can one system/instrument accommodate the laboratory’s volumes? Are modules available so that the system can evolve with changing test volumes? Specimen collection containers may need to be standardized to integrate with automated systems. This seemingly trivial task can be monumental in a large healthcare setting. Instrument evaluation may not always be feasible with full-laboratory automation, impacting the decision-making process (i.e., should the laboratory adopt a specific platform). Laboratories will need to address strategies to validate automation. Finally, as laboratories become more reliant on automation, it will be challenging to deal with system failure (due to instrument breakdown or lack of availability of disposables). Back-up plans will need to be carefully considered. We have experienced multiple situations where we have moved all of a certain type of testing to an automated platform only to experience an inability to utilize the platform due to instrument failure or lack of availability of required disposables (which are often offered from sole source suppliers). In such situations, the laboratory may be stranded in terms of testing. Lack of availability of disposables for commonly used systems may have a substantial impact on healthcare across the nation and around the world.

How would automation impact your laboratory operation and workflow? Will microbiology laboratories make a shift towards “24 hour microbiology”?

Robin Patel: In our experience, automation has dramatic affects in these areas. For each system adopted, laboratories need to reevaluate operations, workflow, space and staffing assignments. Our laboratory operates 24/7, so increased automation won't change our routine operating hours! Over the next decade, however, I expect to see more automation, including robotic incubation of culture plates, and automated reading of culture plates, as well as automated identification and antimicrobial susceptibility testing of colonies growing on plates (i.e., using "colony pickers"). Automation of tedious tasks will allow reassignment of staff to high value work areas requiring increased use of their intellectual skills. The microbiology technologist of the future will likely apply some of their expertise via computer interfaces (rather than handling culture plates one-by-one).

Wm. Michael Dunne, Jr.: If a tree falls in the forest and no one is there to hear it, does it make a sound? It follows that the sooner clinically actionable patient results were provided to clinicians, the sooner appropriate therapy would be administered. This, in turn, could potentially reduce overall length of hospitalization with concomitant reduction of patient care costs, risk for nosocomial infection, and improved outcomes. Time to results (TTR) can be reduced in a number of ways including the use of rapid diagnostic platforms (e.g., real-time PCR) or the performance of testing on a more frequent basis. Automation in microbiology holds the promise of specimen processing on a real-time basis that, when coupled to rapid diagnostic modalities could significantly reduce TTR and, by inference, generate positive patient outcomes. Automation, however, doesn't mean the system runs by itself. Additional shifts of operation require personnel support (at least until artificial intelligence algorithms permit accurate interpretation and processing of cultures in the absence of humans). If pertinent patient results are generated and posted on the laboratory information system in the wee hours but not acted upon by medical personnel, then the opportunity is lost and the additional expense of 24 hour operation is not realized in terms of patient outcome. I recall a situation where the laboratory adopted RT-PCR

screening for MRSA. Because of the cost of controls, the test was performed once daily in the afternoon. Upon further evaluation, the results were not reviewed by infection prevention staff until the following morning. If the samples had been plated on MRSA screening media when they were received, the results were available sooner in many cases with similar performance characteristics and an isolate for subsequent testing. This does not necessarily apply to reference laboratory testing where results are billed directly to clients and the additional workload of off-shift testing generates real income. In this case, the decision to offer 24-hour testing is found in the balance sheets where additional revenues are offset by labor expenditures and operational costs. In summary, the answer to this question should be based on at least two options - improved patient outcome and/or improved laboratory income. It would be nice if both were realized.

Gilbert Greub: A 24/24 7/7 availability of some immunochromatographic tests, some direct microscopic examination such as blood smear for *Plasmodium* spp. and of selected PCRs is warranted given the clinical impact and the added value of short time to results. However, given the painfulness of night shift, the associated social cost and the relatively low clinical impact of 24/24 7/7 shift for most microbiology processes, a 24 hour microbiology is not a goal of our core bacteriology laboratory. Nevertheless, automation will clearly modify our workflow and organization. Since agar plates may be automatically checked by digital imaging at regular intervals and sterile plates automatically discarded, time to results is significantly improved, especially if the technician working time is extended for instance from 6 a.m. to 10 p.m. Moreover, moving towards paperless telebacteriology will be a major opportunity to improve the working atmosphere by reading agar plates in quiet offices located next but outside the core laboratory, with an expected gain in quality and productivity.

Is a full-laboratory automation system appropriate for all types of laboratories? Is there a minimum daily specimen volume required to support an automated platform?

