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The impact of changes in Clinical Microbiology Laboratory location and ownership on the practice of Infectious Diseases

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TITLE: The impact of changes in Clinical Microbiology Laboratory location and ownership on the practice of Infectious Diseases

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Abstract

The number of onsite clinical microbiology laboratories in hospitals is decreasing, likely related to the business model for laboratory consolidation and labor shortages, and this impacts a variety of clinical practices including banking isolates for clinical or epidemiologic purposes. To determine the impact of these trends, infectious disease (ID) physicians were surveyed regarding their perceptions of offsite services. Clinical microbiology practices for retention of clinical isolates for future use were also determined. Surveys were sent to members of the Infectious Diseases Society of America's (IDSA) Emerging Infections Network (EIN). The EIN is a sentinel network of ID physicians who care for adult and/or pediatric patients in North America and who are members of IDSA. The response rate was 763 (45%) of 1,680 potential respondents. Five hundred forty (81%) respondents reported interacting with the clinical microbiology laboratory. Eighty-six percent of respondents thought an onsite laboratory very important for timely diagnostic reporting and ongoing communication with the clinical microbiologist. Thirty-five percent practiced in institutions where the core microbiology laboratory has been moved offsite, and an additional 7% (N=38) reported that movement of core laboratory functions offsite was being considered. The respondents reported that only 24% of laboratories banked all isolates with the majority saving isolates for less than 30 days. Based on these results, the trend towards centralized core laboratories negatively impacts the practice of ID physicians, potentially delays effective implementation of prompt and targeted care for patients with serious infections, and similarly adversely impacts infection control epidemiologic investigations.

Introduction

During the past three decades, clinical laboratories have faced a new business model driven by a reimbursement system that encourages economies of scale and large volume testing (1,2). At the same time there have been the additional issues of increasing labor force shortages of experienced microbiologists and the emergence of new complex and costly diagnostic technologies (2). In response to these economic realities, a number of clinical microbiology laboratories have either moved to locations remote from the main hospital facility in order to expand laboratory capacity whereas others have consolidated laboratory facilities in multi-hospital systems.(3-6) Yet while these consolidations can offer economies of scale and the more ready introduction of sophisticated expensive technologies, these remote site laboratories present challenges both for quality of services and communication.(6,7). The partnership of the clinical microbiologist and the infectious disease physician can result in better use of laboratory services and improvement in patient care quality; distance can strain, if not completely eliminate, these benefits.(8,9) Beyond this, as off-site laboratories lose a primary relationship with a given institution, and may in fact become separate for-profit entities, the associated costs associated with retaining clinical isolates for future epidemiologic may now require formal budgetary justification.(9)

To determine the impact of these trends, infectious disease physicians were surveyed regarding their experiences with offsite services. This survey was not designed to determine the impact of offsite laboratory services on the quality of patient care, but rather to describe the impact on infectious diseases physicians. The move away from hospital-based laboratories also may have decreased the number of institutions which save isolates, which allows for repeat or additional testing for a variety of needs, including infection control investigations, further investigation for public health purposes, and for quality control purposes. We also were

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interested in whether clinical isolates were retained for future use and policies regarding this practice.

Methods

We sent a twelve-question primary survey and a 5 question sub-survey on isolate retention to physician members of the Infectious Diseases Society of America's (IDSA) Emerging Infections Network (EIN). The EIN is a sentinel network of infectious diseases (ID) physicians who care for adult and/or pediatric patients in North America and who are members of IDSA.(10) The survey was collaboratively developed by the study authors and reviewed by ID physicians currently in clinical practice for content validity and pilot testing. On May 22, 2018, all 1,830 members of the EIN received the confidential survey by email link or by facsimile. Non-responders received two reminders, and physicians who had joined the EIN but had not yet responded to any surveys were excluded (N=150), resulting in a denominator of 1,680 physician members. An opt-out option was provided for those physicians who did not interact with the clinical microbiology laboratory in their primary institutions. The survey remained open until June 14, 2018, and is provided as an appendix.

