Strategic Overview of the Clinical Laboratory Industry
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Introduction

From a service industry viewpoint, clinical laboratories face two primary questions related to strategy: (1) how can they win in the marketplace, and (2) how can they outperform rivals by creating sustainable competitive advantage? While some in the clinical laboratory arena may not believe they are in a competitive environment, the majority understand this more and more every day as they vie for resources, expertise, and volume with both not-for-profit and for-profit entities. Creating a viable health care service calls for more than clinical excellence. It requires business process excellence as well, particularly as the market expands globally while consolidating and integrating on a regional basis.

With the goal of supporting clinical laboratories’ ability to be competitive via knowledge and insight, this article presents perspectives and observations regarding certain elements critical to the future of the industry. It is not intended to be a comprehensive review of all strategic matters but will touch upon those issues encountered most often in working with laboratories across the U.S.

Impact of Health Care Reform

Health care reform is now upon us. While it is clear that the final format of the legislation will change, the U.S. has no choice but to deal with this issue in some manner; the economic consequences of not doing so are too great. General comments about the impact of health care reform on clinical laboratories follow.

Some believe that significant disruption of the health care industry is necessary to force change, arguing that “[t]he hospitals providing much of today’s health care cannot and therefore ought not be relied upon to transform the cost and accessibility of health care. Instead, hospitals need to be disrupted.” (1) It would appear that the overall mechanism for achieving this disruption will be a reduction in reimbursement combined with increased numbers of people covered under some future reimbursement mechanism (i.e., lower cost to provide more services).

To remain competitive under health care reform, the industry will see continuing movement toward the regional delivery of laboratory services in concert with hospital services, with a concomitant reduction in reliance on national laboratory services. This will require regional laboratories to anticipate future service needs and significantly improve financial performance in the delivery of those services.
No matter how the health care reform legislation is modified, the following are recommendations for regional laboratories:

- Understand that expansion of laboratory market share within the hospital’s/health system’s defined market will be essential.
- Organize and enhance outreach infrastructure to facilitate provision of a competitive service offering (including IT, patient service centers, laboratory capacity, sales, high levels of laboratory service, professional customer service, and billing).
- Achieve a minimum of top quartile performance in total and testing cost; top 10 to 15 percent is better.
- Develop financial models for future utilization and bundled payment challenges.
- Ensure that the laboratory space, design, and workflow will meet future needs.
- Secure long-term capital now before things get worse. Consider an equity partner if capital is not available through the health system.

**Will Environmental Issues Trump Health Care Reform?**

A key question on many minds is whether the importance of a growing list of national and global issues will overshadow the need for or ability to implement health care reform. We have all been witness to the recent massive earthquake and tsunami that have devastated Japan. While the full global impact is not yet evident, it is certainly possible that this event, as well as other natural disasters, could have far-reaching effects on the environmental, economic, or political will to make health care reform a top priority today. As Maslow’s hierarchy of needs theory posits, when events begin to relate to personal well-being (e.g., environmental disasters, terrorism, ongoing war, etc.), people tend to focus on the physiological and safety elements of their world, resulting in minimal attention on other strategic issues.

**Regional Delivery of Health Care**

Much has been written and reported about accountable care organizations (ACOs). While it may appear to have emerged from health care reform, the ACO concept actually precedes the current law and has already been implemented and tested by some “early-adopter” health entities. Whether the current model is recommended as part of the modified health care reform legislation or not, one outcome is certain: the pressure to reduce costs while providing a higher volume of services to a larger, aging population will force changes in the provision of health care. Local/regional management of health care delivery, including laboratory services, will be an essential component for meeting this mandate.

