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Consolidated Clinical Microbiology Laboratories

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The manner in which medical care is reimbursed in the United States has resulted in significant consolidation in the U.S. health care system. One of the consequences of this has been the development of centralized clinical microbiology laboratories that provide services to patients receiving care in multiple off-site, often remote, locations. Microbiology specimens are unique among clinical specimens in that optimal analysis may require the maintenance of viable organisms. Centralized laboratories may be located hours from patient care settings, and transport conditions need to be such that organism viability can be maintained under a variety of transport conditions. Further, since the provision of rapid results has been shown to enhance patient care, effective and timely means for generating and then reporting the results of clinical microbiology analyses must be in place. In addition, today, increasing numbers of patients are found to have infection caused by pathogens that were either very uncommon in the past or even completely unrecognized. As a result, infectious disease specialists, in particular, are more dependent than ever on access to high-quality diagnostic information from clinical microbiology laboratories. In this point-counterpoint discussion, Robert Sautter, who directs a Charlotte, NC, clinical microbiology laboratory that provides services for a 40-hospital system spread over 3 states in the southeastern United States explains how an integrated clinical microbiology laboratory service has been established in a multihospital system. Richard (Tom) Thomson of the NorthShore University HealthSystem in Evanston, IL, discusses some of the problems and pitfalls associated with large-scale laboratory consolidation.

POINT

Laboratory testing plays a central role in the care of 70% of patients who seek medical care (1). The goal of modern medical laboratories is to provide high-quality services that are both timely and affordable. In an age of declining reimbursement, this is challenging. Declining reimbursement began in the early 1980s with the introduction of legislation that mandated the use of diagnosis-related groups (DRGs) for purposes of reimbursement (2, 3; https://www.govtrack.us/congress/bills/98/hr1900, accessed 12 July 2014). This trend continued with the more recent dictum of the reimbursement policy under the Affordable Care Act (4; http://finance.yahoo.com/news/obamacare-regulations bankrupt-diagnostic-laboratories-181600055.html, accessed 12 July 2014). To survive in the current health care environment, many hospital systems have merged or evaluated the possibility of merger with other health care facilities in and out of their identified care areas (5–7). Consolidation of medical care into large hospital systems is a reality. In North Carolina, five hospital systems now dominate the health care landscape. The catchment areas of these systems often exceed hundreds of miles.

Core microbiology laboratories. One major consequence of consolidation is the evolution of the concept of the "core laboratory," in which a central laboratory performs testing for multiple health care facilities and physician offices. The core laboratory phenomenon began in the 1970s and has since grown. Currently, core laboratories can be located either in a large tertiary care hospital that performs testing for smaller hospitals or can be freestanding, that is, not physically connected to a hospital. Core laboratories may provide services for hospitals within a system or act as a commercial reference laboratory for hospitals not aligned with the parent organization (5–7).

A core microbiology laboratory functions in such a way that little if any testing remains in non-core hospital laboratories (6, 7). The rationale for developing a core laboratory is predicated on decreasing reimbursements and the resultant need for greater efficiency, something that is difficult to achieve in small laboratories. The goal of consolidation of microbiology laboratories is to deliver high-quality, cost-effective laboratory testing around the clock in order to enhance patient care while reducing lengths of stay and readmission rates. New technologies, such as total laboratory automation, MALDI-TOF mass spectroscopy, and next-generation sequencing (7, 8), and various nucleic acid amplification tests (NAATs) have the potential to accommodate increased test volume and achieve reduced turnaround times (TATs) without increasing labor costs. This potentially provides benefits to both the laboratory and the health care system (7, 8).

What stays locally, and what goes to the core laboratory? STAT testing needs to remain at all sites, but determining which additional tests will continue to be performed in remote locations is challenging (6, 8–10). Maintaining even rudimentary microbiology services in small facilities presents three challenges.

