Clinical Chemistry 47:8
1526–1535 (2001)

Beckman Conference

The Total Laboratory Solution: A New Laboratory E-Business Model Based on a Vertical Laboratory Meta-Network

Bruce A. Friedman

Major forces are now reshaping all businesses on a global basis, including the healthcare and clinical laboratory industries. One of the major forces at work is information technology (IT), which now provides the opportunity to create a new economic and business model for the clinical laboratory industry based on the creation of an integrated vertical meta-network, referred to here as the "total laboratory solution" (TLS). Participants at the most basic level of such a network would include a hospital-based laboratory, a reference laboratory, a laboratory information system/application service provider/laboratory portal vendor, an in vitro diagnostic manufacturer, and a pharmaceutical/biotechnology manufacturer. It is suggested that each of these participants would add value to the network primarily in its area of core competency. Subvariants of such a network have evolved over recent years, but a TLS comprising all or most of these participants does not exist at this time. Although the TLS, enabled by IT and closely akin to the various e-businesses that are now taking shape, offers many advantages from a theoretical perspective over the current laboratory business model, its success will depend largely on (*a*) market forces, (*b*) how the collaborative networks are organized and managed, and (*c*) whether the network can offer healthcare organizations higher quality testing services at lower cost. If the concept is successful, new demands will be placed on hospital-based laboratory professionals to shift the range of professional services that they offer toward clinical consulting, integration of laboratory information from multiple sources, and laboratory information management. These information management and integration tasks can only increase in complexity in the future as new genomic and proteomics testing modalities are developed and come on-line in clinical laboratories.

One never notices what has been done; one can only see what remains to be done. — Marie Curie

Major forces are reshaping organizations throughout the world, and information technology (IT)[1] is one of the most important of these forces. The goals of this report are (*a*) to describe the ways in which IT, the Internet, and the Web are modifying the clinical laboratory industry and (*b*) to show how IT is enabling a new model for the laboratory industry based on a vertical laboratory meta-network, which will be referred to here as the "total laboratory solution" (TLS). Hybrids of the TLS have been in existence for years, but IT is now facilitating the emergence of a vertical laboratory meta-network with multiple participants, each contributing in its area of core competency, that will provide total support for both laboratory testing and laboratory information management for an entire hospital system.

To better understand the TLS, a precursor to it, referred to here as the virtual laboratory, will be described, accompanied by details about the general nature of virtual organizations and their relationship to IT. The organizations potentially included in the TLS will be then discussed, with a description of their core competencies and individual contributions to its success. Finally, factors that both support and work against the emergence and ultimate success of the TLS will be presented, allowing the reader to judge whether this hypothetical model for the total delivery of laboratory services can and will be successful.

Reinforcing the sense of the opening quotation to this

Department of Pathology and Clinical Support Information Systems, University of Michigan Medical School and Health System, 1301 Catherine Rd., Ann Arbor, MI 48109-0602. Fax 734-764-8333; e-mail bfriedma@umich.edu.
Received February 20, 2001; accepted April 30, 2001.

[1] Nonstandard abbreviations: IT, information technology; TLS, total laboratory solution; IVD, in vitro diagnostics; LIS, laboratory information system; ASP, application service provider; PC, personal computer; and HIPAA, Health Insurance Portability and Accountability Act.

Table 1. Major business organizational changes occurring during the last decade.

- Globalization of the world economy and integration of world capital markets, increasing competition
- Restructuring of companies through standardization, simplification, and refocusing of the mission
- Focus on core business skills and processes with outsourcing of noncore processes and procedures to outside organizations
- Increased deployment and reliance on IT, leading to transformation of all businesses
- Exponential growth of e-business and Internet-driven processes, leading to less profit from "information friction"

report, it is not the goal of this communication to criticize the past or current organization and delivery of clinical laboratory services. Rather, the intention is to explore what may yet be accomplished to improve clinical laboratory services using newly available IT tools. This discussion must also be set in the context of the new healthcare environment with its emerging and vibrant genomic and molecular diagnostic sectors, which will also radically alter the business of the clinical laboratory.

Forces Causing Changes in Global Business, Healthcare, and the Clinical Laboratory

Table 1 lists some of the major business organizational changes occurring during the last 5–10 years: globalization, restructuring, integration, outsourcing, IT, and e-business *(1)*. All of these terms and trends will be familiar to anyone with even a passing interest in the current business climate, and all of them need to be taken into consideration in any strategic planning process to understand the future and then plan for it. References to all of these forces will be woven into the subsequent discussion.

Healthcare has seen its own share of cataclysmic changes recently, not the least of which is managed care. Managed care, with its emphasis on cost containment and competition, has had a profound effect on the clinical laboratory industry, and no end to the effects of these changes is in sight *(2)*. Table 2 summarizes some of the most salient changes of managed care and the regulatory climate on the clinical laboratory industry, the special focus of this report. These changes have deeply affected hospital-based laboratories, reference laboratories, the in vitro diagnostics (IVD) industry, and laboratory information system (LIS) vendors alike. Many of the changes prompted by managed care are related to, or are the sequelae of, the major forces noted in Table 1. For example, the consolidation of health systems, reference laboratories, and IVD manufacturers is the result of the competition and restructuring that were the major driving forces behind the introduction of managed care. As an illustration of the consolidation that has occurred among the IVD manufacturers, approximately three-quarters of the global market for this business sector is now controlled by eight large companies: Roche Diagnostics, Abbott Laboratories, Johnson & Johnson, Bayer Diagnostics, Beckman Coulter, Dade Behring, Becton Dickinson, and bioMèrieux *(3)*.