Wm. Michael Dunne, Jr: The simple answer is "it depends." So what does it depend upon? 1. Scalability and modularity. Can an automated microbiology system be appropriately scaled to accommodate the specimen volume and sample types of individual microbiology laboratories with associated cost adjustments and the potential to increase throughput at a later date? For example, I recall an instrument developed in the early 2000's that would screen 300 urine samples per hour and generate rudimentary identification and susceptibility data for the samples if positive. The problem with this business model was that very few laboratories had volumes to justify purchase of the instrument and a scaled down version wasn't available. The system was also very large and was difficult to get into the laboratory proper without demolition activities. So if a one-size-fits-all option is developed by manufacturers, it might limit the market to very large volume laboratories. Modularity would also allow laboratories of various sizes to implement specific units of the system. 2. Availability of skilled labor. As the pipeline of individuals completing training in clinical laboratory science programs at all degree levels decreases, the competition for their services among laboratories will likely increase with the associated cost of competitive salaries and benefits (supply and demand). The reduced availability of a skilled workforce even in smaller laboratories would likely push the equation in favor of automated systems such that fewer individuals could handle the workload while devoting more time to interpretation and other complex processes. 3. Medical economics. Labor, I believe, still remains the single most costly component of any laboratory budget line item so it would be desirable to stabilize and minimize the effects of rising labor costs and shortages. Reimbursement should also be considered in the equation

and I can't help but believe that reimbursement rates from third-party payers and government agencies won't be going up any time soon. 4. Specimen complexity. Clearly a laboratory that processes several hundred urine samples per day would be more amenable to automation than one that processes a mix of complex sample types. To get back to the question, the answer obviously lies somewhere in between the office lab that processes 5 throat samples and 10 urine cultures per day and a large university-based or reference laboratory that evaluates hundreds to thousands of mixed sample type cultures daily.

Gilbert Greub: Below a given threshold, the cost of the automated system and its maintenance will outweigh the benefit in term of hands on time and quality. The minimum daily specimen volume required to support an automated platform will be different for each platform and cost-effectiveness studies are warranted to define such cut-off. However, these cost analyses are yet completely lacking for automated microbiology systems. For example, when considering the different inoculation systems currently on the market, it readily appear that they target mid-size laboratories since they may inoculate as many as 180 to 270 agar plates per hour. Such throughput of these inoculation systems is also optimal for larger laboratories that generally use several inoculation systems in parallel to ease workflow organization and to provide the necessary back-up during technical failures. Automated systems are optimal when the workflow is continuous, i.e. the efficiency decreases when samples are processed by batch.

Susan M. Novak: Because all laboratories are not created equal based on depth and scope of work performed, I do not believe that full laboratory automation systems will be appropriate for all laboratories. Incorporation of full laboratory automation will be highly dependent on specimen volume and the need to become more efficient in the workplace and reduce FTE's associated with manual tasks that can be automated. I believe the medium to large size laboratories will be able to justify full

laboratory automation more readily because the purchasing of equipment can be tied to a "return on investment" relative to the amount of staff needed in the laboratory to perform certain tasks. Smaller volume laboratories will perhaps take a modular approach with automation, choosing modules or pieces of automation that support the laboratory. In speaking with various vendors of plating instrumentation platforms, the cut off for a plating instrument appears to be approximately 200 specimens per day. But some vendors do believe smaller labs could still use this automation. That said, given that full laboratory automation is new to microbiology, each lab must perform an analysis to determine what automation, if any, would be suitable.

Do you anticipate that adoption of an automated microbiology platform would restrict you to using products from one vendor?

Susan M. Novak: This is a very interesting question and one many laboratories that are considering automation in microbiology are most likely grappling with. Today there are several pieces of automation that have been fixtures in the clinical microbiology laboratory for years (i.e. identification/susceptibility and blood culture systems). In some laboratory settings, such as ours, specimen plating instruments have been incorporated to meet pre-analytical needs. Because these instruments are unrelated to one another there has never been the need for connectivity. The need for integration all changes with the onset of full laboratory automation. For example, if plates are transferred via a conveyor below to a smart incubator with a digital camera and a colony is chosen for identification or susceptibility testing, the plate must be sent to a piece of equipment that can pick the colony and inoculate needed materials. In this scenario, connectivity is a prerequisite to full laboratory automation. How will that occur if each piece of automation is from a different vendor? Just because a

laboratory chooses pre-analytical plating instruments or a digital incubator should not mean that the identification/susceptibility instrument would need to be changed or that the laboratory will have the money to do so. The question remains will the software on these systems be "open" and can various instruments from varied manufacturers talk to one another? If this is not the case then this could place a huge burden on the laboratory. Switching out several instruments at once would impact the capital expenditure and also impact the number of validations that need to be performed when integrating new equipment into the laboratory setting.

