

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

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27 **Abstract**

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

48

49 **Introduction**

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

66

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

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

76

77 **Methods**

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

90

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

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

103

104 **Results**

105 The overall response rate to the survey was 763 (45%) of 1,680 potential respondents, with 441
106 (26%) respondents answering only the Clinical Microbiology Laboratory Services survey, 95
107 (6%) respondents answering only the Isolate Retention (banking) sub-survey and 227 (13.5%)
108 responding to both. All regions of the U.S. were well represented (see Table 1). The years of
109 experience since infectious disease fellowship ranged from less than 5 years to more than 25
110 years with the largest number of respondents (29%) having more than 25 years of experience.
111 A university/medical school work setting accounted for 47% of respondents, and 48% (364/763)
112 were associated with community and non-university teaching hospitals. A sizable number of
113 respondents (N=190, 35%) practiced in institutions where the core microbiology laboratory has
114 been moved off site, and an additional 7% (N=38) reported that movement of core laboratory
115 functions offsite was being considered.

116

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

126 results met respondents' expectations least often, with 35% saying their expectations were
127 always met and 63% indicating that their expectations were either mostly or sometimes met.
128

129 In the area of post-testing physician needs, the respondents reported that only 24% of
130 laboratories banked all isolates with the majority saving isolates for less than 30 days.
131 However, 72% of the laboratories would save isolates on request. Of the respondents, over
132 50% had made use of banked isolates in the last year with 160 (51%) of 321 doing so for direct
133 clinical care and 168 (54%) for epidemiological investigations. Additionally, 166 (52%)
134 respondents indicated there had been a time in the past year when an isolate was needed but
135 was not available because of the laboratory's retention policy.
136

137 Five hundred forty (81%) respondents reported interacting with the clinical microbiology
138 laboratory, and the laboratory services available onsite at their institutions are summarized in
139 table 2. Those services include: 74% have after hours Gram stain interpretation; 88% have on
140 site blood cultures, but only 61% have blood culture rapid identification methods; 78% have
141 respiratory virus panel testing but only 61% have Legionella urinary antigen testing; 84% have
142 onsite *Clostridioides difficile* testing; 50% have adopted the MALDI ToF technology for bacterial
143 identification.
144

145 Two hundred nine respondents (all of those whose institutions had moved functions offsite plus
146 19 of those whose institutions were considering such a move) then answered six questions
147 about their offsite microbiology laboratory. Of the respondents who had experience with an
148 offsite laboratory, 74% perceived that the offsite laboratory has a negative impact on overall
149 infectious diseases patient care and outcomes (either major or minor)_with the primary negative
150 effects relating to turnaround time and communication with the laboratory. Of the respondents
151 who had experience with an offsite laboratory, 57% said that the transport time to the offsite

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

157

158 **Discussion**

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

167

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

178

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

190

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

197

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

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

210

211 Another concern arising from the move to centralized non-institution based laboratories is the
212 ability of the microbiology laboratory to assist in infection control/public health activities,(6, 9,
213 12, 13, 14) and the finding that only a minority of laboratories are now retaining isolates. There
214 has been increasing concern about healthcare associated infections, cross transmission of
215 multidrug resistant organisms, as well as point source outbreaks within hospitals and the
216 general community. However, the ability to determine actual cross transmission events is
217 dependent on the ability to type or sequence pathogens; and multiple studies have shown that
218 for epidemiologic purposes typing needs to be performed using molecular typing methodologies
219 such as pulse field gel electrophoresis or whole genome sequencing. (15-17) Such additional
220 characterization can only be done if there has been retention of isolates potentially linked to
221 cross transmission events or presumed outbreaks, and if measures are not in place to retain
222 such isolates, the public health benefit of identifying and controlling outbreaks is lost. While the
223 ability to retain isolates is independent of location of the laboratory, retention of isolates serves
224 as an indicator of meeting an essential need of the physician.

225

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

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

237

238 **Conclusions**

239 It has been recommended that “maintaining high-quality clinical microbiology laboratories on the
240 site of the institution that they serve is the current best approach for managing today’s problems
241 of emerging infectious diseases and antimicrobial agent resistance by providing good patient
242 care outcomes that actually save money.”(9) Unfortunately, the findings of this survey indicate
243 that the shift from institution-based to core laboratory facilities is having a negative impact on
244 infectious disease physicians and their relationship with the clinical microbiology laboratory. As
245 yet unanswered is the impact of this trend on the care of the patient, the cost of medical care for
246 those with serious infections, and the public health issues of antimicrobial resistance and
247 emerging infectious diseases. Going forward it will be important for institutions to develop key
248 performance indicators related to laboratory services so that the relative utility of on-site and off-
249 site laboratories in all of these can be better defined.

250

251

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257

258 **Potential Conflicts of interest**

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

260

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319 **TABLES**

320

321 **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)

	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	Yes	190 (35)
	offsite	No	312 (58)
		Maybe	38 (7)
322	DOD- U.S. Department of Defense		
323			
324			

325 **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%)
<i>C. difficile</i> 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 <i>M.</i> <i>tuberculosis</i>	231 (43%)	158 (29%)	151 (28%)

326