The purpose of this discussion about the forces affecting global business, healthcare, and the clinical laboratory industry is to prepare the reader for the subsequent discussion that focuses on the current and potential effects of IT on the clinical laboratory industry. The fundamental argument advocated here is that IT and the new realities of the healthcare industry, such as consolidation and competition, will stimulate the emergence of a new business model for the delivery of clinical laboratory services based on the establishment of collaborative vertical laboratory meta-networks. A meta-network is a network of networks. An important underlying assumption to this argument is that the current laboratory business model, with its high degree of fragmentation, redundancy, and excess capacity, is no longer adequate for this IT-driven era. A second underlying assumption is that the emergence of the e-laboratory and the TLS is embedded in a larger trend of the evolution of various forms of e-health services *(4, 5)*.

Defining the Virtual Organization

The term "virtual" arose in the IT world to describe a computer feature, such as virtual memory, that appears to exist but does not. "Virtual reality" refers to a process that appears be real but is not because of the use of IT to mimic reality. By inference, a virtual organization is a network of multiple cooperating organizations that appear to be a single organizational entity but that are actually separate organizations. The cooperating organizations composing a virtual organization are often linked together by contractual arrangements specifying the various tasks and responsibilities of each party in the virtual organization.

Large automobile manufacturing companies fre-

Table 2. Changes in the clinical laboratory stimulated by managed care and new regulatory initiatives.

- Weakening and shifting of professional boundaries with increased emphasis on organizational, technical, and information integration
- Cost of laboratory testing continues to be a dominant issue, but quality and patient satisfaction are also emerging as critical value-added features
- Increased emphasis on outsourcing of testing with evolution of new relationships with reference laboratories and regional laboratory networks
- Decentralized laboratory operations, including point-of-care testing, requiring new managerial and technical skills in logistics, training, and informatics
- Major consolidation of commercial reference laboratories and the IVD industry

quently operate virtually in the sense that they seldom manufacture all of the various component parts of a finished automobile. In other words, they are no longer vertically integrated as in the past. The manufacturing of these component parts is outsourced to external firms that participate in the company's manufacturing network. Similarly, some clothing manufacturers also operate virtually in the sense that they may only design and distribute their garments, outsourcing the actual manufacturing of them to other firms. Such a strategy allows the enterprises to avoid the capital investment in bricks-and-mortar manufacturing plants. This notion that an e-business model can be the means for avoiding capital investment is important to the success of the TLS and will be discussed later

A virtual organization is one that is frequently decentralized, downsized, and networked in comparison with its former organizational structure, and has also forged external strategic alliances to better achieve its primary business objectives. In today's business climate, these are all considered desirable traits because they can lead to increased flexibility, efficiency, and profits. Healthcare organizations should strive to achieve similar goals. In healthcare, the term virtual organization usually is applied to a network of organizations that work cooperatively but have not merged their assets.

IT as the Glue Holding a Virtual Organization Together

It is no coincidence that the growth of interest in virtual organizations corresponds to the beginning of the IT era because sophisticated IT capabilities are the sine qua non of any virtual organization. Recall that the virtual organization is composed of separate organizations that agree to cooperate to achieve common business goals. Such cooperation and coordination cannot be achieved without efficient communication between the two organizations. The means for achieving such effective communication today is IT in all of its various forms. Think of fax, e-mail, and sophisticated telephone services, including mobile phones, for information exchange, and finally think of the Web for order fulfillment and the communication of details about a product to customers.

Although much attention has been paid to the business-to-customer aspect of e-business, the fasted growing components of e-business today are business-to-business applications and transactions. Business-to-business applications encompass all of the myriad processes by which two separate cooperating businesses conduct their necessary activities, from the exchange of design specifications, to parts ordering, to invoicing and bill payment. Before the advent of e-mail, fax, and Web-based ordering, such activities took days to weeks to complete rather than the current time requirement of minutes. Facilitating information exchange between two interoperating organizations reduces so-called "information friction" and thus the cost of doing business.

Most Clinical Laboratories Are Virtual Today

The flexibility of a virtual organization advantages is based in part on the fact that many of its critical business functions are outsourced to external business partners. Virtual companies purchase and coordinate much of their business through the marketplace, thus harnessing the power of market forces in ways that fully integrated companies cannot duplicate. This predisposition of the virtual organization to outsource many of its processes is the logical corollary of the belief that an organization cannot be skilled at all tasks and also that the virtual organization retains its flexibility and ability to adapt to changing circumstances in the external world by the use of outside contracted-for services. Recall the changes described in Tables 1 and 2 and the earlier discussion about them. Virtualness and outsourcing, enabled by IT, are important keys to success in today fast-moving business climate. The clinical laboratory of today, and tomorrow, is highly dependent on IT and uses it to differentiate its information product offerings. Table 3 lists some of the information-driven shifts of the laboratory of the future, and Table 4 provides arguments why IT is now the primary driver for the entire clinical laboratory industry.