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1. Maintaining microbiology competency in a declining work force composed primarily of generalist medical technologists (11, 12). One of the most important STAT procedures in clinical microbiology is the Gram stain. It can be used to guide initial antimicrobial therapy, and mistakes in interpretation can have serious clinical consequences. Of note, a study by Munson et al. which examined the competency of generalist laboratorians showed that they misinterpreted sputum Gram stain findings significantly more often than laboratorians with microbiologic expertise (12). Of even greater importance is the accurate identification of bacteria in Gram stains of normally sterile body fluids, such as cerebrospinal fluid (CSF), and the interpretation of positive malaria smears. Maintaining competency for these critical microbiology functions outside the core laboratory is a major challenge for consolidated clinical microbiology laboratories.
2. Determining the test menu for small facilities that support diverse clinical specialties. Microbiology tests in which TAT is critical to patient care should be maintained at the referring-hospital site. Based on physician input, any test that has a TAT of <4 h should remain at the hospital site. Any test (e.g., blood cultures) in which a delay in generating results would negatively impact patient outcomes should also be processed at remote sites. Transporting blood cultures to a distant centralized laboratory may adversely delay provision of results to health care providers. As Barenfanger and colleagues (13) have shown, a delay of as little as 1 h in provision of Gram stain results from positive blood cultures negatively affects patient outcomes. In this study, all blood cultures were placed into an automated blood culture instrument within 1 h of collection. However, when transport of blood culture bottles to an automated instrument is required, delays of 4 to 16 h may occur, depending on courier routes and automobile traffic patterns. With an average time to positivity for some organisms of as little as 7 h, transport times may exceed the time to a positive culture result, in turn adversely affecting patient care.
3. Developing and implementing approaches that will maintain the viability of microbes in clinical specimens. One of the challenges facing core laboratories is how to ensure the viability of microbes in clinical specimens that may have to be transported hundreds of miles in a variety of weather conditions. A 2012 questionnaire survey of 18 consolidated microbiology laboratories addressed the issue of specimen transport. The 18 laboratories included in the survey were located in 18 diverse regions of the United States. The results of the survey indicated that there was no "template of best practice." Some laboratories transported all samples to the core laboratory for processing and culture/detection. Some laboratories inoculated blood culture and sterile body fluids in the referring hospital and incubated and/or transported subculture plates to the core laboratory. Other laboratories used a mixed model dependent upon the distance of off-site hospitals to the core lab, with nearby hospitals sending all specimens to the core facility and more-remote hospitals performing initial processing and culture.

A potential paradigm shift for core laboratories is the widespread implementation of molecular diagnostic testing in both referring and centralized laboratories. Near-patient testing would include so-called 1- to 2-h "plug-and-play" NAATs, such as those available for influenza virus and enterovirus, for which a rapid answer directly impacts the care of patients. More-complex or more-high-volume tests, such as *Chlamydia*, *Neisseria gonorrhoeae*, and human papillomavirus NAATs and respiratory and gastrointestinal NAAT panels, could be transported to a core facility. Concerns about organism stability with NAATs are less compelling, since nucleic acid integrity is much easier to maintain than organism viability. Outcome studies that can help guide what test stays and what test goes are needed.

What are the advantages of consolidation of laboratory services? In 1996, the Harrisburg Hospital and Polyclinic Medical Center made the decision to merge services in order to utilize the resources of the two largest health care systems in the greater Harrisburg, PA, area, serving a population of approximately 500,000 people. The goal was to offer quality care in the central Pennsylvania region in a more cost-effective manner. The merger resulted in the formation of the PinnacleHealth System (www.pinnaclehealth.org/General/About-Us/History.aspx, accessed 15 July 2014).