Another impact of the need to decrease costs while serving more patients is the consolidation of health care services. Hospitals and health systems—as well as laboratories—are seeing an increase in collaborative activity. The trend towards integration of laboratories within owned operations is on the rise, as is collaboration among otherwise rival institutions to leverage their vital laboratory resources for the benefit of all participants. In addition, private equity interest in the U.S. laboratory market continues to grow, and options exist from divesting current laboratory assets to forming ventures with firms interested in becoming capital partners. Global health care and non-health care companies have also shown interest in acquiring laboratory entities. All of
this activity points to the burgeoning recognition of the critical role that clinical laboratories play in health care delivery and the value it creates.

In this environment, clinical laboratories should ask themselves the following key strategic questions:

- What is the laboratory’s current cost structure, and how does it compare to market expectations?
- Are effective processes in place to gain efficiencies and leverage the cost structure to remain competitive?
- Is the laboratory positioned to service the inpatient, outpatient, and outreach markets in support of the regional delivery of health care? Does its IT capability support the need for medical record continuity?
- Should the laboratory aggressively pursue consolidation of laboratory services in its region or collaboration with other parties to pool resources?

### Utilization of Mission-critical Services: Laboratory Testing and Interpretation

Going forward, three trends will drive higher utilization of laboratory testing. First, pressure and financial incentives to provide all of the recommended care to 100 percent of their patients will drive physicians to order increased volumes of laboratory procedures. To underscore the magnitude of this trend’s impact, imagine 100 percent of diabetic patients getting HgA1c tests annually at the same time that doctors work diligently to diagnose more of the tens of millions of undiagnosed diabetics in this country. Many in the health care industry encourage the increased utilization of laboratory tests for this purpose as a means to ultimately reduce the cost of care. However, documentation of the future benefit is not yet sufficient to convince people (and insurance companies) to conduct or fund more diagnostic testing.

The second trend is the natural increase in laboratory testing that occurs as baby boomers leave their fifth decade of life and push into their sixties. Both payers and laboratories know that, on average, an individual 65 years and older (i.e., a “Medicare” life) has more than four times the number of laboratory tests performed per year than a “commercial” life. Again, this increased utilization is a natural consequence of the aging process, and the system should ethically be prepared to provide these services as appropriate.

The ongoing addition of new diagnostic tests to the laboratory test catalog represents the final trend. As new diagnostic assays that support more precise and earlier diagnosis for an expanding number of diseases become available, physicians will naturally and appropriately order a higher volume of tests. As with the two previously discussed developments, this trend underpins higher diagnostic and treatment accuracy, which benefits the health care system by reducing the overall cost per episode of care.

In light of these events, fundamental questions that clinical laboratories should address include:

- Does the laboratory have the capacity and staffing to take on higher volumes?
- Has the laboratory invested in new technology to optimize on-site vs. referral testing and maintain high service levels and competitive cost?
- Is outreach infrastructure adequate to ensure the laboratory can service the regional community as will be required under future models?
- Is financial management capability sufficient to ensure the laboratory is viewed as a revenue center that produces a return to the organization?

The Pending Shortage of Clinical Laboratories’ Most Important Asset

All laboratory leaders now acknowledge the impending staff shortage. This looming change specifically affects three categories: laboratory technical staff (medical technologists and technicians), histology technical personnel, and laboratory management. Within the next five years, the initial wave of baby boomer retirements will have a significant impact. In anticipation of this deficit, laboratories have been following several courses of action, including:

- Automation of high-volume testing, even in smaller laboratories.
- Renovation of existing space to allow for the larger platforms required by automation.
- Process redesign to permit more work to be done in a layout conducive to optimizing staff efficiency.
- Referring out testing when the complexity warrants or when staff expertise and knowledge are not sufficient to perform the test in-house.

From a management standpoint, this critical issue is exacerbated by the younger generation of laboratorians’ diminished interest in assuming leadership roles. A focus on work-life balance is not always in sync with the demands of managing a section, division, or entire laboratory. As a result, the use of self-managed work teams will grow significantly as more retirements occur in the industry.