This notion of outsourcing will not seem unusual to the seasoned laboratory professional because most hospital-based clinical laboratories have been outsourcing esoteric tests to regional and national reference laboratories for decades. Similarly, nearly all laboratories outsource the ongoing support for their LIS software to the vendor of their system. The incentive for clinical laboratories to outsource esoteric testing is obvious: the majority of clinical laboratories have neither the expertise nor sufficient test volume to justify the day-to-day performance of many esoteric tests. In fact, it is somewhat misleading to speak about the conversion of most hospital-based clinical laboratories to virtual organizations because such laboratories have been virtual for many years on the basis of

Table 3. Information-driven shifts of the clinical laboratory of the future.

- Technical and organizational integration of departmental laboratory processes and information management into larger organizations
- Evolution of the clinical laboratory into a digital/virtual organization designed to serve decentralized provider networks
- Evolution of LISs based on Web-based architecture and, potentially, the ASP model for computing support
- Enhancement of text-based laboratory reporting with Web-based, image-enhanced laboratory reports
- New emphasis on information needs of laboratory customers (both physicians and patients), stimulated by their increased IT sophistication and increased consumerism
- Increased surveillance of issues pertaining to security and confidentiality, driven by HIPAA and similar legislation

Table 4. Reasons that IT is now the primary driver for the entire clinical laboratory industry.

- Information creation increasingly commoditized on the routine testing side and challenging on the esoteric side
- Information management challenges can only accelerate as advances in genomics and proteomics generate ever more complex and abundant data
- The major professional challenges facing hospital-based laboratory professionals are now information accession, storage, reporting, and integration from multiple sources
- The solutions for these professional challenges will almost certainly come from the IT sector and not from the IVD industry
- IT solutions from the IVD industry players are usually designed to enhance the utility and quality of their own instruments and reagents rather than address information management challenges at the enterprise level

their relationship with commercial laboratories. In other words, most clinical laboratories are partly virtual today. The adoption of Web-based laboratory portals to support laboratory test ordering and result reporting (discussed later) combined with laboratory and hospital consolidation will be a stimulus for even more laboratory virtualness *(6, 7)*.

To the customers of the hospital-based virtual clinical laboratory, such as physicians and nurses, the range and extent of the virtualness of the clinical laboratory serving them, as demonstrated by the outsourcing of esoteric tests, usually is obscured by the fact that test requests for such tests continue to be submitted to the hospital laboratory and specimens are drawn by the laboratory phlebotomists. The results of the esoteric tests are then transmitted by the reference laboratory back to the submitting laboratory and frequently are integrated into the laboratory report. In other words, order entry and results reporting are supported by the on-site laboratory LIS. This is analogous to the use of outsourced component parts that are integrated into an automobile with some well-known nameplate affixed to the front of the vehicle.

The Value of an Outsourcing Strategy for a Clinical Laboratory

The outsourcing strategy pursued by a clinical laboratory with regard to esoteric testing parallels that used in other organizations with various degrees of virtualness. The incentive to outsource any particular activity or process within an organization usually derives from the conclusion that the particular activity or process could be performed better, and frequently at lower cost, by the organization to which it is outsourced. In other words, the external organization has a higher level of expertise, is more efficient, or can take advantage of greater economies of scale for the outsourced task or service. The decision by an organization such as a hospital clinical laboratory to outsource part of its testing is thus based on an analysis of which of its various activities are strategic or core for the laboratory and which are not. Strategic in this context means critical to the long-term growth, planning, and productivity of the organization. An organization does not usually choose to outsource strategic activities because, in so doing, it incurs the risk that the organization will lose its ability to perform these mission-critical tasks.

Although noncore competencies frequently are the primary targets for outsourcing options within virtual laboratories, this shifting of work from inside a laboratory to an outside source, even when clearly it saves money or adds quality, should not be viewed as a "free lunch". There is always a cost that accrues to an organization when it outsources a task that is incremental to the pure cost paid for the outsourced good or service. To be more specific, the cost of any outsourcing is the time and energy expended by the virtual organization in managing the outsourced relationships and in controlling the quality of the incoming product or data and other necessary tasks such as data normalizing.

One of the reasons that some virtual organizations operate with such a relatively small cadre of personnel is that the list of activities that they consider strategic may be relatively small and other activities can be safely outsourced. This point calls into question whether it would be possible for a clinical laboratory within a hospital to perform no testing whatsoever, or perhaps only a small menu of immediate response testing, reserving for itself strategic activities such as providing clinical consultations to its physician customers, managing its outsourced relationships and contracts, marketing, quality control, and strategic planning. This question is largely rhetorical in the context of this report, where the strategic roles of the hospital laboratory are defined as specifically these functions—the answer is most emphatically yes. This assumes that that the cost and quality implications of outsourcing specimens are understood and can be managed.

Defining the Unique Core Competencies of the Hospital Clinical Laboratory

The unique core competencies of hospital-based laboratory personnel include, first and foremost, their ability and opportunity to develop ongoing professional relationships with the clinicians ordering tests and to serve as consultants to this group for test ordering and interpretation. This is based on their proximity and relationship with the hospital-affiliated physicians and also their knowledge of hospital processes and procedures *(8)*. By and large, other participants in the laboratory industry, such as regional reference laboratory personnel, do not share this competency.