The physicians were asked to indicate if a list of clinical microbiology laboratory services were performed onsite in their primary institutions as well as their satisfaction with this laboratory's services, whether any core microbiology functions had been moved offsite, and if so, a series of questions about the offsite location. Also, physicians were queried as to whether the microbiology laboratory banked any isolates, and if so, were asked to open a second link to respond to a brief sub-survey on isolate retention. In this sub-survey, questions asked included which isolates were saved and for how long, whether these saved isolates had been used, and any impact on clinical practice. Practice information for each respondent, including employment, geographic location and years of practice, was imported from an EIN database. Not all

respondents answered all questions, so totals for individual questions vary. Chi-square and Fisher's exact tests were used for univariate analyses. Data were analyzed using SAS software version 9.4 (SAS institute, Cary, NC).

Results

The overall response rate to the survey was 763 (45%) of 1,680 potential respondents, with 441 (26%) respondents answering only the Clinical Microbiology Laboratory Services survey, 95 (6%) respondents answering only the Isolate Retention (banking) sub-survey and 227 (13.5%) responding to both. All regions of the U.S. were well represented (see Table 1). The years of experience since infectious disease fellowship ranged from less than 5 years to more than 25 years with the largest number of respondents (29%) having more than 25 years of experience. A university/medical school work setting accounted for 47% of respondents, and 48% (364/763) were associated with community and non-university teaching hospitals. A sizable number of respondents (N=190, 35%) practiced in institutions where the core microbiology laboratory has been moved off site, and an additional 7% (N=38) reported that movement of core laboratory functions offsite was being considered.

Eighty-six percent of respondents thought an onsite laboratory to be very important for timely diagnostic reporting and ongoing communication with the clinical microbiologist. Slightly fewer felt that onsite laboratories were important for education/teaching (75% very important, 20% slightly or moderately important). Respondents most often reported that their primary microbiology laboratories always met their expectations with communication with laboratory management/director (64%) and with microbiology laboratory bench personnel (59%). The overall quality and accuracy of microbiology laboratory results always met expectations for 50% of respondents, followed by electronic reporting of micro results (48%) and handling of mycobacteriology specimens and issues (46%). Turnaround time for microbiology laboratory

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results met respondents' expectations least often, with 35% saying their expectations were always met and 63% indicating that their expectations were either mostly or sometimes met.

In the area of post-testing physician needs, the respondents reported that only 24% of laboratories banked all isolates with the majority saving isolates for less than 30 days. However, 72% of the laboratories would save isolates on request. Of the respondents, over 50% had made use of banked isolates in the last year with 160 (51%) of 321 doing so for direct clinical care and 168 (54%) for epidemiological investigations. Additionally, 166 (52%) respondents indicated there had been a time in the past year when an isolate was needed but was not available because of the laboratory's retention policy.

Five hundred forty (81%) respondents reported interacting with the clinical microbiology laboratory, and the laboratory services available onsite at their institutions are summarized in table 2. Those services include: 74% have after hours Gram stain interpretation; 88% have on site blood cultures, but only 61% have blood culture rapid identification methods; 78% have respiratory virus panel testing but only 61% have Legionella urinary antigen testing; 84% have onsite *Clostridioides difficile* testing; 50% have adopted the MALDI ToF technology for bacterial identification.

Two hundred nine respondents (all of those whose institutions had moved functions offsite plus 19 of those whose institutions were considering such a move) then answered six questions about their offsite microbiology laboratory. Of the respondents who had experience with an offsite laboratory, 74% perceived that the offsite laboratory has a negative impact on overall infectious diseases patient care and outcomes (either major or minor) with the primary negative effects relating to turnaround time and communication with the laboratory. Of the respondents who had experience with an offsite laboratory, 57% said that the transport time to the offsite

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location is greater than 30 minutes. Ten percent of these respondents reported a positive impact (either minor or major) most often related to overall availability of lab services and technologies. In addition, 47% felt that an offsite laboratory adversely impacted infectious disease medical education. Only 65% felt that infectious disease physicians have any input into microbiology laboratory policies that affect their practice.