The clinical microbiology laboratories at the institutions completed the process of consolidating services and achieved goals of increasing provision of clinically relevant results to health care providers, reducing laboratory test TATs, and lowering the costs of services to the clients of the new laboratory. A major advantage of the new core laboratory was the expansion of coverage in the clinical microbiology section. The traditional day shift coverage of the microbiology laboratory was augmented with a second shift. Same-day, direct assays, including molecular assays for selected organisms, were performed on the third shift. Expansion of testing to all shifts resulted in notable decreases in TATs. The average length of completing the workup of routine cultures decreased 20% (i.e., from 60 h to 48 h). A decrease in turnaround time was also noted for positive blood cultures because they were processed during both the first and the second shift. In light of the critical nature and time sensitivity of blood cultures, patient outcomes were favorably affected. For serology and molecular testing, which were performed on the second and third shifts, respectively, TATs were shortened by 24 h (i.e., from 36 to 12 h). In addition to these advantages, the average cost for selected tests decreased substantially (e.g., 12% for blood donor screening for infectious disease markers and 33% for blood cultures). Many of the savings were the consequence of reduced costs of acquisition of reagents and supplies as a result of discounts from purchasing in volume. A portion of these savings was used to purchase new automated instrumentation, leading in turn to additional efficiencies.

Critical testing, including STAT Gram stains, rapid antigen testing, and processing of critical samples, remained at the referral hospitals. Selected rapid NAAT methods could be positioned in referral hospitals for critical infectious disease testing. Overall satisfaction of health care providers and reference clients was extremely positive. Central to the success of the core laboratory was involvement in decision-making of individuals from a broad range of medical disciplines, including infectious diseases, pathology, surgical specialties, and critical care. Their input was taken into account when decisions on specific test methods, defining ideal TATs, and determining the format of test result reports were made.

The second type of core laboratory is one that has moved to a site not physically attached to any hospital. The challenge with this type of laboratory is that the laboratory is now freestanding and is not readily accessible to care providers. Such a core laboratory is currently being developed to serve the Carolinas Health Care System, centered in Charlotte, NC. This system encompasses 42 hospitals in 3 states: North and South Carolina and Georgia. The hospitals near Charlotte, NC, have had a core laboratory for many years located at the Carolinas Medical Center, a 900-bed tertiary care teaching hospital. Beginning in 2015, an outside core laboratory will be built to serve 8 to 10 area hospitals. The main microbiology services will be located in the outside core laboratory. Multidisciplinary teams of technologists, pharmacists, purchasing agents, central receiving personnel, and other health care professionals participated in the on-site design of the microbiology laboratory. Issues considered in designing the laboratory included the logistics of sample receiving, processing, and interpretation. Teaching of internal medicine, pediatric, and family practice residents, medical laboratory scientists, and gastrointestinal (GI) fellows will take place on site weekly and by remote video learning. On-site, face-to-face interactions with infectious disease physicians and members of other medical specialties will occur on a daily basis at the main teaching hospital and less frequently at other hospitals throughout the system. Video conferencing capabilities were evaluated with physician groups by displaying culture plates and Gram stain smears for review to simulate microbiology rounds and resident teaching. Laboratory administration and infectious disease and critical care physicians had input into what microbiology testing would be performed at each hospital and what tests would be sent to the core laboratory.

Also, since the hospitals are located at various distances from the new core laboratory, courier routes and transport times were considered to be extremely important. Travel time via automobile to the core lab from remote hospital sites was extremely variable, i.e., 20 min to several hours. Because of transport time variability and because of clinical needs deemed to be critical by the medical staff, any test in which a result could be forthcoming within $\leq$4 h of obtaining a specimen continues to be performed on site at the local hospitals. On-site testing will include blood culture processing and incubation, STAT Gram stains, various rapid microbiology testing, processing of normally sterile body fluids in blood culture instruments, cerebrospinal fluid processing, and operating room (OR) tissue processing. Specimens processed at each site (OR tissue, sterile body fluids) will be inoculated to media and incubated until they are transported to the central laboratory. During transport to the core laboratory, previously inoculated plates will be transported in temperature-controlled/monitored containers to preserve culture integrity. Blood cultures will be incubated in continuous-monitoring instruments; when they become positive, they will be Gram stained locally, and then positive blood culture bottles will be transported to the core laboratory for identification and susceptibility testing. Plate reading at the core laboratory will be expanded from 2 to 3 shifts daily, and most microbiology samples will be processed 24 h a day.