A second core competency is the ability and opportunity to manage and integrate laboratory information derived from multiple sources flowing into the hospital. It would be difficult for external parties to develop this competency. Friedman and Mitchell *(9)* emphasized this same theme in 1992 by stating: "Because there has been little opportunity or need until relatively recently for laboratory professionals to actively manage information. . . , it is not surprising that [their] scope must now be modified in response to the new information realities and environment. The generation of information within laboratories should be considered the beginning—not the end—of the professional responsibility of laboratory professionals".

A third core competency of hospital-based laboratory personnel involves the proper collection, transport, processing, and storage of specimens before testing, the so-called preanalytic phase of testing. An argument might be made that these tasks are not unique because similar activities are engaged in routinely by reference laboratory personnel and physician office support staff. What is daunting about these specific tasks in the context of laboratory operations in complex hospital and healthcare delivery setting is their parallel integration with other complex tasks that are occurring simultaneously without undue stress and disruption of routines. This knowledge would be difficult to obtain on an outsourced basis.

Hospital-based laboratory professionals, even at the expense of performing fewer tests in house, should optimize their relationships with clinicians ordering tests and carve out a larger role in on-site information and disease management. Clinicians will inevitably need more assistance in the interpretation of test results as testing becomes more complex and genomic and proteomics testing become the norm for many hospital patients *(10)*. Failure to do so may provide commercial reference laboratories, which may already have a price advantage or a quality advantage over hospital-based laboratories because of economies of scale and expertise of personnel, the opportunity to develop their own electronic consulting relationship with hospital-based and affiliated office-based physicians. This could further marginalize the perceived added value of hospital-based laboratory professionals. No professional group in healthcare should assume that they have a perpetual franchise to some particular set of activities. Professional boundaries today are in a constant state of flux in many areas.

It could be hypothesized that the majority of the tests currently performed in most hospital laboratories can be outsourced from hospital laboratories and performed in regional reference laboratories. However, some relatively high percentage of commonly ordered tests will continue to be performed on site, either in the central laboratory or as point-of-care testing, because of the need for rapid turnaround time and low cost per test. One of the justifications for such an outsourcing strategy should be that hospital laboratory personnel will then divert their professional attention toward consulting with hospital physicians, managing/integrating information flowing into the hospital from multiple sources, and also managing the outsourced relationships with external reference laboratories that will be necessary to provide a full range of laboratory tests. Such a redirection of professional talent on the part of laboratory professionals will be a formidable challenge because of the fear of "letting go" of current competencies.

E-Business and Its Relationship to the Virtual Laboratory

Simply put, an e-business is an enterprise that has transformed its key business processes using Internet/Web technologies and standards. There is a spectrum of involvement with the Internet and the Web for any business. Some businesses have little or no dependence on the Internet and the Web and are often referred to as "bricks-and-mortar" business, whereas some business are totally dependent on the Internet and Web and are referred to as "dot-coms". Hybrid businesses have evolved and are referred to as "clicks-and-mortar" businesses, particularly in the area of retailing.

To conceptualize the operations of a typical e-laboratory, imagine a continuum of laboratories. At one end of the continuum would be a laboratory that performs all testing in house and supports all of its own electronic transactions with an on-site LIS. This would be an example of a laboratory that utilizes IT but does not use the Internet to support its business processes. Midway along the continuum would be a laboratory that performs some tests, outsources some to a reference laboratory, and perhaps is experimenting with the use of a Web-based laboratory portal whereby physicians in their offices equipped with a personal computer (PC) and a browser could order tests, review test results, and acquire information (i.e., content) about individual tests; this is an example of an early "Internet-powered" laboratory and is where many organizations exist today *(11–17)*.

At the far end of the spectrum is a laboratory that has evolved nearly completely into an e-business/e-laboratory. Such a laboratory exists only in the imagination today and would support key transactions, such as test ordering and result reporting, using a remote laboratory portal or laboratory portal software running on a local server; would run its LIS applications remotely using an application service provider (ASP) model; would outsource the majority of its test menu to an external reference laboratory; and would collaborate with a networked set of exemplary partners to deliver a full range of laboratory services, including comprehensive consultative support to clinicians. Because it is difficult to outsource preanalytic steps and because they are critical to the quality of test results downstream, it is likely that such an e-laboratory would continue to collect, transport, process, and store specimens rather than outsource such activities. Additional explanatory information about laboratory portals and the ASP model is now provided.

Traditional LIS Architecture Becomes Web-ized with a Browser and Laboratory Portal

The traditional LIS consists of a hardware platform located in the laboratory, or frequently in the hospital machine room, running software leased from an LIS vendor. Access to the system is provided by PCs located in the hospital or remote clinic sites. Order entry and result reporting is managed by the LIS or, in many health system settings, by a central information system with an interface to the LIS. The LIS and its associated database are generally considered the "source of truth" with regard to laboratory data within the health system, with the test results from the LIS copied to the central data repository or to the electronic medical record.

It has frequently been observed that IT destroys time and distance. The Internet provides the opportunity to separate some or all of the components of the LIS from the integrated on-site LIS architecture just described and the ability to manage them at some distance from the hospital physical plant. For example, the order-entry and result-reporting transactions supported by the LIS can be Web-ized, that is, executed within the hospital or from doctors' offices using a browser running on a PC, sometimes known as a "thin client". This is in contrast to the situation that prevails today whereby orders are placed on a "thick client", which is a PC fully loaded with a suite of applications. The appeal of the thin client rather than the thick client as a front end to the LIS is that the hospital is relieved of the cost burden and complexity of maintaining numerous PCs, at least to provide laboratory-oriented transactions. Browser access to a LIS and its functionality is an increasingly common feature provided by many LIS vendors.

