Laboratory Medicine: Challenges and Opportunities

Technologic innovations have substantially improved the productivity of clinical laboratories, but the services provided by clinical laboratories are increasingly becoming commoditized. We reflect on how current developments may affect the future of laboratory medicine and how to deal with these changes. We argue that to be prepared for the future, clinical laboratories should enhance efficiency and reduce costs by forming alliances and networks; consolidating, integrating, or outsourcing; and more importantly, create additional value by providing knowledge services related to in vitro diagnostics.

During the last decade, business has undergone fundamental changes (1) as the world economy has become more global and competition has grown. Reliance on information technology has increased along with exponential growth of internet-driven processes. The knowledge economy, described by Cooke as “knowledge working on knowledge to create value” (2), has become a key economic driver (3) and is critical for global competitiveness. Laboratory medicine, the medical specialty that deals with testing of specimens from patients and consulting with physicians who order the tests, has undergone major transformations during the last decade (4). Ongoing technological developments have considerably improved the productivity of clinical laboratories. Information on laboratory services is globally available, and clinical laboratories worldwide face international competition and a huge pressure to reduce costs. Clinical laboratory services have been increasingly commoditized. Moreover, there is a gap between what is technically possible on the one hand and the available financial resources on the other.

In this report we reflect on how current and anticipated developments may affect the future of laboratory medicine and how one can deal with these changes. We propose that the clinical laboratory industry should imitate the trend in other industries toward networks, consolidation, integration, outsourcing, and emphasis on core competencies and, more importantly, create additional value by providing knowledge services related to in vitro diagnostic services.

TOWARD A NEW BUSINESS MODEL FOR THE OPERATIONAL ORGANIZATION OF CLINICAL LABORATORY SERVICES: CONSOLIDATION, INTEGRATION, NETWORKS, AND VIRTUAL LABORATORIES

In most European countries, the current laboratory business model suffers from fragmentation, redundancy, and excess capacity. Such a model has competitive disadvantages and is no longer adequate in the new reality of cost containment and competition. Therefore, business models that increase efficiency, such as horizontal and/or vertical integration, have been suggested (5). Friedman (6) proposed a business model for clinical laboratories that is based on establishment of collaborative laboratory (meta) networks for the delivery of clinical laboratory services. Laboratories should cooperate, consolidate, and/or form strategic alliances to enhance efficiency and reduce costs. The advances in information technology and Internet applications allow for efficient communication between collaborating laboratories (6). Standards for electronic communication are available (7). Friedman (6) states that “virtualness and outsourcing, enabled by IT [information technology], are important keys to success in today’s fast-moving business climate”. Many laboratories already outsource esoteric tests to other (reference) laboratories, but outsourcing should also be considered for nonesoteric tests (6). The motivation to outsource should be that a specific test can be done better, more often, and at a lower cost in an external organization. In other words, the external organization has a higher level of expertise, is more efficient, and can take advantage of greater economies of scale (6). Consolidation and integration (e.g., in networks) of laboratory services has a number of benefits. Excess capacity, fragmentation, and redundancy are decreased, and the exploitation of process expertise knowledge is facilitated. In addition, existing fixed costs of plants and equipment are spread over a larger base. Higher analysis volume lowers the unit cost and speeds up the diffusion of (expensive) state-of-the-art technology. Finally, the turn-around time improves, allowing more rapid diagnosis. Cost and quality should improve, as efficiency is boosted (8).

Friedman (6) proposed a total laboratory solution that consists not only of a horizontal network but also of a vertical (meta)network. Variants of a total laboratory system already exist, especially in the United States. Many hospital-based laboratories have developed outreach programs for reference laboratory work to maintain profitability in the face of competition. For example, Jersey Shore University Medical Center (NJ) provides services for outpatients, physician offices, nursing homes, assisted living facilities, and managed care organizations (9). At the University of Utah Health Center, ARUP (Associated Regional and University Pathologists, Inc.) was formed in 1984 as a for-profit organization that performs outreach testing (10). The Mayo Clinic developed a community outreach program 35 years ago (11). By implementing a centralized core laboratory, the North Shore–Long Island Health System (NY) established a regional laboratory network and reduced overall laboratory costs while improving overall laboratory efficiency at all of its 13 network hospitals (12). Laboratory Corporation of America has a network of more than 20 clinical laboratories and...
approximately 900 patient service centers across the United States (13). The organization has a Center for Esoteric Testing where rare analyses are centralized for the network (13).