Management Expertise

Clinical laboratory management in hospitals and health systems is branching out beyond its historical role. In the past, technological and scientific knowledge were the primary prerequisites for selection for management positions. As a result, the industry has performed well relative to quality, service, and test menu growth. Business management responsibilities (revenue, expense, and non-technical process management) have been left lacking, however. This can be attributed to several reasons:

- It was “someone else’s job” to deal with the business elements.
- Health care leadership was more focused on delegating the management of technology and science—with which they were not comfortable—rather than business aspects to leaders most closely associated with given technical functions.
- Effective management of the business process had not been a part of the clinical laboratory teaching curriculum until the last 15 years.
- Accountability for business elements was never as high as accountability for quality and service.
- As scientists first, business applications were not of personal interest to laboratory managers, and they gravitated towards areas in which they were confident in their knowledge.
Whether one agrees or disagrees with the statements above, one fact remains clear: there is a projected shortage of the talent, knowledge, and expertise necessary to manage both the technical and business responsibilities of clinical laboratories in the future. If that is the case, what are the potential scenarios under which laboratories will be managed? Two possibilities are:

1. Acquisitions of laboratories by companies with the knowledge to manage will result in significant consolidation of the laboratory industry using a for-profit corporate model.
2. Regional laboratories controlled by hospitals or health systems will consolidate management in an effort to continue the not-for-profit model.

Because the focus of for-profit (revenue growth and earnings per share) and not-for-profit (mission and service) entities are so different, and because the majority of hospitals and health systems are non-profit, the second scenario is the most likely. However, that strategy will only succeed if not-for-profit hospitals and laboratories get better at managing the business aspects of the operation. For laboratorians, that means embracing a future in which operations are managed as a profit center by incorporating outreach services. In addition, past practices that viewed laboratory financial performance as inconsequential to overall performance must be replaced by processes that focus on every nickel of cost and revenue. Going forward, the mantra should be that laboratory services are mission-critical and a key element of the hospital’s financial success.

**Laboratory Industry Information Technology**

As most laboratorians and caregivers recognize, laboratory data and information are essential to the delivery of health care. Laboratory-generated data comprises more than 60 percent of electronic medical record (EMR) content but represents only two to four percent of the total cost of health care. The demand for care and continuity of medical information requires inpatient, outpatient, and outreach laboratory data to be provided via electronic connectivity in all delivery scenarios and markets. This will lead to an increase in requests for interfaces and connectivity.

A substantially higher number of requests for laboratory integration from physician office/clinic EMR systems will be the major IT challenge for laboratories. The federal government has set a goal to have 480,000 physicians using EMRs by 2015. This includes 360,000 physicians who did not use them as of 2010. As an incentive, physicians can receive up to $44,000 in additional reimbursement if they meet the requirements of “meaningful use” of an EMR.

The implementation of EMRs will affect regional laboratories in several ways:

- The sheer volume of requests for interfaces/integrations will require a significant increase in IT resources. Experts predict a doubling of the current number of requests in each of the next several years.
- Because each implementation requires both result transmission and order entry, these projects will be significantly more complex during the first phases. If they are not already doing so, laboratories may need to partner with a third-party connectivity software vendor to complete these projects.
- The competitive EMR environment includes many different vendor systems. While some of the vendors are familiar, many are not, and laboratories will be expected to interface with both established systems and new products.
• Laboratories will be called upon to help address some of the functionality (i.e., medical necessity checking) lacking in many first generation EMRs. The need for this information for billing purposes will drive these efforts.

• Laboratories will need to get involved as early as possible with the EMR selection/implementation process to facilitate timely integration and avoid suboptimal system selection.

In summary, successful regional laboratories will have to offer the necessary support to interface providers with the current LIS/HIS systems. This will be a competitive requirement, not an option. As indicated, the IT manpower required to keep up with demand is expected to increase in the future. The challenge for the laboratory will be that, although it provides much of the data and information that resides in the EMR, the resource allocated to laboratory needs is usually not sufficient to meet them on a timely basis. Laboratories must focus on creating internal IT expertise within their operations or convince IT leadership of the importance of prioritizing laboratory requirements. For those that wish to compete successfully in their regional markets, the days of claiming they cannot get the IT support they need must come to an end.