Another means for achieving order entry and result reporting on the Web is by the use of a so-called laboratory portal as a gateway to the hospital LIS. A laboratory portal is a Web site, most frequently provided by a dot-com that provides these same transactions at a Web site, often accompanied by other value-added features and with laboratory "content" wrapped around these transactions. Such a laboratory portal, a specialized variant of an e-health portal, needs to be supported by a two-way interface to LISs to transmit the test orders to the clinical laboratory and receive the test results back from the laboratory and via the LIS for access via the laboratory portal. Laboratory portal software can also be leased by a laboratory from its LIS vendor or from a specialized laboratory portal dot-com to the hospital laboratory or health system to which the laboratory is organizationally related.

Moving All LIS Functionality Off Site with the ASP Model

The ASP model of laboratory computing, simply put, consists of moving most or all LIS functionality to a site remote from the hospital, the usual location for the LIS hardware. Laboratory clients and laboratory technical personnel alike access the remote LIS/ASP for transactions and for system maintenance via the Internet. Although multiple variations on this ASP theme are emerging, under one ASP option the laboratory database is maintained remotely in a secure fashion by the vendor of the ASP services. At the risk of sowing more confusion into this discussion but to emphasize the potential for outsourcing in this new Internet-mediated environment, LIS vendors themselves frequently outsource the maintenance of the ASP hardware platform and its associated operating system to yet another firm that specializes in the development and maintenance of server farms across the country. The LIS vendor is then allowed to pursue its core competency, the development and provision of LIS software.

Although the development and offering of ASP services to hospital laboratories are only in their early stages, several distinct advantages are emerging in connection with this new model for laboratory computing. For example, cost advantages are becoming apparent because the vendor can run several "instances" of the LIS software for multiple remote customers on a single server, thus optimizing the use of the hardware platform. Fewer laboratory-based personnel are required to maintain the system, and their job responsibility is confined to tasks such as the maintenance of computer tables that are unique to the particular site and to training for the system. There is also a major advantage for the laboratory and hospital in terms of disaster recovery for the system that runs remotely from the hospital and has extensive hardware redundancy engineered into it. Finally, the architecture of LIS/ASP is generally designed to permit substantial growth of testing activity as well as data archiving. For example, if additional back-end storage capacity is required, this can be accomplished with very short notice because server-farms used by the LIS/ASPs are prepared for such contingencies.

At this time, it is uncertain whether the total ASP model as it applies to LISs and other healthcare applications will be successful. A laboratory portal can be considered as a truncated ASP/LIS with only the order-entry and result-reporting functionality transferring to the Web. The most uncertain aspect of this outsourcing approach to laboratory computing currently derives from the fact that the business model for the ASP/LIS vendors is ambiguous. In other words, the vendors are groping for an effective and acceptable means for charging the laboratory customer for the LIS services that they are offering. Another dilemma for the LIS vendors is that the switching costs for LIS services are lower for the ASP model than for the traditional LIS computing model. Stay tuned for further developments in this area. The ASP may be yet another example of "Internet spawn" with a very short half-life.

The Virtual Database and Its Relationship to the TLS

One more technical concept needs to be presented at this point, the virtual database. In the same way that a virtual organization or virtual laboratory does not physically exist, it is also possible to develop a virtual laboratory database that does not exist in a physical sense but actually consists of a series of physically separate, but linked, databases that operate as a single logical laboratory database. In the case of interoperability of the participating parties in a TLS, for example, it would be possible for a reference laboratory serving a hospital and participating in the vertical meta-network to both perform esoteric testing for the hospital and to store the test results generated as a result of that testing in the reference laboratory's own LIS database.

The clinical data repository or the electronic medical record of the client hospital would maintain pointers to the test results maintained in the reference laboratory database, and test results could be retrieved by hospital personnel whenever needed. Such an approach avoids the need to replicate the test results generated in the reference laboratory to multiple information systems as well as the need to synchronize multiple clinical databases when any one of them is updated with new information. The concept of the virtual database may actually cause more problems than it solves, however. For example, as the patient ages, changes names, moves around the country, and changes providers, it is not clear who would be responsible for updating the linkages to the disparate data islands pertaining to that patient and addressing post-Health Insurance Portability and Accountability Act (HIPAA) privacy issues when the data are accessed.

An interesting aspect of this idea of a virtual database is that it changes the role of the reference laboratory from that of solely the creator of test information to that of the provider of a broader suite of services, such as the long-term storage and access of test results. Such an approach would also provide the reference laboratory with the opportunity to offer additional value-added services to hospital clients, such as decision-support systems to assist laboratory professionals and clinicians in the interpretation of complex test results. Such decision-support systems will generally be supplemental to those directly associated with the electronic medical record. Needless to say, the creation of virtual clinical databases in support of hospital laboratories raises a host of complex issues, not the least of which is the need to acquire totally accurate and reliable patient demographic information that will allow merging of longitudinal test results for the same patient generated in multiple laboratories. In the absence of any reasonable hope of creating a unique patient identifier in the United States because of civil libertarian concerns, only a major breakthrough in the use of a unique patient biometric such as a fingerprint or iris scan will solve the data-merging conundrum. However, this approach may also vex the civil libertarian community.