Discussion

While the model of test delivery is changing, the science of clinical microbiology is becoming more complex. The need for a strong partnership between the infectious disease physician and the clinical microbiology laboratory has always been important, but the need appears to becoming even greater in recent years given the development of new methods, instruments, automation, and the desire for shorter turnaround times.(8) Moreover, optimal utilization of these newer technologies such as MALDI-ToF, multiplex PCR systems, next generation sequencing, and rapid antimicrobial resistance determination will be dependent on consultation between the infectious disease physician and the laboratory director.

Based on the results of this survey, the trend towards centralized core laboratories has impacted the practice of infectious disease physicians and, in their perspective, not in a positive way. A marked majority of the survey respondents indicated that they felt that onsite testing is important for timely diagnostic reporting and ongoing communication with clinical microbiology. However, 35% of the respondents reported that their clinical microbiology laboratory is now located offsite, with more than half of these laboratories more than 30 minutes from their institution which would impede any possibility of a brief in-person meeting or the possibility of the infectious disease physician quickly visiting the laboratory. This points to the need for laboratory directors to consider alternate means to connect with the infectious disease physician community to build the necessary communication channels.

Importantly, many respondents to this survey are not satisfied with the services provided by their clinical microbiology laboratory given that on only 35 to 64% of six measures were the laboratories always meeting their expectations. This lack of satisfaction is supported by the reported limitations in clinical microbiology services at the respondents' hospitals as only 74% had known onsite Gram stain interpretation after hours, and many clinical microbiology laboratories are not keeping up with new technology with only 61% of the facilities providing rapid blood culture identification methods and only 50% having adopted MALDI-ToF technology. As another indicator of service, infectious disease physician respondents were asked about the retention of isolates by the clinical microbiology laboratory. Seventy-two percent responded that they could have an isolate saved if requested yet over 50% had a need for a retained isolate in the past year.

A significant impact of an offsite clinical microbiology was to medical education as noted by 47% of the respondents. However, the respondents also felt that they did not have much impact on the operations of the laboratory, and the lack of communication impedes the ability of microbiologists and clinicians to work together in optimizing the selection and utilization of the new technological advances in clinical microbiology such as rapid blood culture identification and MALDI-Tof systems.(5)

From the available data in the literature, consideration of costs (10) is a major factor in the decision to send specimens to an outside laboratory, but administrators do not quantify or know the cost of keeping patient in hospital longer or the cost of additional tests or empiric treatment until culture or other results return.(11) In addition, despite the recommendations that the clinical microbiologist collaborate in antibiotic stewardship programs,(10) when the laboratory is offsite there is not sufficient opportunity for interaction between the infectious disease physician and

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the clinical microbiology laboratory to allow this. It is possible that the use of video conferencing and tele-microbiology may compensate for direct interactions, but such services do not appear to be routinely available at this time. Beyond all of these issues, ongoing efforts to improve the quality of patient care, decrease length of stay, and meet benchmarks such as for sepsis protocols (e.g., treating patients at the earliest possible time) are all driving the need for near patient diagnostics, and offsite laboratories may have difficulty supporting these needs (10).

Another concern arising from the move to centralized non-institution based laboratories is the ability of the microbiology laboratory to assist in infection control/public health activities,(6, 9, 12, 13, 14) and the finding that only a minority of laboratories are now retaining isolates. There has been increasing concern about healthcare associated infections, cross transmission of multidrug resistant organisms, as well as point source outbreaks within hospitals and the general community. However, the ability to determine actual cross transmission events is dependent on the ability to type or sequence pathogens; and multiple studies have shown that for epidemiologic purposes typing needs to be performed using molecular typing methodologies such as pulse field gel electrophoresis or whole genome sequencing. (15-17) Such additional characterization can only be done if there has been retention of isolates potentially linked to cross transmission events or presumed outbreaks, and if measures are not in place to retain such isolates, the public health benefit of identifying and controlling outbreaks is lost. While the ability to retain isolates is independent of location of the laboratory, retention of isolates serves as an indicator of meeting an essential need of the physician.

