Role of Clinical Practice Guidelines and Clinical Profiling in Facilitating Optimal Laboratory Use

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Many studies have demonstrated the potential benefits of clinical practice guidelines in improving clinical practice. Moreover, several different kinds of clinical profiles have been developed to address issues related to quality, utilization, and outcomes of specific healthcare practices. With this expanded use of clinical practice guidelines and clinical profiles, clinical laboratory specialists have an opportunity to play an influential leadership role.

As the importance of utilization, quality, and outcomes issues has expanded, clinical practice guidelines and clinical profiling have emerged as two major strategies to improve clinical practice (1–5). Healthcare professionals, delivery systems, regulatory bodies, accrediting organizations, and governmental agencies have promoted the use of clinical practice guidelines and clinical profiling. Supporters of clinical practice guidelines and clinical profiling include national organizations such as the American Medical Association, College of American Pathologists, American Hospital Association, Joint Commission on Accreditation of Health Care Organizations, National Committee for Quality Assurance, Commission on Office Laboratory Accreditation, Health Care Financing Administration, Agency for Health Care Policy and Research, Institute of Medicine, US General Accounting Office, and Physician Payment Review Commission (6–10). These initiatives are likely to have significant impact on clinical laboratories and clinical laboratory specialists.

Practice Guidelines

More than 1700 clinical practice guidelines developed by national organizations are currently available (11); many others have been developed at the regional and local levels (12–19), either adapted from national guidelines or developed independently.

Practice guidelines address a wide range of clinical issues, including laboratory issues. Guidelines often include recommendations regarding which laboratory tests should be provided for which patients. For many guidelines, laboratory issues are the primary focus. For example, the Agency for Health Care Policy and Research published practice guidelines regarding sickle cell screening (20) and laboratory tests in end-stage renal disease patients undergoing dialysis (21); the American Thyroid Association published guidelines for the use of laboratory tests in thyroid disorders (22). Laboratory issues are also addressed in many practice guidelines that focus primarily on other clinical issues. For example, the American College of Cardiology/American Heart Association practice guideline on the management of patients with acute myocardial infarction discusses laboratory testing for cardiac enzymes (23); the Agency for Health Care Policy and Research practice guideline on benign prostatic hypertrophy addresses the laboratory test for prostate-specific antigen (24).

Many studies have demonstrated the potential benefits of clinical practice guidelines in improving clinical practice. These guidelines provide a basis for clinical pathways used in patient management (25, 26), and also provide a foundation for review criteria used in quality and utilization management (27).

Many complex issues surround the development, dissemination, and implementation of practice guidelines. For example, in development, there are issues such as how to evaluate the scientific literature, the role of expert opinion, and how to update practice guidelines (28, 29); in dissemination, issues arise such as the relative impact of various publication strategies, clinical algorithms, and computer technology (30–32); in implementation, the issues involve the use of practice guidelines in quality improvement and utilization management activities. Researchers have demonstrated that providing information regarding the cost of specific laboratory tests at the time tests are ordered can have significant impact on physician practice patterns (33).

Professional liability issues related to practice guidelines have received considerable attention (34, 35). The impact of practice guidelines on professional liability and malpractice determinations is controversial, and whether practice guidelines will increase or decrease professional liability litigation is unresolved (36, 37). One of the most challenging issues is the existence of practice guidelines that provide conflicting recommendations. For example, different organizations have developed conflicting recommendations for the use of various laboratory tests such as cholesterol testing (38). In addition, local organizations may implement laboratory-related practice guidelines that have been modified from national practice guidelines (39). Conflicting practice guideline recommendations may create controversy and confusion and may undermine support for their use (40, 41).

Clinical Profiling

Many clinical profiling initiatives are currently underway. Profiling strategies include national initiatives, such as the National Committee for Quality...
Assurance's Health Plan Employer Data and Information Set (HEDIS) initiative (42). Laboratory issues are prominently featured in this initiative. For example, HEDIS measures evaluate the annual rate of cholesterol screening in adults through use of claims data and laboratory records. HEDIS measures also assess cervical cancer screening by identifying the percentage of women who received a Pap smear in the last 3 years. Practice guidelines often provide a foundation for clinical profiling activities (6, 25).

Regional and local clinical profiling initiatives have also been developed and initiated by many managed-care organizations (43). Different kinds of clinical profiles have been developed to address issues related to quality, utilization, and outcomes. Profiles can be compiled at various levels of aggregation, ranging from high-level summary data (e.g., population or health plan level) to very detailed data (e.g., individual laboratory, physician, or patient).

Many complex issues surround clinical profiling (4), such as which laboratory data are most useful for profiling? Administrative data, such as the use, frequency, timing, or cost of specific laboratory tests, can provide valuable information regarding practice patterns. For example, one study demonstrated significant variation in the use of glycohemoglobin tests in the management of patients with diabetes (44). Clinical data, such as specific laboratory test results, are also useful in profiling. Laboratory results can be used in risk adjustment systems to predict patients' severity of illness (45), and laboratory data can provide important information to predict the survival of patients in intensive care units (46).

In clinical profiling, many technical issues related to data access, data management, and data analysis must be addressed (4). Multiple data sources might contain potentially useful data. For example, administrative data might be obtained from insurance files, claims payment databases, or patient enrollment data. Additional administrative data might be obtained from public databases. Clinical data might be obtained from inpatient data or outpatient data, including clinical laboratory, pathology, and radiology databases. Collecting and linking data from multiple data sources presents often complex technical challenges. In different databases, patient and physician identifiers might differ, identifiers for specific tests might vary, or test results might be presented differently. In addition, databases might be technically incompatible.

Data analysis is also complex. Hundreds of performance measures are currently used in clinical profiling (47). For example, the problems of which data to select for analysis and how to analyze data are challenging. Concerns have been raised regarding frequent errors in claims databases related to issues such as coding for patient diagnoses (48), challenges in adjusting for severity of illness (49), and the potential pitfalls of profiling (49, 50). Nevertheless, the benefits of profiling have been demonstrated. For example, the Harvard Community Health Plan demonstrated that clinical profiles, through routine feedback of performance information, improved the success with which internists performed Pap smears that were adequate for satisfactory laboratory evaluation (51).

Recommendations

With the expanded use of clinical practice guidelines and clinical profiles, clinical laboratory specialists have an opportunity to play an influential leadership role. Suggested recommendations to clinical laboratory specialists include: (a) provide recommendations for optimal laboratory use; (b) become familiar with the potential impact on the clinical laboratory of clinical practice guidelines and clinical profiles; (c) understand the benefits and limitations of clinical practice guidelines and clinical profiles; (d) evaluate clinical practice guidelines and clinical profiles that address laboratory issues; (e) develop strategies to participate in initiatives to develop and improve clinical practice guidelines and clinical profiles; (f) provide assistance to the developers and users of clinical practice guidelines and clinical profiles that relate to laboratory issues; and (g) assist efforts to link laboratory databases with other administrative and clinical databases.

Such involvement by clinical laboratory specialists is essential as efforts expand to use clinical practice guidelines and clinical profiles to address quality, utilization, and outcomes issues.

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References

13. Eagle KA, Mulley AG, Skates SJ, Reder VA, Nicholson BW,