Gilbert Greub: Adoption of an automated microbiology platform may restrict the use of products proposed by another vendor. Some companies try to protect their market by proposing automated system with no or very low compatibility with systems from other manufacturers. Fortunately, the increasing awareness of clinical microbiologists of the importance of such technical compatibility is progressively pushing the industry to propose flexible solutions. Moreover, some middleware options are available that may solve some incompatibilities between different automated systems and between an automated system and the laboratory information system (LIS).

In an era of laboratory automation, do you think that "routine" microbiology will continue to be done by specialized microbiology technologists, or do you think that generalists and/or chemistry technologists will be involved in this testing?

Gilbert Greub: Microbiology laboratories will still need technologists trained in microbiology at several steps, including microscopy and agar plate interpretation, since these activities will still represent a

pivotal step governing decision on downstream steps. With automation, the proportion of repetitive tasks requiring limited knowledge will decrease whereas specialized tasks will increase, as will the need for specific skills in information technology (IT).

Wm. Michael Dunne, Jr.: Yes (another hedge!). On one end of the spectrum, less-complicated processes i.e., specimen accessioning, loading of samples into automated plating systems, reading and interpretation of screening media, pulling, subculturing and preparing gram-stains of positive blood cultures, setting up samples for nucleic acid extraction, antimicrobial susceptibility testing (AST), identification (including MALDI-TOF) and interpretation of certain culture types (e.g., urine) can be readily accomplished by well-trained laboratory technicians and generalists. I am a firm believer, however, that the correct interpretation of more complicated specimen cultures (respiratory, GU, GI, nephrostomy urine, CSF, blood, tissue, abscess material, implants, etc.) in the context of relevant patient information requires more focused training and experience. This is especially true for the interpretation of antimicrobial susceptibility testing results. Heck, I've been a clinical microbiologist for more than 30 years and still run across results that I can't explain. That is not to say that generalists and/or clinical chemistry technologists can't gain this level of experience over time, but it requires guidance and mentoring. Automation in microbiology doesn't negate the need for interpretive skills. On the contrary, automated systems should enhance the efficacy of microbiology specialists by allowing them to devote their attention toward problem solving and interpretation of complicated sample results or processes. Further, automation in microbiology has not yet supplanted the need to explain test results to clinicians in a clear and knowledgeable manner or to suggest further supplementary testing. So in my estimation, it would behoove the fully automated clinical microbiology laboratory to establish a good mix of microbiology specialists for training, hierarchical result interpretation, and physician interface with generalists capable of maintaining the accelerated workflow.

Susan M. Novak: Clinical laboratory scientist pools are diminishing due to many technologists retiring and fewer replacements in the workplace due to the elimination of training programs. I believe that the microbiology laboratory will continue to evolve and change relative to how it appears today. Based on the development of more sophisticated automation and software tools there will be a place for the less specialized laboratorian in microbiology. With the advancement of digital microbiology and integrated software programs perhaps a less skilled laboratorian can review cultures that once required a licensed technologist. That said, microbiology will still need to report clinically relevant information to the provider, since not all bacteria growing from a culture is relevant to the patient condition or illness. The specialized microbiologist will still have a place in the laboratory but it is anticipated that the overall mix will change. Advances in molecular testing have already resulted in the introduction of moderately complex instrumentation that is easy to run and can be run by a generalist or chemistry technologist today lacking microbiology expertise.

What are the challenges in bringing full-laboratory automation in microbiology to market?

Wm. Michael Dunne, Jr.: From my point of view (and, again, factor in 30+ years as a clinical microbiologist), the primary hurdle to overcome toward total laboratory automation in microbiology is perception. Unlike our colleagues in clinical chemistry and hematology who have handled much higher levels of automation for many years, clinical microbiology has traditionally been a very tactile, hands-on, interpretive practice that is equal parts art and science. Converting an analog discipline into a digital one will require a paradigm shift. The process of evaluating microbial growth by holding plates, touching colonies with loops and the associated odors (accidentally acquired of course) would be replaced by

