

Role of Clinical Microbiology Laboratories in the Management and Control of Infectious Diseases and the Delivery of Health Care

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Modern medicine has led to dramatic changes in infectious diseases practice. Vaccination and antibiotic therapy have benefited millions of persons. However, constrained resources now threaten our ability to adequately manage threats of infectious diseases by placing clinical microbiology services and expertise distant from the patient and their infectious diseases physician. Continuing in such a direction threatens quality of laboratory results, timeliness of diagnosis, appropriateness of treatment, effective communication, reduction of health care-associated infections, advances in infectious diseases practice, and training of future practitioners. Microbiology laboratories are the first lines of defense for detection of new antibiotic resistance, outbreaks of foodborne infection, and a possible bioterrorism event. Maintaining high-quality clinical microbiology laboratories on the site of the institution that they serve is the current best approach for managing today's problems of emerging infectious diseases and antimicrobial agent resistance by providing good patient care outcomes that actually save money.

The current era in health care, with its intense focus on controlling expenditures, has led to important changes in the management of infectious diseases. Improvement of available vaccines, development of new vaccines, and expanded vaccine delivery have prevented illness in millions of persons, and prevention is an obvious element to reduce costs of medical care [1]. During the past decade, an important reduction in the number of health care-associated infections in critically ill patients who receive intensive care was accomplished on a national scale [2]. The recent Quality Interagency Coordination Task Force report outlining the federal response to improving overall quality outcomes for health care delivery singled out infection control practice as a successful model available to improve care (reduce errors) in other aspects of our complex

health care environment [3]. The members of the Infectious Diseases Society of America (IDSA) are fortunate to have actively participated in these acknowledged achievements in advancing patient care outcomes.

The new direction in health care also has some undesired outcomes when management and control of infectious diseases are considered. The shift from fee-for-service payments to a capitated, or managed care contract, reimbursement system has taken significant financial resources away from hospital-based laboratories [4, 5]. An additional cost-containment measure has been to restructure, centralize, or consolidate laboratory services, including clinical microbiology laboratories, into larger working groups that serve multiple hospitals and retain fewer staff with dedicated microbiology expertise. Such restructuring has occurred on both a regional and national basis. The rationale for such consolidation of laboratories is to maximize testing efficiency and (primarily) lower costs. Occasionally, another espoused benefit is the provision of facilities with an increased variety of services.

Laboratory consolidation is occurring at a time when several alarming trends challenge the assumption that what seems economically optimal will also serve the changing needs for the management and control of infectious diseases. From 1980

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through 1992, infectious diseases rose from the fifth to the third leading cause of death in the United States, a 58% increase [6]. Therapy for bacterial infections is becoming more difficult, with the rapid emergence of clinically relevant drug resistance [7]. Patients infected with multidrug-resistant organisms are now seen routinely in both community and hospital settings [7]. In addition to detecting infectious microbes and determining useful therapy, laboratories of the 21st century must now recognize new pathogens and support the national infrastructure needed for surveillance to ensure food safety and counter bioterrorism [6–9]. Meeting these challenges may not be compatible with the current administrative strategies for laboratory restructuring and/or consolidation.

In the present report, the recent trends in microbiology laboratory practice, in relation to their likely impact on the management of infectious diseases-related health care issues is assessed. On the basis of this review, the IDSA will develop policy statements and an action plan that support the best use of our clinical microbiology resources to benefit the people of the United States.

BACKGROUND DATA

Few data are available as to the actual medical impact of the consolidation or restructuring of clinical microbiology laboratories. Current changes mainly consist of moving from a hospital-based service with close interaction among interested physicians, laboratory professionals, and other staff involved with patient care hospital-wide to a centralized laboratory service that is distant from many hospital sites and thus renders frequent, direct interaction impossible. A recent review that discussed contemporary controversies in clinical microbiology concluded that much of infectious diseases testing is not amenable to such altered practice [10]. This panel of experts also raised the concern as to whether meaningful patient care quality would be lost as a result of centralization of microbiology laboratories, because this strategy often results in integration of testing that is driven by equipment capabilities rather than by disease-based expertise. When such centralization is undertaken, staff usually consists of generalists, rather than medical technologists and professionals with training and expertise in clinical microbiology [10]. These concerns are not new, and they have been expressed in the past in relation to the impact of diminishing resources for those microbiology laboratories that remain in the hospital environment [11].