Impact of Diagnostic Technology

Innovation will be a key requirement for future success under health care reform, no matter how the final model is structured. Not only will new tests and methods for diagnosis and monitoring be required, clinical laboratories will be expected to reduce the cost of services while providing more complex testing for a larger patient population.

Molecular testing continues to evolve as a significant impetus for change in the laboratory industry. Since the mid-1980s, Roche’s PCR technology has dominated molecular testing. However, the genomic information gathered from the sequencing of the human genome and pathogenic organisms has led to new assays, techniques, and test services over the past few years, including bead arrays, electrochemical arrays, microarrays, SNP-it, WAVE, and others.

These new technologies have resulted in the commercialization of rapid, user-friendly, inexpensive, high-quality tests. Facilities that have not previously invested in molecular testing can now perform these procedures, which have been miniaturized and simplified for use in routine laboratories. Another driver for adaptation of these innovations is the ever-increasing demand for quicker turnaround times. The availability of bench-top technology will have to be balanced with the availability of staff to operate the equipment and produce test results.

Some of the more recent molecular testing trends include:

1. Multiplex testing, which is a group of related molecular tests that can be performed on one specimen. Examples include infectious disease or genetic multiplex test groups.

2. Integration of anatomic pathology molecular results into diagnostic reports containing both traditional anatomic pathology information and imaging studies performed on the same patient. These integrated reports will provide clinicians with a more complete view of the patient’s diagnosis as well as information about treatment options.

3. Pharmacogenetic and pharmacogenomic initiatives in which genetic characteristics are used to determine the effectiveness of certain drug therapies.
In order to remain competitive, regional laboratories will need to invest in new technologies as they emerge. Additionally, advising practitioners on the proper ordering of molecular tests will help control costs. In fact, managing test utilization will become a growing responsibility of laboratories—this is a function that most laboratories today do not perform. While a pathologist-led process may be most effective, most pathologists do not have the time to continuously monitor and direct the laboratory’s response to referral testing requests. Successful models have included medical technologists who can demonstrate rapport with medical staff and provide the conduit for referral test management. In any event, the combination of pathologist, PhD, and technologist will be essential to manage this ever-growing need and expense.

The increasing focus on community-based services will place laboratory outreach programs in a position of greater value. Having an adequate test menu that allows for local molecular and genetic testing will be essential. Some project that the national laboratories will focus only on reference testing as they recognize they cannot provide the community services required under a regional delivery of health care concept. Others believe that these companies will work to “buy their way” into outreach programs to remain an involved local provider.

Summary

Clinical laboratories in the U.S. are well-positioned to meet the short- and long-term needs of regional markets. They have demonstrated their ability to adapt to change and modify their methods of operation while delivering quality services. To meet the challenges of the future, however, resource and financial performance management in the industry must be improved. This can be accomplished by:

- Leveraging shrinking resources through the creation of collaborative activities to share knowledge, expertise, and opinions.
- Gaining the knowledge, expertise, and methodology to improve financial performance.
- Accepting the responsibility that the laboratory must be accountable for every aspect of its operation and not assuming that others control its ability to manage.

Collaboration is the key to fulfilling customer expectations and creating sustainable advantage. These concepts may seem mutually exclusive unless one clarifies the meaning of the latter. In this context, “sustainable advantage” refers to laboratories’ ability to provide service within their regions in support of hospital and medical staff and to the benefit of the population they serve. It allows laboratories to continue offering services within a stressed reimbursement environment because leadership can effectively manage the cost structure while generating additional revenue via outreach. Further, it facilitates communication with physicians and providers by permitting an efficient exchange of data and information, the vital products of the laboratory industry. In this sense, competitors are those who believe that moving control and responsibility for laboratory services to some structure outside of the region is the right strategy. This approach represents the true adversary to the future delivery of clinical laboratory services.

Cited Source