Computer-Assisted Laboratory Test Ordering and Interpretation

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Abstract

Electronic systems that provide knowledge support connected to extensive databases will allow major advances to occur in clinical laboratory test ordering, result presentation, and patient treatment. Emerging systems will guide test ordering, capture required clinical information, and assist with the interpretation of the results. Additional benefits will be to control utilization and redundancy of testing and thereby reduce costs, help reduce patient risk to adverse events, and improve patient outcomes by assisting with adherence to clinical practice guidelines and standardized care. Such systems will be vital as medical care becomes increasingly structured with evidence-based guidelines and as highly sophisticated proteomic and genomic testing enters the mainstream. Pathologists must be prepared to participate in these developments or risk being professionally disintermediated by evolving clinical systems.

Automated Test Interpretation

Computer-generated interpretive laboratory reports were first provided by Ledley and Lusted who described a system that listed the possible clinical causes of results produced by an out-patient multichannel chemistry profile. Pribor in the late 1960s and McNeely developed systems that provided interpretations of specialized tests (eg, parathyroid hormone, TSH, ferritin). These systems maintained a high degree of accuracy (>95%) because the test order provided a clear indication of the clinical question under investigation. During the past 25 years, software applications have been described that provide computerized interpretations for most laboratory tests, though few have been rigorously evaluated.

“Canned” comments are generally agreed to be necessary components of a laboratory report, but it is unclear what the extent of such commentary should be. Such systems have limited clinical information and therefore must provide lists of unweighted diagnoses rather than specific interpretations. Interpretations usually take up considerable space on a paper report and also suffer from the constraint of a rigid format. Moreover, the “canned” interpretation is added to all reports regardless of whether it was previously reported in conjunction with an earlier result or whether the clinician actually needs the assistance. Some physicians object to the comments because they feel insulted, or threatened, or are wary of the interpretation becoming known to patients who are now gaining access to reports.

There is certainly valid concern over the potential for inaccuracy. Lim and coworkers reported on an evaluation of human-generated interpretive comments and found an error rate approaching 50%. This raises the medical-legal issue of who should be permitted to prepare such interpretations, whether the comments are part of the legal report, and whether they should stay with the laboratory report when it is transferred to an electronic medical record. Marshall and Challand studied the effectiveness of human-generated interpretations and observed a number of limitations: there was a considerable variation amongst interpreters, communication style was important, clinical information on the test request was limited and often not appropriate to the test, there was little feedback from recipients regarding the usefulness of the service, and interpretations should be modified to the recipient. Clearly, such considerations need to be respected in any automated interpretive system.

Laposata has discussed and demonstrated the need for human-generated, patient-specific narrative interpretations. He notes that the barriers to this service are: lack of sufficient specialists in each medical center, turf problems with specialist physicians, and lack of reimbursement and institutional financial incentives.

Electronic technology provides answers to some of these criticisms. The advent of Web-based reporting with hyperlinks allows knowledge to be held in the background and elicited only when needed. This eliminates the formatting problem of
paper reports and allows the interpretation to be segregated from the official (legal) report. Turf problems can be mitigated by involving clinicians in the preparation of “their” knowledge support tools. Sufficiently sophisticated expert systems should be capable of producing a report that cannot be distinguished from that of a human expert and such reports are more consistent, do not suffer memory lapses, and are available 24 hours a day, 7 days a week.

**Electronic Test Ordering**

Electronic ordering has been available for several decades but has almost exclusively been used in a clerical support mode by nonphysicians who enter orders on behalf of clinicians. Electronic ordering has been particularly slow to be used directly by physicians. This is because such systems are expensive and paper “check off” requisitions are extremely efficient. If order entry software is easy and fast to use, if computers are accessible, if knowledge support makes the ordering task more medically appropriate, if physicians are engaged during the development phase, and if drug prescribing is mandated to be done this way, then physician uptake will increase. (This is also known as computerized physician order entry (CPOE) with CDS). Computerized physician order entry has been reviewed by Kuperman.7

Electronic ordering is an absolute requirement for all knowledge-based value-added laboratory services (guided ordering, result interpretation, utilization control, risk avoidance, and protocol adherence). An extra benefit of electronic ordering is the ability to capture key clinical information that can be used to enhance interpretations and to be “mined” at a later time in order to validate practice guidelines and protocols.