In 1999, a ClinMicroNet (a worldwide electronic information network of leading clinical microbiology laboratory directors; not available to general public) survey was conducted to determine the experiences of clinical microbiology health care experts with consolidation [12]. Some 35 members of this distinguished group indicated having had direct involvement with

microbiology laboratory restructuring designed to centralize testing services. The top 5 benefits, in rank order, achieved by those laboratory directors who reported positive experiences with such restructuring were as follows: (1) cost reduction; (2) perceived improvements in test accuracy on rarely performed tests occurring as a result of increased volume in the centralized laboratory; (3) expanded testing menus resulting from a larger number of patients being covered by the laboratory; (4) standardization of test methods between several facilities; and (5) increased funding for education resulting from enhanced profitability [12].

In the same survey, the top 5 detriments (outnumbering the benefits by almost 2 to 1) after consolidation were as follows: (1) poor communication between physicians and laboratory personnel; (2) recurrence of serious problems with timely specimen transport; (3) time-consuming customized reporting as a result of lack of report standardization at various patient care sites; (4) impaired Gram stain analysis resulting from initial smears being read by generalists at on-site rapid-response laboratories; and (5) compromised infection control surveillance resulting from a lack of personal interaction with staff at the hospital. It is of interest that communication figured so prominently in the issues detracting from the cost-saving benefits of laboratory consolidation.

A similar, yet unanticipated problem was recently raised in an article reported in the College of American Pathologists' newsletter, *CAP Today* [13]; there was concern that (1) the loss of subtle communication between the laboratory and the infectious diseases physician would adversely impact patient care outcomes, and (2) reestablishment of this contact has never been successfully achieved from a remote testing site. Furthermore, a comprehensive review of the clinical implications of increasing antimicrobial resistance in patient isolates from one of the premier medical centers in the world included the statement that "Effective surveillance (for resistance identification and control) depends on a fully equipped, efficient, and accurate microbiology laboratory that maintains close contact with clinicians" [7].

Subsequently, the ClinMicroNet group performed a survey to determine which microbiology laboratory services were most commonly considered amenable to consolidation [14]. In this latter survey, 68 laboratory directors responded, with each listing 4 potential areas for performance of testing at a referral laboratory, for a total of 272 possible sections to consolidate. The 4 microbiology sections assessed were general bacteriology, parasitology, virology, and mycobacteriology. In this survey, a total of 27 sections (10%) from responding laboratories had been restructured so that some portion of testing was performed in a distant, centralized facility. It is interesting that 21 of the 27 centralized areas involved virology or mycobacteriology testing. Although certain virology tests may arguably lend

themselves to a centralized laboratory, rapid antigen detection tests should be performed on site so that their results—which, for pediatric and immunocompromised patients, are crucial to guide specific therapies, speed patient isolation to limit health care–associated spread of transmissible agents, and avoid invasive diagnostic procedures—are available within a few hours of specimen collection. On-site virology laboratories optimize outcome, especially for children’s hospitals. If the low-volume testing areas of virology and mycobacteriology were excluded in the survey, only 6 (2%) of 272 other clinical microbiology testing areas were successfully centralized. These data indicate the difficulty in maintaining quality for most infectious diseases tests by use of a management approach that moves microbiological analysis too far from patient care.

Concern about maintaining test quality has been underscored by 2 recent reports that measured the ability of microbiology laboratories to perform satisfactorily in proficiency surveys [15, 16]. In one of these reports [15], the investigators reviewed test performance before, during, and after restructuring that occurred from 1993 through 1998 as one measure of quality in the Canadian health care system. What they found is very worrisome.

Many laboratories were restructured so that they no longer had medical technologists or pathologists and/or medical microbiologists dedicated to the performance of microbiology testing. However, they still chose to perform all levels of laboratory testing for the diagnosis of infectious diseases. The laboratories that were not restructured and that maintained testing done by experienced, dedicated personnel continued to show improvements in performance on the proficiency test samples; by the end of the observation period, they made errors in bacterial identification and susceptibility testing <5% of the time. Those laboratories that were restructured and staffed with generalists as well as increased the variety of what they offered continued to make many serious errors in identification and susceptibility testing. This finding is likely because they downgraded their technical expertise by employing less-experienced personnel, in contrast to the laboratories that maintained staff with focused expertise. In doing so, the restructured laboratories doubled the number of errors made in bacterial identification. Overall, the technical staff in these laboratories made errors of identification or susceptibility testing on >30% of the proficiency test samples that they received.

