Introduction

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ABBREVIATIONS: CL – Clinical Laboratory, CLS – Clinical Laboratory Scientists, QI – Quality Improvement, HITECH - Health Information Technology for Economic and Clinical Health, EHR – Electronic Health Record

INDEX TERMS: Quality Improvement, Patient Safety

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According to Harvard economist Michael Porter, the healthcare delivery system should transition to one based on value for patients rather than quality of processes.[1,2] Applied to the clinical laboratory (CL), this proposal seems intuitive until examined closely. The ramifications of such a transition are extensive when first, the distinction between quality and value is considered and then, their definitions reconstructed for CL as a result of that examination.

Traditionally, CL analytic processes have been the focus of quality measurement and improvement efforts. Value has been defined as "maximum quality for minimum cost" and evaluated at the analytic level. Processes are efficient, and therefore valuable, if results are accurate and direct costs (including labor) are low. Traditionally, CL value for patients is consolidated in specimen collection, transportation, analysis, and resulting processes. In this traditional interpretation, the value of CL processes is evaluated through analytic indicators, i.e., quality control, quality assurance, through a standardized quality improvement (QI) program. In this interpretation, quality measures on the testing cycle, to include sample collection, transport and analysis of patient specimens, and the subsequent reporting of these results, are proxies for patient safety. Excepting the collection process, CL patient safety is actually one step removed from patients; patients' specimens are the operational focus rather than patients themselves.

Environmental Pressures Redefining Patient Safety in the Clinical Laboratory

In a patient-centered, value-based healthcare delivery system, how should patient safety be interpreted relative to CL services? In the extended definition of patient safety are such considerations as both long-term and immediate health outcomes, privacy, informed consent, shared decision-making, and even patient compliance in the care process. Understanding the central position patients must be afforded in healthcare services delivery has begun a cascade of changes in the customary pressures driving innovation, e.g., regulatory (coercive), competitive (mimetic), and professional (normative) pressures.[3]

Regulatory (Coercive) Pressure

One of the most significant change agents is the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009. Through the funding from this legislation, providers are encouraged to adopt and fully utilize electronic health record technology (EHR). Because with time penalties will be levied for non-compliance, the HITECH Act brought new regulatory pressure on providers, including the clinical laboratory, to move quickly toward totally electronic systems. Equally as quickly issues of patient privacy and evaluation of protected health information have arisen. Patient safety concerns over the unauthorized release of potentially damaging personal information have assumed as much importance as validation of interfaces among disparate electronic databases. Addressing these

concerns has added to the already intense regulatory environment shaping changes in the health delivery system.

Competitive (Mimetic) Pressure

The potential for customized, tailored patient care moves closer to realization with electronic systems like the EHR. With EHR data storage comes the ability to analyze patient and utilization data for diagnostic and treatment algorithm development customized for specific individuals. Potentially, outcomes of these applied algorithms could be aggregated and analyzed in real time for evidence of effectiveness. In order to fully realize this promise, clinical laboratory scientists (CLS) need to expand QI efforts to include studies assessing the impact of laboratory information on patient health outcomes; CL QI studies should be value-based. Though some best practices development is underway, efforts should be increased to provide the basis for more efficient and effective delivery of laboratory services.[4] Benchmarking these best practices is necessary for the CL to remain competitive in a value-based healthcare environment.

In order to provide patients with some understanding of their personal healthcare journeys, many larger health systems are implementing portals affording patients a window into a repository of their personal health data. In some instances, patients are able to add information to their health repositories describing their status related to care paths and any developing compliance challenges. These experiments with open and interactive health information are raising issues concerning miscommunication, information validity, and patient education and are opening doors for CLS in direct patient care through consultation.[5] Along with value-based QI, patient-centered practices such as these are changing competitive forces among providers in the health delivery system.

Professional (Normative) Pressure

Rapid changes in healthcare delivery affecting patient safety are of concern to health professions educators, who struggle to translate knowledge into applications in the workplace. Capabilities of the EHR for documentation, analysis, and transmission of laboratory information should be researched, benchmarked, and taught along with and integrated into traditional curriculum. The instructional needs associated with rapid reformatting of information delivery add significant normative pressures in CLS education programs for curriculum expansion by tapping the expertise of CLS informaticians and/or the experience and knowledge of those in other allied health professions, e.g., health information administration.

There is increasing urgency for educators to prepare our workforce for the rapid advances in health services delivery and the resultant practice applications. The articles in this Focus section begin to identify specific practice areas affecting patient safety and preservice and graduate curriculum components that could address them. Hopefully, you will find them helpful in teaching these emerging value-based, patient safety concepts.

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