The foregoing discussion about the Web-enhanced LIS, laboratory portals, the ASP model, and the virtual laboratory database has been introduced as a prelude to the discussion of the major theme of this article—the TLS—because it underscores several major themes of this report: (*a*) that the Web and the Internet are revolutionizing laboratory computing; (*b*) that test performance can be outsourced by hospital laboratories to external reference laboratories when such testing is deemed nonstrategic; (*c*) because IT destroys time and distance, remote applications and services can now be outsourced and seamlessly integrated into routine hospital laboratory operations; and (*d*) the outsourcing of certain functions and tasks by hospital laboratories frees up time for their personnel to pursue those activities best accomplished on site, such as training on the system, and also allows laboratory personnel the time and opportunity to cultivate supportive consulting relationships with hospital personnel and physician customers of the hospital laboratory.

IT as the Prime Enabler of the TLS

As was mentioned previously, IT is the "glue" that holds the virtual organization together. Similarly, IT is also the primary enabler for the emergence of the TLS at this time. In the context of the activities of the clinical laboratory, IT has the ability to compress the time and distance that separate patients and physicians from the laboratory and the interoperating businesses participating in the TLS. The clinical laboratory is predominantly in the business of moving information from place to place, notwithstanding the daunting challenge of specimen transportation. This helps to explain the question of "Why now?" in relation to the emergence of the TLS, that is, why is the time now ripe for the emergence of the full-featured TLS when variants of this approach have tended to be unsuccessful in the past? The answer is that the IT infrastructure, including abundant bandwidth, the Internet, and the Web, has not previously been in place to move information around the globe seamlessly and therefore facilitate the development of networked organizations designed to inexpensively and efficiently move information across distances. This is not to say, however, that the application layer and functions such as global specimen tracking are robust enough at the present time to support the fully featured TLS.

Take the simple example of test order entry and result reporting to reinforce this "Why now?" argument. Until fairly recently, test order entry was carried out exclusively using hard-copy requisitions. Even now at a time when test orders and result reporting can be executed electronically, successful order-entry/result-reporting projects are commonly the result of laborious work effort and LIS interface development to a hospital's central computer system. Moreover, such order-entry/result-reporting functionality is usually not widely available and often is confined to the hospital domain or some selected set of remote doctors' offices. With the aid of a laboratory portal, discussed earlier, and an interface to a hospital-based LIS, a test can be ordered from any physician office in the world and the results from that test can be rapidly disseminated back to that office by the same laboratory portal at minimal cost. Moreover, interpretive information (i.e., content) about that test can be "wrapped around" the order-entry and result-reporting transactions available on the same laboratory portal to encourage appropriate test-ordering behavior.

Table 5. Participants in the TLS with their core competencies.

Participants in the TLS	Core competencies
Hospital-based laboratory	Managing and integrating information; consulting with hospital clinicians
Reference laboratory	Performing routine and esoteric tests
LIS/ASP/laboratory portal vendor	Automated information management systems with increased emphasis on Web technology
IVD manufacturer	Providing analytic instruments, reagents, and total laboratory automation solutions
Pharmaceutical/biotechnology manufacturer	Development of pharmacogenomic and proteomic tests; drug discovery and manufacturing

Major Participants in the TLS and Their Subvariants

The TLS that is being proposed here as an exemplar for the delivery of laboratory services for a healthcare delivery system, as mentioned previously, consists of a network comprising multiple participants, each working in one or more core competency areas. Friedman and Mitchell *(18)* first proposed the creation of what they called a value-added regional laboratory network 7 years ago in a discussion of the integration of information from decentralized laboratory testing sites. Their concept, similar to the TLS being advocated here, was proposed as a voluntary network of hospital laboratories, reference laboratories, and hospital chains. In this earlier incarnation of the TLS, the authors emphasized data integration rather than the virtual organizational structure proposed here. They predicted the following at that time: "The partition of information along hospital geopolitical boundaries will appear archaic and will be replaced by an emphasis on local and regional integration of medical information . . . . ". Since that time, of course, health systems and regional laboratory networks have become commonplace in the healthcare industry, many of which use IT to achieve their business goals *(19)*.

Table 5 is a list of the potential participants in the TLS accompanied by the perceived core competency of each participant. Participants at the most basic level include a hospital-based laboratory, a reference laboratory, an LIS/ASP/laboratory portal vendor, an IVD manufacturer, and a pharmaceutical/biotechnology manufacturer. It must be emphasized that the TLS may consist of fewer participants if a single player assumes more than one major function (i.e., core competency) within the network. One of the arguments in favor or the emergence of the TLS model in some form is that subvariants of it have existed for many years and will be familiar to the reader. Subvariants in this context should be taken to mean a form of the TLS in which one of the participants listed in Table 5 assumes more than one of the core competencies listed.

Some examples of such subvariants, both currently operating and from the past, include hospital-based laboratories that have developed an outreach program for reference laboratory work, regional laboratory networks that have been organized to triage (and thus retain) specimens among the members of the network, and pharmaceutical manufacturers that have developed or purchased reference laboratories. Prime examples of a TLS subvariant, of course, have been commercial reference laboratories that have developed interface solutions for their hospital client LISs as an incentive for hospitals to outsource their esoteric testing to the reference laboratory. Such interfaces, managing both order entry to the reference laboratory and the return reporting loop, eliminate the need for data-entry clerical functions within the hospital laboratory.