The training and continuing education of technologists who perform analytical work at the remote sites is fundamentally important. The leadership at the core laboratory as well as the remote hospital laboratory must work as a team to ensure high-quality testing and the competency of technologists at both sites. At Carolinas Healthcare, a core laboratory has been in operation for many years with a mixed model of testing. The major advantage of developing an off-site central laboratory was the maintenance of a standard process for providing microbiology services across the system.

Overall, the challenges of a core laboratory may be broad-ranging; however, the rewards can be great, as demonstrated by Shah (14). He and his colleagues achieved overall laboratory cost savings of 20% as a result of laboratory consolidation at the Detroit Medical Center in the 1980s. Although cost savings associated with core microbiology laboratories are clear, less certain is our understanding of the impact of the core laboratory on patient care. Rigorous studies to determine the impact of this testing model on patient metrics, such as length of stay, mortality, and readmission rates, are needed.

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I am an employee of the Carolinas Pathology Group and serve as technical director of the consolidated laboratory that I describe in the article.

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COUNTERPOINT

Clinical microbiology and clinical infectious diseases are medical disciplines with common, if not identical, roots. Although ancient descriptions of maladies did not differentiate infection from other diseases, the mid-18th- and early 19th-century discoveries of microbes and their connection to disease resulted in a medical practice paradigm devoted primarily to the understanding of fevers and infection. There was no need for infectious diseases specialists, since every physician was versed in infectious diseases. Decades passed where advances in laboratory and public health knowledge improved the health of communities, but other than vaccinations and therapeutic antisera, directed therapy for individual patients remained limited. At best, treatment of infection was restricted to surgeons who were consulted for drainage or excision.

After World War II, the discovery of antimicrobials and their use in treating infections in individual patients led to the need for rapid etiologic diagnoses and selection of patient-directed therapy. The successful application of laboratory and clinical skills spawned the disciplines of clinical microbiology and infectious diseases as we know them today. Early pioneers were skilled in both. Patient examinations were followed by staining and culturing performed by care providers. Microscopes were conveniently located in clinics or inpatient wards for clinician use. Incubators and culture plates were examined by patient care teams for immediate result interpretation and application. Understanding the laboratory and clinical details was essential for the best patient care (1).

The separation of clinical microbiology from the treatment of clinical infectious diseases became necessary when the incidence and consequences of infection became so great that is was no longer tenable to expect practitioners to be competent in both disciplines (2). This change was also driven by the emergence of antimicrobial resistance in the 1940s and 1950s. As the problem of antimicrobial resistance grew, antimicrobial susceptibility testing methods were developed and then standardized in the 1960s. In addition, growing sophistication in laboratory practice resulted in the need for self-contained laboratories and laboratorians with specialized expertise in clinical microbiology. Gradually, this led to two separate teams, one to provide laboratory data and one for clinical examination (3).

Laboratories were located within hospitals in order to provide rapid, face-to-face communication between clinicians and those in the laboratory. Within the memory of many medical microbiologists still practicing is the routine where health care providers visited hospitalized patients each morning before returning to an outpatient office practice. Result reporting systems were manual, slow, and unreliable. Health care providers often stopped in radiology and laboratory medicine departments to acquire information and test results prior to making their rounds to hospitalized patients. Viewing X rays and microscopic Gram stains and discussing the interpretation of culture results were necessary for optimal patient care. In addition, the growing discipline of clinical infectious diseases opened the laboratory to daily visits by infectious disease specialists and to formal rounds during which laboratory findings from the sickest patients were discussed and debated. In many hospital settings, the laboratory director would accompany clinicians on ward rounds to observe and contribute to patient management. Joint observations and communication between clinical microbiology and infectious diseases specialists was essential for the best patient care and education. Should we work to maintain or restore such collaborations today? Quaint, outdated, and mere wishful thinking, you say?