Our findings are subject to a number of limitations. To maximize the response rate, the survey was designed to be relatively straightforward for respondents to complete. Consequently, more detailed analyses of the use of newer technologies or the breakdown of services available on- and off-site were not possible. While the EIN represents about 18% of IDSA physician

members and about 20% of subspecialty boarded physicians, our members are not randomly selected. Since our members "self-select" to join the EIN, we do not make any claims that our members are representative of the broad population of infectious diseases physicians. This was a descriptive survey which reflects the perceptions and opinions of the responding infectious diseases physicians and should be validated with additional data about specific interactions between infectious diseases physicians and laboratory personnel. Moreover, the perceptions and opinions of laboratory directors were not incorporated into the survey.

Conclusions

It has been recommended that "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."(9) Unfortunately, the findings of this survey indicate that the shift from institution-based to core laboratory facilities is having a negative impact on infectious disease physicians and their relationship with the clinical microbiology laboratory. As yet unanswered is the impact of this trend on the care of the patient, the cost of medical care for those with serious infections, and the public health issues of antimicrobial resistance and emerging infectious diseases. Going forward it will be important for institutions to develop key performance indicators related to laboratory services so that the relative utility of on-site and off-site laboratories in all of these can be better defined.

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Potential Conflicts of interest

All authors report no conflicts of interest relevant to this article.

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TABLES

Table 1. Practice characteristics of 763 respondents

Infectious diseases practice	Adult	672 (75)
	Pediatric	191 (25)
U.S. Census Bureau division	New England	52 (7)
	Mid Atlantic	114 (15)
	East North Central	106 (14)
	West North Central	79 (10)
	South Atlantic	134 (18)
	East South Central	37 (5)
	West South Central	52 (7)
	Mountain	40 (5)
	Pacific	141 (18)
	Puerto Rico	1 (0.1)
	Canada	7 (1)
Years' experience since ID fellowship	< 5 years	173 (23)
	5-14	225 (29)
	15-24	145 (19)
	≥25 years	220 (29)
Employment	Hospital/clinic	224 (32)
	Private/group practice	167 (22)
	University/medical school	305 (40)
	VA and military	43 (6)
	State government	4 (0.5)

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Primary hospital type	Community	163 (22)
	Non-university teaching	201 (26)
	University	323 (42)
	VA hospital or DOD	48 (6)
	City/country	28 (4)
Practice settings where laboratory is offsite	Yes	190 (35)
	No	312 (58)
	Maybe	38 (7)

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Table 2. Which of the following lab services are performed ONSITE in your primary institution? *[N=540]*

	Available onsite	Offsite only	Not sure / Not answered
Gram stain interpretation Monday through Friday 8am-3pm	491 (91%)	25 (5%)	24 (4%)
Blood culture bottle processing	476 (88%)	44 (8%)	20 (4%)
C. difficile testing (e.g. GDH, NAAT)	453 (84%)	50 (9%)	37 (7%)
Identification and susceptibility testing of sterile site isolates	429 (80%)	60 (11%)	51 (9%)
Respiratory virus panel testing (e.g. RSV, influenza)	421 (78%)	63 (12%)	56 (10%)
Blood smears for infection (e.g. malaria, Anaplasma, Ehrlichia)	403 (75%)	64 (12%)	73 (13%)
Gram stain interpretation Monday through Friday 11pm-6am	399 (74%)	37 (7%)	104 (19%)
AFB stains and culture	338 (63%)	105 (19%)	97 (18%)
GI pathogens panel (e.g. Salmonella, norovirus)	335 (62%)	94 (17%)	111 (21%)
Blood culture rapid ID (e.g. BioFire, Verigene)	331 (61%)	90 (17%)	119 (22%)
Legionella urinary antigen	327 (61%)	97 (18%)	116 (21%)
MALDI-TOF identification system for bacteriology	270 (50%)	121 (22%)	149 (28%)
Nucleic acid amplification test (NAAT) for *M. tuberculosis*	231 (43%)	158 (29%)	151 (28%)