Such an observation further validates similar conclusions derived >1 decade ago about what type of staffing and professional direction is required for accurate laboratory testing [17]. This evidence suggests that dedicated leadership and staff are important to reliable testing, regardless of where the clinical microbiology laboratory is located. However, hospital-based laboratories may be more likely to retain such expertise, because the medical director of microbiology can participate in insti-

tution-wide functions, such as infection control and the work of the antibiotic formulary committee as part of his or her work responsibilities on site, rather than be responsible only for the management of a laboratory that is located away from the hospital campus and that may not require a full-time medical director.

The second report surveyed US laboratories and validated the concern with the current capacity of clinical microbiology laboratories to detect important emerging resistance to antimicrobial agents [16]. From August 1998 through September 1998, a survey from the Centers for Disease Control and Prevention was sent to 447 laboratories in their Active Bacterial Core Surveillance and Emerging Infections Program networks, to assess their ability to detect *Staphylococcus aureus* that is intermediately resistant to vancomycin and *Enterobacteriaceae* that produce extended-spectrum β -lactamases (ESBLs). Of the 416 laboratories that responded (93%), 369 (89%) actually performed microbiology testing. In this survey, 66 (33%) of 201 laboratories did not use an acceptable method to confirm the detection of *S. aureus* that is intermediately resistant to vancomycin, and >73% failed to use recommended methodology to detect ESBLs (at most 98 used adequate screening methods for ESBLs). Hospital-based laboratories were significantly more likely to perform adequate testing for these organisms (OR, 2.1–8.2) than were other sites. Managed care–based laboratories were much less likely to perform adequate testing (OR, 0.3) than were other sites. These data confirm the serious concern as to whether there will be adequate laboratory infrastructure resources available to meet the challenges posed by current threats of infectious diseases, especially in resource-constrained practice settings like managed care.

A major question to consider is whether maintaining microbiology laboratories within hospitals or medical centers is financially viable. Not many institutions have been able, or willing, to study this important issue. Investigators at Northwestern Memorial Hospital, Chicago, reported their results after 2 and 5 years of experience, respectively, with a clinical microbiology laboratory that is staffed and equipped to fully handle local patient care and infection control needs, and that has the on-site infrastructure capability to report their data to a national repository, such as the Centers for Disease Control and Prevention [18, 19]. What they found, after enhancing their microbiology laboratory capability as part of a hospital-wide infection control effort, was that there was an annual reduction (exceeding \$2 million) in the costs of health care–associated infections, and that each year they avoided approximately 285 of these infections that likely would have resulted in at least 10 deaths [19]. For their 700-bed medical center, the full cost of this enhancement was not inconsequential, totaling approximately \$400,000 annually. Most importantly, this savings amounts to a 5-fold return on the investment made for better

patient care. Their results are fully in keeping with the federal plan for reducing errors associated with health care encounters in the United States [3]. However, because of the consistent reductions in reimbursement from governmental health care payers since the mid-1990s, most hospitals and medical centers are unwilling or unable to undertake such a bold program.

Peterson and Noskin [19] suggested that hospital-based clinical microbiology laboratories should be offered easily obtainable annual federal grants of \$300,000–\$500,000 (depending on hospital size and complexity of care) to enhance their clinical microbiology laboratory support for infection control purposes. The ability to reduce health care–associated infections by as much as 30%, by use of a comprehensive infection control program, is supported by an early study on the efficacy of nosocomial infection control [20]. Peterson and Noskin [19] reported a 13%–23% reduction in health care–associated infections with use of their integrated infection control program, depending on how the measurements were taken, and suggested that this program is both medically and economically justified. The added benefit of such a comprehensive infection control program is improvement in the basic microbiology laboratory infrastructure for supporting clinical diagnosis, detecting food-borne illness, and recognizing possible bioterrorism events. Although other researchers have not presented financial data from their institutions, they have reported similar integrated approaches that can have a major impact on improving patient care outcome [21, 22]. The IDSA supports these observations.

SUBJECTIVE CONSIDERATIONS

Whenever consolidation of a clinical microbiology laboratory is considered, especially if consolidation involves moving testing to a site distant from the hospital or medical center, several critical issues that subjectively involve the practice of infectious diseases should be considered and openly discussed. These issues must be substantively addressed before a final decision is made to move a clinical microbiology laboratory to a location distant from the health care faculty, staff, and patients that it supports. These issues include those raised earlier in this report, and training functions crucial to our long-term ability to manage the ever-present problem of infectious diseases. The additional elements are as follows.