**Combination of Electronic Ordering and Interpretation**

By combining electronic ordering with automated reporting, key clinical information can be obtained and the diagnostic accuracy of the system can be enhanced. Smith and McNeely8 evaluated an electronic order and interpretation system (Laboratory Advisory System, Clinical Intelligence Ltd., 233-237 Old Marylebone Road, London NW1 5QT) and demonstrated significantly improved diagnostic accuracy and fewer referrals to specialists when physicians used the system.

**Utilization**

Test use in many jurisdictions is increasing at 10% to 20% or more each year, and this relentless expansion of service and cost is of increasing concern. Peters and Broughton9 have summarized various methods for controlling test ordering. All the successful approaches (physician feedback, education, administrative changes, and protocols) can be enhanced using electronic knowledge support tools.10 By far the most powerful and medically acceptable approach is the application of ordering protocols. These are a set of commonly agreed-upon requirements that must be met before a test is permitted. For example, in the Canadian province of British Columbia a thyroid protocol that specifies that a TSH is the only thyroid function test that can be routinely ordered without specified abnormalities being present or clinical questions answered has resulted in a sustained 18% reduction in thyroid function testing.11 When British Columbia thyroid test ordering was compared to 3 centers in the United States an average of 25% fewer tests were noted with the difference being the addition of total T3 or free T3 assays and combinations of free T4 and TSH (personal observation 2002). Van Walraven12 showed that in Ontario, protocols were responsible for reductions in ESR (58%), T4 (96%), urea (57%), and serum iron (80%). It is to be noted that in some cases the proper implementation of clinical guidelines will result in increased utilization. In the Ontario example, the reduction in serum iron of 80% was coincident with an increase in ferritin of 34%. In addition, diabetes care guidelines, if properly implemented will result in an increase in hemoglobin A1c and urinary albumin testing.

Van Wijk13 in Holland developed the BloodLink system that allowed practitioners to order laboratory tests guided by the extensive set of clinical practice guidelines that have been developed by the Society of General Practice. A study of 50 physicians using the system for a year compared to a control group using a similarly designed, free entry system demonstrated a 20% reduction of testing. This is similar to the guided ordering experience of Peters,14 the Lab Advisory System of Smith and McNeely,8 and the WizOrder system (30% reduction) developed at Vanderbilt University.15

Another approach to utilization control is to prevent tests being ordered when they have been performed previously. Walraven16 studied all the testing carried out on both inpatients and outpatients in Ontario over a 12-month period and concluded that duplication of ordering was a significant problem although it was unclear from the study to what extent it could be reduced. This is similar to an inpatient study by Bates17 that reported a 28% potential redundancy rate amongst 12 common tests. Tierney18 reported 13% lower cost when previous results were made available to clinicians at the time of ordering. The Vanderbilt experience19 showed that physicians may modify orders when the results were already available, the test was ordered but the result pending, or when a trending report indicated that repeat testing was not necessary.

**Risk**

Medical errors and methods of reducing them is a topic of major significance today.19 Computerized physician order entry is now generally regarded as effective and necessary for reducing (up to 55%) the adverse drug events that affect up to 1 million persons in the United States each year. Computerized physician order entry has been advocated by the Institute of Medicine (1999), the State of California (1999-2000 Senate Bill 1875, www.leginfo.ca.gov), the Leapfrog Group (www.leapfroggroup.org), and the National Quality Forum (www.qualityforum.org).20 It is clear that similar advantages can be gained from CPOE for laboratory testing particularly when linked to drug ordering systems. To be kept in mind is the observation of Koppe21 that CPOE systems can facilitate medication errors through poorly designed information presentation and software flaws.