The time-tested model of clinical microbiology and infectious diseases appears to be succumbing to a consolidation model where many hospital laboratories are centralized and, as a result, located in spaces distant from the setting in which health care is provided (4). The successful quest to reduce medical care costs through consolidation has trumped the need for communication (5). The vast electronic transformation that has occurred in medicine during the past 40 years is at odds with the sort of visual and conversational interchange that has long been considered essential to the needs of practitioners caring for patients with infection. Not meeting the demands of health care providers who care for patients with infection means not meeting the needs of patients.

This may be the least of our shortcomings as a clinical microbiology profession. Most infections are not treated by clinicians with specialized expertise in infectious diseases. They are treated by primary care physicians (e.g., family practice providers, general internists, pediatricians, and hospitalists), surgeons, and critical care doctors. With a change in medical school curricula away from specific training in clinical microbiology, health care providers today often have a poor understanding of smear, culture, and antimicrobial testing results. As a consequence, we are failing to meet the demands of patients across the entire clinical spectrum.

In addition, there are the usual arguments against centralized laboratories that include delayed specimen processing and entry into incubation, delayed availability of Gram stain results that are no longer available for personal viewing or integration into acute-care decisions, loss of viability or overgrowth of fastidious pathogens during hours of transport, delayed appearance of growth resulting in longer TATs for identification, untimely provision of antimicrobial susceptibility test results, and the loss of understanding by health care providers of new technology, new microorganisms, and important epidemiologic trends. Few, if any, studies have addressed the impact of these variables on the outcome of patients with infection. Further, in educational settings, the front-line experience of clinical interaction is lost. Medical microbiologists who for generations have provided a microbiology consultative service will no longer help train future clinicians, either in the laboratory or in the hospital (6).

Two important shifts in medical care and clinical microbiology are poised to change the clinical microbiology laboratory landscape: the Affordable Care Act and total laboratory automation. In this regard, we may be able to have our cake and eat it too! Value-based purchasing stipulated in the Affordable Care Act will modify the financial incentive to centralize microbiology laboratories. Hospitals are migrating from volume-based to quality- and efficiency-based delivery systems. Performance objectives will switch

from how many cultures one can do to how few can be done to provide the same outcomes more quickly and with greater accuracy. How does a remote laboratory convince a physician that isolates in sputum and wound cultures are unlikely to be pathogens? Can a part-time, hospital-based, generalist technologist working on the second shift on a Saturday night be expected to accurately interpret a CSF Gram stain while the clinician awaits the definitive review by more-experienced personnel at a centralized laboratory? Can a successful health system of the future afford to have 50% of urine culture reports misinterpreted, leading to unnecessary treatment and erroneous diagnoses (7)? Can a successful health system allow the inappropriate ordering of *Clostridium difficile* disease testing, resulting in excessive antimicrobial use and inaccurate disease prevalence data (8)? The cost of insidious laboratory deficiencies will be greater under new reimbursement rules. Locating the clinical microbiology laboratory in close proximity to patients with infection can help to eliminate the shortcomings of a centralized laboratory and, in turn, lead to enhanced patient care.

How does total laboratory automation contribute to the care of patients with infection and ultimately enhance overall medical care? Automation has the capacity to provide digital images of all microbiology results. In one sense, this represents "back to the future," as it allows the clinical microbiology laboratory to do what it did best 30 years ago! In one scenario, the technologist on the bench will generate a computerized report which summarizes relevant smear and culture results; he or she then adds representative images of the direct specimen Gram stain and positive culture plates. The laboratory director then provides an interpretation which synthesizes all of the information derived from the laboratory analyses, and lastly, the information is provided to care providers electronically in a manner that is both understandable and timely. Handheld tablets or phones will show what a visit to the laboratory provided decades ago.

With this changing landscape, what are our options? Consolidating some or even many microbiology laboratory services into a central facility can work but not with current models. Based on available evidence and the consensus, here is one model that may provide quality and efficiency.