Specimen handling and transport. This aspect is important to both the patient and the attending physician. A delay in transporting the specimen to the laboratory where processing begins not only prolongs the time until the attending physician receives a test result but also impacts specimen integrity that may lead to a false-negative or false-positive result of analysis and a misleading answer. This delay affects a broad variety of samples that range from feces, for which commensals like *Escherichia coli* can overgrow a *Shigella* species, to meningococci

in CSF, which die if not rapidly cultured; for both of these examples, a false-negative result of testing can be life-threatening [23]. Some laboratories have successfully addressed this problem by inoculating specimens on site and then transporting media plates and tubes to the centralized laboratory, but this approach presents its own unique problems. Inoculation of media to avoid initial processing errors ideally should be performed by technologists with expertise in clinical microbiology, rather than generalists. Initial processing of samples for microbiology testing is critical, since errors that occur at this stage cannot be corrected at a later time, and since mistakes require collection of new specimens. Such an approach creates 2 microbiology laboratories and negates many of the financial benefits desired from consolidation.

Furthermore, new regulations for the transport of infectious agents on public roadways are cumbersome at best and add another cost to centralization of microbiology testing [24]. Therefore, any proposal (other than direct tube transport) that claims that shipping clinical specimens to a distant site adds mere minutes to transportation time, preserves high-quality diagnostic testing, and is easily accomplished is clearly unrealistic. Transport, in reality, requires initial on-site registration, specimen triage, careful packaging, temperature control, secure transport, and subsequent registration and triage at the distant site. This transport has not been accomplished regularly without adding hours to the overall time of moving a specimen from the patient to the final testing area. Short transport times to a distant site have been accomplished only by directly connecting the laboratory to the testing facility by means of an automated (tube-type) transport system.

Communication between the physician and the microbiology laboratory. Effective communication is one of the most important characteristics of a microbiology laboratory, wherever it is located. To be effective, the opportunity for dialogue between health care providers and laboratory personnel must be readily accessible, if not immediately available. Provision must be adequate for bidirectional interaction, because the information provided is nearly always qualitative and interpretive. Face-to-face meetings that occur either at scheduled times or on an ad hoc basis whenever necessary, as dictated by the patient's needs, best accomplish this goal. Although telephones, facsimiles, e-mail, and information systems are helpful, especially for documentation, they are less useful for the kind of interchange that fosters optimal patient care and infection control practices under complex circumstances. Visual and electronic communications can be employed as educational tools, but the logistics are limiting in time, quality, and immediacy. Experience gained at other facilities where the laboratory is off-site indicates that communication not only decreases, but also, may actually cease. Proposed video conferencing has proven to be inefficient, expensive, and rarely used. Furthermore, the

perception of quality influences the behavior and decisions of the attending physician.

A 1993 survey of >500 infectious diseases physicians who were members of the IDSA reported that 78% of respondents thought that consultative services by a doctoral-level microbiology laboratory director were extremely important to quality [25]. This survey found higher quality scores in all specialty areas ($P < .0001$) for laboratories whose director was certified in the practice of medical microbiology, as opposed to those laboratories whose director had not obtained specialty training [25]. Failure to achieve an appropriate level of communication with a distant laboratory will result in unwillingness to use, if not total rejection of, laboratory data perceived to be erroneous. Accurate assessment of results of susceptibility testing at times requires face-to-face discussion of the treatment implications. Development of rational therapeutic guidelines needed for prudent use of antimicrobial agents in the battle against emerging drug resistance cannot be accomplished without ongoing review of results of susceptibility testing by the professionals in the microbiology laboratory and the practicing physician [26]. Distrust of results of testing in microbiology laboratories makes formulary control of antibiotics difficult to enforce and invariably leads to increasing therapeutic empiricism, which is something that should be abandoned as part of the historical practice of medicine. Trends identified by a survey of infectious diseases physicians indicated that overall quality ratings for microbiology laboratories were based on long-term experiences and ongoing communication [27]. In such a setting, even a rarely occurring serious testing problem did not significantly detract from overall high-quality perception and trust of the laboratory's reported results.