Rather than relying on “warning flags” being displayed during ordering another effective approach has been to automatically initiate appropriate background actions without human intervention. This was done by Bronzin22 whose system automatically ordered laboratory monitoring when certain drugs were ordered. Similarly, the HELP system at LDS Hospital23 has used a warning system for many years.
An article by Wright reviews how diagnostic errors can be made when data presentation is poor, and she indicates how organized, graphical, and interpreted data can reduce risk. In the “off-line” mode, the laboratory database can be studied to provide epidemiology reports (including the emerging discipline of real-time epidemiology and bioterrorism warning). The database is also necessary to determine if clinicians are adhering to recommended clinical practice guidelines, whether improvement in patient care is resulting from the program, and whether changes in the algorithm logic are required.

Disease Management

It is now accepted that better medical care is provided when it is directed using carefully prepared evidence-based guidelines. The laboratory provides easily obtained objective evidence and therefore provides a focal point for many CPGs. Unfortunately, the adherence to guidelines is universally less than desirable. The reasons for this have been enumerated by Cabana, and it can be shown that almost all of these barriers can be eliminated or reduced using knowledge-based systems. Even the problem of differing expert opinion can be handled by sophisticated algorithms that allow the clinician and patient to make informed choices. In fact, it is so apparent that computerization will enhance the application of CPGs that Elson and Connolly have stated that it may be unethical to continue to perform trials to answer this question.

Disease management is the logical extension of the success of Clinical Practice Guideline (CPG) development in which an entire package of guidelines can be used to direct the overall care of patients suffering from chronic diseases. This is most mature in the treatment of diabetes. An example of a more extensive program is that developed by Innes and Cameron wherein a laboratory undertook the initiative to identify and enroll diabetic patients in a program that provided reminders when the next testing was required and a set of special reports for patients and physicians. Over a period of 2 years, 96% of physicians and 75% of estimated diabetics in a geographic region of 150,000 people had been enrolled. The A1c compliance of this group has grown to 80% compared to the 40% rate reported generally and in adjacent jurisdictions. In a similar way, it is expected that “wellness” management will be provided to both doctors and patients.

Summary

Laboratory testing is increasing 10% to 20% each year, test interpretation is becoming progressively more difficult, the number of laboratory physicians is declining, financial controls continue to squeeze, and health care workers (like all citizens) are becoming dependant on electronic knowledge and communication tools.

It is likely that the laboratory report of the future will throw off the shackles of paper presentation and will offer not only the core data that is the essence of the test but will provide an easily accessible knowledge-rich environment. Friedman and Berman have called this the “Contextualized Report,” which they suggest, might provide (using hyperlinks): literature articles, chapters in medical texts, controlled clinical trials, and a laboratory manual. It would also be reasonable to consider that linkages would also be available to: images, graphical presentations, expert system interpretations, notes from other members of the health care team commenting on the results, and the data intensive detail that will accompany proteomic and genomic investigations. A report of this nature that uses text, images, and graphic data has been developed by Lin for kidney stone reporting. A disease-oriented laboratory report that brings together a variety of data into a unified knowledge-based entity has been proposed by Dupree. Similar reports will be made available directly to patients.

The electronic medical record, handheld PDAs (personal digital assistants), and the Internet are all playing a greater role in medical practice. Laboratory ordering and reporting will soon be an essential and fundamental part of a new electronic clinical milieu. Winsten reviewed a number of commercial systems and indicated that vendors have been working vigorously to develop presentation tools to distribute clinical and diagnostic information “in a form conducive to rapid interpretation and full understanding.” Jones has provided an extensive description of an integrated laboratory system that brings together most of the modalities discussed in this article. Now is the time for pathologists and other laboratory professionals to become imbedded in the development of these applications or risk being relegated to the role of data provider rather than consultant.