Factors for and against the Success of the TLS

Tables 6 and 7 list factors that will work against the emergence and success of the TLS, fully formed or as subvariants, and, contrariwise, factors that contribute to the success of these laboratory networks. The reader can review these points and decide on which side the stronger arguments reside. From a theoretical perspective, the proposed model certainly has some appeal. However, a key question to ask is whether a compelling business case can be made for the emergence of fully formed laboratory meta-networks, particularly if they develop as voluntary coalitions, as well as which player or players would take the initiative and financial risk to help create such networks.

In the final analysis, the success or failure of the e-laboratory and the TLS, which is a vertical network of collaborating e-enabled businesses, will hinge on the merits of the e-business concept itself. In characterizing

Table 6. Major factors working against the success of the TLS.

- Clinicians do not value consultations from laboratory professionals, and it is frequently difficult to charge third-party payers for such services
- Laboratory professionals will be reluctant to outsource the bulk of their testing because such activity provides satisfaction and helps to define their current role
- Collaborative laboratory meta-networks will never be created or maintained because of competitive pressures among players vying for advantage and profits
- Models similar to the TLS with all laboratory testing from a hospital outsourced to a reference laboratory have been tried before and failed for various reasons
- Success of the TLS is too dependent on information technology solutions that are currently immature or unavailable in the market

Table 7. Factors that will increase the chance of success of the TLS.

- Hospital laboratory professionals, invigorated by the enhanced challenges of the TLS and their enhanced roles, will become more effective and efficient
- The professional status of hospital laboratory professionals is becoming increasingly marginalized so that radical changes in roles and responsibilities are required
- The clinical laboratory industry should emulate the trend in other industries toward outsourcing, emphasis on core competencies, and brand protection. The TLS would be able to mobilize more capital investment for hospital laboratories that their cash-starved parent health systems are unable to provide
- Hospital laboratory professionals can best capture the "after-purpose" value of the laboratory database by partnering with others such as the pharmaceutical industry
- The TLS approach could provide incentives to reduce unnecessary testing and reallocate resources into newly developed genomic and proteomics testing

the transformation and environment that is now occurring toward e-business, Means and Schneider *(1)* noted the following with regard to e-business: "Competition will be characterized by the emergence of brand-owning companies that devote their energies to meeting customer requirements and driving product innovation. They will be allied with companies that focus on key parts of the supply and demand chain. Efficient supply chains will support deeper levels of customer satisfaction while demand chain activities will also increase customer satisfaction through e-supported customer relationship management".

The TLS model advocated here aligns well with this view of Means and Schneider *(1)* about e-businesses. As participants in the proposed TLS, hospital-based laboratory personnel can devote the bulk of their energies to supporting the brand of the regional health system for which they work by increasing customer satisfaction, with customers defined as both the physicians ordering the tests and the patients. Laboratory personnel can foster appropriate test-ordering behavior on the part of their customers through their consultative relationships with them. They can participate in new test development through their network supply chain by communicating with their TLS partners about how hospital test offerings can be improved. They can participate in the field evaluations of new analytic devices and reagents in the hospital laboratory environment. Various other necessary and desirable services can be outsourced up the TLS supply chain, thereby stimulating the network partners to make physical and working capital investments that the frequently cash-starved health system may be unable to make.

The IVD Industry and the TLS

The roles, current and potential, of the IVD industry within the proposed TLS remain difficult to predict at this time. At first glance, one might logically assume that this segment of the clinical laboratory industry would be eminently suited to play a major role in the development and evolution of the TLS model. The companies in this sector are well funded, aggressive, and technically adroit. They have an obvious stake in increasing the success of clinical laboratory testing at the patient and physician level. Many of them have also made substantial investments recently in Web development. Some have also appointed e-business executives with the goal of developing a strategy in this arena. However, many of these e-business initiatives have placed emphasis on back-end supply-chain reengineering, which would generally be transparent to hospital laboratory personnel who would be operating downstream rather than upstream from the companies.

These facts notwithstanding, it is difficult to develop a scenario whereby an IVD industry player would function as the prime mover or initiator of a TLS network with a health system, as described here. Part of the difficulty in imagining such a scenario is based on the fact that IVD companies tend to be focused largely on the development and marketing of their own analyzers and reagents and not on information management at the enterprise or interenterprise level, which would be one of the most important business objectives of the TLS. In other words, they tend to focus on how information is managed by and among their own analyzers and the interoperability of these devices, but they do not dwell on how information moves among and across the various heterogeneous nodes within a total laboratory and healthcare delivery system.

This is not to say that the IVD industry would not potentially have a major stake in participating in TLS networks if they emerge, but their stake would seem to revolve around the opportunity for research and innovation at the hospital or physician office level that would be a major benefit of such participation. A large health system would be ideal for testing new equipment and test methodologies. Moreover, LIS databases are resources that have never been adequately exploited for clinical research; rather they have generally been assigned the more mundane task of storing and retrieving tests results for individual patients. The opportunity now presents itself, through a coalition of more research-driven partners within TLS coalitions, to make better use of this valuable database resource, particularly if linked to companion clinical information and demographic information stored in other allied healthcare systems. Needless to say, HIPAA privacy regulations, scheduled to take effect in 2 years and with their restrictions on the use of protected health information for research, may dampen the enthusiasm for such uses of the laboratory database.