1. The technical and medical aspects of all clinical microbiology laboratory testing, including point-of-care, molecular infectious disease, hospital-based, and centralized laboratory-based testing, should be overseen by a medical microbiology board-certified doctoral-level laboratory director (9).
2. The selection and use of microbiology laboratory tests should be overseen by a medical staff-level committee that provides input into the use, interpretation, and location of testing services (10).
3. The location of microbiology testing must be driven by patient care considerations, clinical consultation, educational goals, infection prevention demands, applied research needs, and financial considerations (11).
4. The medical microbiologist directing the clinical microbiology laboratory should undertake to become fully integrated into the process of delivering care to patients with infection. This is accomplished by developing relationships with relevant care providers, providing consultative services directly to providers who care for individual patients with infection, maintaining an active presence on oversight committees that are responsible for formulary decisions and infection prevention policies, and actively participating in educational initiatives that pertain directly to care providers as well as care system administrators. When appropriate and needed, written interpretive consultations should accompany microbiology results. Examples might include changing technologies and taxonomies, new and emerging pathogens, and complex antimicrobial resistance phenotypes (12). A key consideration in all of this is the process of results reporting. Above all, laboratory reports must be unambiguous, well organized, and provided in a timely, efficient, and accessible manner.
5. Total microbiology automation should be welcomed and encouraged as an efficient step toward laboratory standardization and clinical consultation (13). Clinical microbiology laboratories of the future must be automated, economical, relevant, and consultative (14). Finally, they need to be located wherever they can best serve the needs of patients with infection.

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I am an employee of Evanston Hospital.

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SUMMARY

Points of agreement:

1. The establishment of inpatient reimbursement based on diagnosis-related groups (DRGs) plus the provisions of the 2010 Affordable Care Act have placed significant financial pressures on clinical microbiology laboratories.
2. Consolidation of laboratories is driven by the need to gain cost efficiencies, some of which can be obtained by the purchase of expensive laboratory equipment. Examples of procedures requiring expensive equipment include matrix-assisted laser desorption ionization–time of flight (MALDI-TOF) mass spectroscopy, next-generation sequencing, total laboratory automation, and various automated molecular diagnostic tests. Consolidation also allows for expansion of laboratory testing to a 24-h/7-day model, something that may not be available or even possible in large teaching hospitals. Around-the-clock testing has the potential for achieving reduced laboratory test turn-around-times (TATs), in turn resulting in shortened lengths of hospital stay and improved patient outcomes.
3. Determining what tests will remain at referring hospitals and what tests will be sent to the consolidated laboratory must be determined by the various stakeholders, especially care providers at the referring hospitals. This cannot be a "top down" decision mandated by system administrators or the leadership of consolidated laboratories.
4. New developments in communication technologies, such as the use of video technology allowing electronic review of microscopic images and culture plates for consultation between laboratories or between microbiologists and health care providers, provide a potential means of replacing face-to-face communications among laboratorians and between microbiologists and clinicians.

Points requiring further discussion:

1. The true cost of consolidation needs to be determined. Does consolidation really lead to improved measures of quality, such as shortened lengths of stay, a reduction in health care-associated infections by more-rapid detection of organisms that are easily transmitted in hospital settings, reduced mortality, and reduced readmission rates? Outcome studies that assess these issues are desperately needed.
2. One of the challenges facing consolidated laboratories is long courier routes, which may compromise the viability of infecting pathogens. The potential for direct molecular testing to obviate this problem must be explored.
3. Strategies for the development and maintenance of microbiology competency among technologists working at system hospitals distant from the core laboratory need to be developed and proven to be effective.
4. How do caregivers, especially infectious disease specialists, view their interactions with consolidated laboratories? Do improved TATs and expanded test menus really translate into better patient care in the judgment of health care providers responsible for the care of patients with infection?

Peter H. Gilligan, Editor, *Journal of Clinical Microbiology*