FOCUSBNG ON NEW CORE COMPETENCIES OF A CLINICAL PATHOLOGIST

Extreme levels of outsourcing lead to a virtual organization, in which the primary function is to coordinate the activities of the suppliers (14). The risk is that a virtual organization may degenerate into a “hollow organization” that cannot adapt to changing circumstances (14,15). Prahalad and Hamel (16) argue that if core competences are embodied in core products, then the more these products are outsourced, the greater is the potential for erosion of core competences. Thus, if laboratory professionals merely focus on analytical aspects, then their professional status will become marginalized if tests are outsourced.

Currently clinical pathologists focus mainly on analytical, technical, organizational, and managerial aspects and to a lesser extent on clinical aspects. Test selection and interpretation of results remain very much the domain of the clinician (17). To be prepared for the future, clinical pathologists should redirect their thinking and engage in clinical value innovation. Perhaps a new core competency of a clinical pathologist should be to improve patient care by providing complementary knowledge service related to diagnostic testing (18). Porter and Omsted Teisberg have argued that “providers of healthcare should develop clear strategies around unique expertise and tailored facilities in those areas where they can become distinctive” (8). In clinical laboratory medicine, the analysis of patient specimens is becoming commoditized (and can be performed in a machine-like organization). Differentiation should be achieved by providing complementary knowledge services related to laboratory testing by specialized and skilled professionals. In previous work, Porter (19) defined 3 generic strategies: cost leadership, differentiation, and focus. In cost leadership, an identical product or service is supplied at a lower cost by exploiting all sources of cost advantages (19). In a differentiation strategy, a firm seeks to be unique along some dimension that is widely valued by the buyer (19). Laboratory professionals can differentiate themselves not only by their technical skills but also by being involved in the creation, distribution, and application of knowledge related to laboratory aspects of patient care. Such extra service should be recognized and implemented in the business strategy.

COMPREHENSIVE CONSULTATIVE SUPPORT TO CLINICIANS

The laboratory test menu has expanded rapidly. Primary care physicians find it difficult to become familiar with the indications and result interpretation for the many tests available, as do specialized physicians for tests that are not specifically useful to their specialty (17). Thus, the complexity of laboratory investigations has increased and clinicians will need more assistance in the use of new laboratory technology (20). This need will increase as even more complex testing becomes available (e.g., genomic and proteomic testing). Therefore, laboratory professionals should optimize their professional relationships with the clinicians who order laboratory tests (6), serving as clinical consultants for appropriate test ordering and interpretation (4,6,21) and for point-of-care testing. The Academy of Clinical Laboratory Physicians and Scientists have recognized medical consultancy as a key competency of clinical pathologists (22). Clinical consultancy may be practiced in several ways (20,23): implementing reflex testing and diagnostic algorithms, providing patient-specific narrative interpretation of complex testing (24), providing probabilistic data related to laboratory results, organizing clinical audits, participating in grand rounds in hospitals, eliminating obsolete tests, achieving consensus with clinicians on guidelines and standardization, and optimizing clinical pathways. Although we now have the IT tools to make information easily accessible, the tools are not yet widely applied. Kay (25) described how IT has been implemented in the Oxford Hospitals. A clinician viewing a blood glucose report is offered a link to the specific entry for glucose in the laboratory handbook, to the criteria for the diagnosis of diabetes mellitus, and to “critically appraised topics” mentioning glucose or diabetes (25). Care must be taken, however, not to overload clinicians with data.

COST-EFFECTIVE LABORATORY TESTING

Appropriate use of cost-effective laboratory tests will become increasingly important (18,26). Intelligent decision support systems should assist clinicians in ordering and using laboratory tests appropriately and more efficiently. Real-time electronic ordering (physician order entry) will ease the move toward rule-driven generation of orders rather than ad hoc ordering (25). Such pathology-driven test use may reveal that certain investigations are of little value and thus reduce costs and enhance quality of life (25). In a prospective study, Poley et al. (27) demonstrated that introducing an electronic decision support system for ordering laboratory tests in primary care resulted in cost savings. Once pathology-driven utilization is implemented it is important that the knowledge base is continuously revised and maintained.

FOSTER EVIDENCE-BASED LABORATORY MEDICINE

Sackett defines evidence-based medicine as “the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients” (28). Laboratory professionals should play a pivotal role in promoting the evidence-based approach to laboratory medicine (29).
MANAGEMENT OF INFORMATION

Laboratory information system databases are powerful resources that can be exploited for clinical research, particularly if they are linked to related clinical and demographic information. Friedman (6) states that “the generation of information should be considered as the beginning—not the end—of the professional responsibility of laboratory professionals”. Advanced information management of diagnostic data (pathology informatics) (22) should become a core competency of laboratory professionals.

