Now that gene tests, markers for tumor receptors, assays for rapid and precise diagnosis of infectious agents, and a variety of other molecular probes have created an entirely new world of personalized medicine, it is time to add new information management tools to capture and manage this knowledge.

With more than 1500 documented tests available for gene testing alone, new strategies are needed for naming and classifying these tests, learning when to use them, and who should pay for all these tests. Even people in the genetic-testing business are struggling to keep up with these advances, especially when one considers that much of the technology driving this explosion is quite new itself. After the completion of the Human Genome Project in 2003, many researchers turned their attention to the implications of gene testing and the clinical applications of molecular diagnostics once the genes themselves were identified.

An immediate problem is keeping track of these new studies with a naming system that uniquely identifies each test. The coding system of the American Medical Association/Current Procedural Terminology and the Centers for Medicare & Medicaid Services/Health Care Financing Administration Common Procedural Coding System (HCPCS) that has been used to order and bill these tests has not kept pace; the current codes predominantly identify the methodology of laboratory process required and are not unique to each analyte or marker. These are sometimes called “stacking codes,” because 5 to 10 codes may be required to describe a particular analysis. Other coding systems, such as SNOMED (Systematized Nomenclature of Medicine) and LOINC (Logical Observation Identifiers Names and Codes), are used effectively in electronic health record systems but have more characters than can be used by payer claims systems.

New Online Testing Registry

McKesson Health Solutions has proposed a solution to this challenge that would use a coding approach modeled after the S codes in the HCPCS system, where a panel of industry experts in molecular diagnostics testing would provide the oversight principles needed to automatically assign a 5-character alphanumeric code to each new test, starting with a Z and using 34 letters and numbers. Their proposal would add the newly registered test to an online master catalog or an online open registry that anyone can view.

A McKesson web-based application, Advanced Diagnostics Management, incorporates just such a test catalog into the heart of its logic. This test registry serves as the master catalog within the application (and would link directly to a universal catalog if a different national standard should emerge); this would allow a physician (or physician’s office staff) to look up a test, learn about the test and indications for it, and place an order for the test from a clinical laboratory.

Evidence-based criteria have been developed for more than 300 molecular tests using clinical guideline development principles originally developed for InterQual clinical care management criteria. In conjunction with order entry and test-reporting capabilities, this software application permits online test authorization, using established health plan coverage policies to verify the appropriateness of the test in accordance with specific diagnostic information entered by a physician’s office.

Medical and Financial Implications

The implications of this approach are significant for personalized medicine. Credible information would be available to providers during the order entry process, ensuring that the appropriate test is being selected for
the proper reason. Furthermore, this approach will ensure that health plan coverage for the test is confirmed; if it is not a covered test, then the patient could make an informed decision at that point whether to proceed with the recommended test. Once laboratories provide pricing information for self-pay tests, full transparency about financial accountability for paying for these tests will avoid unpleasant surprises later.

The implications for managing the healthcare process are critical; this approach permits useful information about specific tests to be made available to the provider before or as the test is being ordered. Selection of the appropriate test to evaluate a genetic coagulation defect or to quantify the disorder in a drug metabolism pathway (eg, warfarin metabolism) is now a real-time possibility. By making all this information available to the physician, the laboratory, and the patient before the test is ordered, all parties are made fully aware of their options—clinically and financially—before committing to the test itself. Because the system is online, changes could be made dynamically in a way that promotes continuous quality improvement.

There are barriers, of course. All key stakeholders need to have confidence that all information conveyed through this system is objective and offers state-of-the-art solutions. The feedback loops that support continuous quality improvement must also be fully transparent. And, finally, health plans and clinical laboratories must achieve a new level of clarity about what criteria are applied to medical coverage for emerging technology, and what criteria are useful in setting prices for new studies.

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