The Pharmaceutical Industry as the Wild Card in the Evolution of the TLS

Regarding the evolution of the TLS and participation of the various participants in a prototypical network, a large pharmaceutical company, particularly one that is also closely aligned with an IVD manufacturer, must be considered a major wild card in the sense that it might well play some type of important role, but what that role would be is not clear at this time. Genomics and proteomics are ushering in a new era of drug discovery. A new term, "theranostics", has been coined to refer to laboratory tests that help direct therapeutic interventions by providing feedback on the biologic effects of a drug *(20)*. New drugs are coming to market that require laboratory testing before they are administered to determine whether an intended patient is a suitable candidate for the drug. This drug gatekeeper function will provide a challenge to the pharmaceutical industry. Will it elect to reserve this testing function for itself or would the task fall to some more neutral broker without a direct financial stake in the sales of the drug in question, such as a hospital-based laboratory or reference laboratory? If a pharmaceutical manufacturer is a participant in a TLS network, it could potentially have a hospital or reference laboratory collaborator willing and able to perform such drug gatekeeper functions.

In conclusion, the TLS model presented here would necessitate a radical restructuring of the extant clinical laboratory business or clinical model that has evolved over many years and that has served the healthcare industry admirably over that period of time. The most likely way for a fully featured TLS to emerge would be through coalescence of one or more of the current subvariants. For example, a regional laboratory network that has already partnered with a reference laboratory could then align with a "pure" LIS vendor or a vendor with a larger suite of healthcare software and subsequently an IVD or pharmaceutical partner. Another scenario would be that a major LIS vendor could be purchased by a IVD or pharmaceutical manufacturer, with the LIS vendor's hospital partners then being brought into the evolving network. In the final analysis, of course, the success of the TLS will hinge on the extent to which it truly provides a better solution for healthcare providers. Such events are difficult to forecast given the rapidly changing IT market and the manner in which the Web and e-businesses are changing the healthcare landscape. The ideas and TLS proposal discussed here will hopefully stimulate discussion about the ways in which the clinical laboratory industry needs to adapt to these rapidly changing conditions. Finally, the indulgence of readers is requested in the use of the word "total" in TLS in that its use may appear to be overblown and immodest. Its use should be taken to refer to the inherent potential of the proposed meta-network to cover the entire gamut of testing services for an integrated delivery network rather than the demonstrated performance of such a coalition.

Dr. Friedman is on the Scientific Advisory Board of a laboratory portal vendor, LabDat Inc.

References

1. Means G, Schneider D. Meta-capitalism. The e-business revolution and the design of 21st-century companies and markets. New York: John Wiley and Sons, 2000:XVI.
2. Friedman BA. The challenge of managing laboratory information in a managed care environment [Review]. Am J Clin Pathol 1996; 105(Suppl 1):S3–9.
3. Halasey S. Niches in the global marketplace. IVD Technol 2000; Sep:8.
4. Licking E. Curing an industry's ills. Business Week:Ebiz 2000;11: 61–4.
5. Frank SR. Digital health care—the convergence of health care and the Internet. J Ambulatory Care Manage 2000;23:8–17.
6. Friedman BA. Integrating laboratory processes into clinical processes, Web-based laboratory reporting, and the emergence of the virtual clinical laboratory. Clin Lab Manage Rev 1998;12: 333–8.
7. Steiner JW. The virtual laboratory: regional clinical diagnostics for integrated delivery systems. Healthc Financ Manage 1997;51: 40,42–4.
8. Laposata M. What many of us are doing or should be doing in clinical pathology: a list of the activities of the pathologist in the clinical laboratory. Am J Clin Pathol 1996;106:571–3.
9. Friedman BA, Mitchell W. The deployment of information technology in the clinical laboratories and its impact on professional roles. Clin Lab Manage Rev 1992;6:87–93.
10. Nakamura RM. Technology that will initiate future revolutionary changes in healthcare and the clinical laboratory. J Clin Lab Anal 1999;13:49–52.
11. Todebush C. The Internet-linked laboratory: fundamentally changing the delivery of laboratory information and results. Am Clin Lab 1999;18:10.
12. Klatt EC. Open your laboratory to the Internet. MLO Med Lab Obs 1997;29:28–32.
13. Braley G. Spotlight on laboratory information systems. The emergence of the Internet. Healthc Inform 1997;14:59–60,62–74.
14. Chou D. Internet: road to heaven or hell for the clinical laboratory? Clin Chem 1996;42:827–30.
15. Hahn AW, Leon MA, Klein-Leon S, Allen GK, Boon GD, Patrick TB, et al. Delivery of laboratory data with World Wide Web technology. Biomed Sci Instrum 1997;33:252–6.
16. Gales K, Reyes R Jr. Cyberspace: an uncertain domain for clinical labs. Healthc Inform 2000;17:135–6,138.
17. Uehling M. Net gain: moving labs to the Web. CAP Today 2000; 14:1,7,11 passim.
18. Friedman BA, Mitchell W. Integrating information from decentralized laboratory testing sites: the creation of a value-added network. Am J Clin Pathol 1993;99:637–42.
19. Workman RD, Lewis MJ, Hill BT. Enhancing the financial performance of a health system laboratory network using an information system. Am J Clin Pathol 2000;114:9–15.
20. Place J. The coming of age of in vitro testing. IVD Technol 2000;Sep:22.