high resolution images displayed on a flat screen monitor and robotic manipulation of colonies using robotics. Factors that are driving microbiology in the digital direction include laboratory consolidation and associated workload, an aging skilled workforce with more folks reaching full-time shell-collecting age than those entering the profession, and paper-thin margins on reimbursement for services. It is my feeling that the conversion to automation is happening at a more rapid pace in Europe, Asia and South America than it is in the US at the moment but that might change shortly. To accommodate this trend, a number of modules have been or will be developed which replicate activities that are currently being performed manually. These include specimen processing, incubation, culture evaluation, identification, antimicrobial susceptibility testing, and result reporting. The modules supporting each of these processes must be able to function independently as well as in a coordinated fashion to deliver the desired results whether laboratories select individual components or purchase the whole shooting match. With respect to the latter, laboratories and manufacturers will need to form "partnerships" to gain the level of trust, support and service necessary to keep the systems operating 24 hours/day. Simple functions that we currently take for granted in daily operations become complex problems for engineers in the design process such as handling unusual specimen types, movement of plates and imaging within an incubator without contamination, processing anaerobic cultures, or even something as simple as preparing a purity plate for AST. I could go on but imagine the process of setting up disk diffusion plates by automation and you get the point.

Another issue that will certainly generate a fair degree of angst for system providers will be the design of clinical trials to gain regulatory clearance for automated microbiology systems. What would be the reference standard, manually processed cultures? What if the culture evaluation module of an automated system provides additional sensitivity in terms of positive growth detection such that specificity appears decreased relative to a manual methods? Should modules be evaluated individually

or as a complete system? These issues will have to be settled with regulatory agencies prior to the onset of clinical trials.

To conclude, expanding automation in clinical microbiology is a certainty that will necessitate a change in skill sets and expertise among microbiologists or laboratorians in the future. Individuals coming out of clinical laboratory science programs at any degree level will need to accommodate these changes. Other major issues that will need to be addressed with the automation of the microbiology laboratory include overall capital outlay, minimizing contamination within the system (moulds, mycobacteria, etc.), instrument maintenance and downtime, and in-house validation processes.

Robin Patel: Challenges include the varied nature of individual laboratories (sizes, physical layouts, test menus, etc.), cost, and ever-evolving biology (including emerging antimicrobial resistance and description of novel infectious agents). Although, chemistry laboratories have enjoyed the benefit of full-laboratory automation for many years, microbiology laboratories have lagged behind because of their multiple specimen types with varying viscosities and container types and sizes, and because of the wide diversity of organisms detected. This variability has hindered the availability of full-laboratory automation for clinical microbiology laboratories. Technology is rapidly changing and improving, however, such that automation in increasingly used in clinical microbiology laboratories, and full-laboratory automation is becoming possible. However, challenges remain. Platforms are not yet fully developed. Laboratories that are early adopters may face availability of newer, “better” options in the near future, and be “stuck” with “antiquated” platforms (analogous to the ever-changing mobile phone or computer industry). There may be a perception on the part of laboratory technologists that they will be “replaced by machines”. My personal perspective is that what will be mainly replaced will be the uninteresting aspects of the job of the laboratory technologist. I find it hard to imagine a scenario where laboratories would not need the expertise of experienced, well-trained microbiologists to oversee microbiology testing.

What is the impact of automation in clinical microbiology on patient care?

Robin Patel: This is an area of tremendous potential. Automation may provide expedited patient results, facilitating prompt diagnosis and treatment and avoidance of unnecessary additional testing and associated costs. (Although it would be intuited that automation would decrease turnaround time for patient results, depending on the system design, turnaround time may be increased.) Automation may increase the availability of results after-hours, necessitating new systems for acting on such results (i.e., at times when healthcare staff is not traditionally available). Automation may avoid falsely positive or negative results associated with human error. Automated reading of culture plates may facilitate recognition of colony growth not appreciated with the naked eye, enabling enhanced sensitivity and earlier detection. Finally, technologic advances will likely bring testing closer to the patient; I predict that some automated microbiology tests will move out of the laboratory, in a variety of formats, including automated patient self-testing (for certain organisms).

Gilbert Greub: During the last ten years, several innovations in microbiology such as MALDI-TOF MS and point of care molecular assays have had major impact on patient care, since these new diagnostic approaches are significantly reducing the time to results. Automation in molecular diagnosis has also contributed to a significant decrease in turnaround time. Automation in clinical microbiology will also have some impact on patient care by improving traceability, reproducibility and quality. This is especially true for automated inoculation system that helps much (i) in term of traceability and (ii) in getting high-quality spreading of the inoculum over the agar plate, with a higher number of isolated colonies that may be used for downstream identification and characterization. Thus, although the precise impact of automation on patient care has not yet been precisely assessed, I am convinced that in addition to the benefit of automation on the laboratory workflow and in avoiding repetitive uninteresting tasks, there is also some benefit of automation on patient care.

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