Different IT systems within the hospital should be linked and shared databases installed. For example, linking the laboratory information system with the pharmacy information system may have direct benefits for patient outcomes, such as the prevention of mismatches between microbiology data and prescription of antibiotics (30). A laboratory data warehouse that is standardized and horizontally and vertically integrated allows for data mining and better management of clinical laboratory test utilization.

TEST DEVELOPMENT

Laboratory professionals should participate in development and field evaluations of new analytical devices and reagents. Evaluations should focus on the clinical diagnostic characteristics and not merely on analytical characteristics of the test (31). A network of collaborating clinicians should support such evaluations.

RESEARCH AND INNOVATION

Multiparameter diagnostics are being developed and should be critically studied for their clinical added value. Newly developed expensive biological therapies are increasingly coming to the market. Before these drugs are administered to patients, laboratory testing will be required to determine whether the drug patent is suitable for the patient. Laboratory professionals should be involved in such developments (22). Finally, genomic and proteomic testing is a challenging new field for laboratory and clinical diagnosticians (4), and new developments in these areas should be explored. Innovation is crucial for progress and can be boosted by partnerships and interactions between laboratories and the biotechnology industry (4).

Discussion

The services offered by clinical laboratories are increasingly perceived as homogeneous, because many tests are performed on automated instruments using commercially available reagents. These changes are signs of the commoditization of laboratory practice. The increased liberalization in Europe and the growing pressure on governments to reduce healthcare costs will probably change the environment of laboratory medicine. The current monopoly situation of hospital laboratories can be expected to disappear as international organizations offer laboratory tests across countries at competitive prices. Rangan and Bowman (32) described 2 proactive responses to anticipate commoditization: a value-added strategy (increasing augmented services) and a price compression/product innovation strategy. In line with the analysis of Rangan and Bowman (32), we argue that clinical pathologists should be prepared for future threats and opportunities by enhancing efficiency and providing value-added services. Enhanced efficiency, and as a consequence improved cost and quality, can be realized through increased “operational excellence” (33) and establishment of (regional) integrated networks. Clinical laboratories should deliver the kind of operational excellence exhibited at Toyota industries. Processes should be continuously improved through quick, iterative experiments and change (34). Setting up integrated networks can boost efficiency by exploiting economies of scale, optimal capacity utilization, optimal process design, and reduced input costs. Integrated networks create additional value through harmonization of test results within the network.

More importantly, laboratory professionals should provide value-added knowledge services by providing comprehensive consultative support to clinicians and fostering evidence-based laboratory medicine. The enhanced interaction [“customer intimacy” (33)] with the physicians who order the laboratory tests should create additional value. Finally, laboratory professionals (especially those working at university hospitals) should focus on more academic tasks such as new technologies, test development, research, and innovation [“product leadership” (33)].

Health insurers should facilitate laboratory integration, consolidation, and establishment of networks and alliances and facilitate provision by laboratory professionals of in vitro diagnostic knowledge services that add value for patients. Laboratories should be rewarded for appropriate use of laboratory tests rather than the number of tests that are performed. Legislators should remove the current barriers to the innovations presented in this report. For example, in Belgium, in which there is national health insurance, appropriate use of laboratory tests is not rewarded and integration and establishment of networks are impeded by complex rules on subcontracting.

Conclusion

The mission of clinical laboratory medicine is to improve patient care by improving laboratory testing. If the discipline wants to be positioned strategically for the future, it must enhance efficiency by consolidation, formation of alliances or partnerships, and (horizontal and vertical) integration. Efficiency is a prerequisite for success, but not a guarantee. The relevant standard is value (19). To add value, the core competency of laboratory professionals must be refocused on providing additional knowledge services related to in vitro diagnostic services.
Grant/funding support: None declared.
Financial disclosures: None declared.

References

Xavier Bossuyt1*
Kurt Verweire2
Norbert Blanckaert1

1 Laboratory Medicine
University Hospital Leuven
Leuven, Belgium

2 Vlerick Leuven Gent Management School
Leuven, Belgium

* Address correspondence this author at: Department of Laboratory Medicine, Immunology, University Hospital Leuven, Herestraat 49, B-3000 Leuven, Belgium. Fax 00-32-13-347042; e-mail xavier.bossuyt@uz.kuleuven.ac.be.

DOI: 10.1373/clinchem.2007.093989