Advancement in health care practice. Important contributions made by microbiology to clinical research, with direct implications for patient care, include studies of optimal conditions for, and performance of, a wide variety of microbiological diagnostic and therapeutic tests. Without rigorous research by credible laboratories, development of improved diagnostic methods is severely retarded, if performed at all. Furthermore, pharmaceutical companies currently depend upon the academic microbiology laboratory to provide diagnostic testing for clinical trials of new antimicrobial drugs. Such studies often require complex and esoteric diagnostic methods and are rarely performed by consolidated laboratories that typically are not associated with the top-rated academic medical centers where the clinical isolates are collected.

Placement of the clinical microbiology laboratory at a distant site clearly threatens the very existence of these studies that are required for continuous improvement in quality care of infected patients and for new drug development. The long-term impact of losing clinical trials from academic medical centers is considerable in that (1) infectious diseases expertise in this im-

portant field will decline; (2) new, potentially life-saving drugs will be unavailable, and care of patients with complex cases will then be compromised because of this lack of access; and (3) direct health care costs saved by patient participation in clinical trials, for which a sponsor pays for antimicrobial therapy, will be abandoned.

Training future health care practitioners. Physicians of the future are obliged to receive clinical training to be licensed. They start in the medical care setting as students, interns, and residents. Ready access to the clinical microbiology laboratory has a major impact on these trainees. This interaction is where they learn the importance of proper specimen collection, ordering practices, laboratory utilization, and the wise use of antimicrobial agents; this training will influence their entire practice career. Such training will never happen when the laboratory is located a great distance from the hospital. For the more specialized trainee, such as an infectious diseases specialist in training, concentrated exposure to the microbiology laboratory may be accommodated on site or at a distant location, but the opportunity to engage daily in the correlation of clinical and laboratory findings so critical to the clear understanding of the ongoing process of infection is lost with an off-site laboratory.

Clinical training in infectious diseases as a subspecialty depends upon continuous interaction with the microbiology laboratory to provide appropriate patient care, obtain information that promotes the judicious use of antimicrobial agents, and receive data to support isolation policies. Therefore, this interaction is not simply a convenience factor. Rather, it is a realization that one can accomplish only so much in one day and that priorities are established on the basis of simple proximity. Locating the clinical microbiology laboratory at a distant site has a deleterious effect on adult and pediatric infectious diseases services, as well as on integrated training programs. Problems arise in the recruitment of trainees, improper or inadequate training in the discipline, and accreditation of residency and fellowship programs. In summary, to maintain the knowledge base for the future health care providers in the United States and, in fact, to enhance their level of understanding, this education of the next generation of doctors must be preserved.

SUMMARY

With national attention focused on an increase in infectious diseases and the goal of improving the quality of health care outcomes [3, 6], a consensus must be reached as to what threat infectious diseases problems pose and what resources are needed to improve microbiology laboratory infrastructure so that the laboratory can deal with them. Such a consensus report on the needs for adequate infection control in health care delivery has been published [28]. Although the report included sophisticated support from the clinical microbiology laboratory,

it did not specifically address where the resources should come from to provide the necessary infrastructure.

On the basis of our current knowledge, it appears that the management of infectious diseases will be best accomplished by the maintenance of clinical microbiology laboratories on the same campus as the health care institution(s) they serve, to provide the American public and the physicians who care for them with the necessary diagnostic testing, means of epidemiological detection, and future innovation required in an era of emerging and reemerging infectious diseases. The microbiology laboratories of the United States, partnering with state health departments and the Centers for Disease Control and Prevention, are the first line of detection and defense in the event of new emerging microbial resistance, outbreaks of food-borne illness, or a bioterrorist attack. These laboratories directly serve the patient through accurate and timely detection of infectious microbes, and this information is critical to the quality treatment of infectious diseases. Successful detection and interpretation of results clearly require adequate staffing with specially trained medical technologists and supervision by laboratory directors who have received training in a clinical and/or medical microbiology program that qualifies them for certification by the American Board of Pathology or the American Board of Medical Microbiology. The microbiology laboratory also is a crucial component of the infection control team responsible for preventing health care-associated infections, thus promoting good patient care outcomes that save money.

The IDSA is firmly committed to supporting the infrastructure requirements for the management and control of infectious diseases, not only for the immediate time but also for the long-term future needs of patients and health care providers. As a society, our goal is to achieve excellence in patient care, diagnosis and treatment that are affordable, and high quality as a measurable outcome. Maintaining high-quality clinical microbiology laboratories supports all these aspirations.

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