

Multiple patient samples of an analyte improve detection of changes in clinical status

January 6 2010

Clinicians rely on laboratory tests to monitor the progression or remission of disease, or to identify pathologic alterations in physiology that may precede clinical events. Monitoring quantitative laboratory results represents a crucial component in the assessment of response to therapy. Researchers at Boston University School of Medicine (BUSM) have developed a mathematical methodology to reduce the effect of biologic variation on the difference necessary to detect changes in clinical status. The findings, which appear in the January issue of *Archives of Pathology & Laboratory Medicine*, may lead to better patient predictions at a lower cost.

When comparing results over time, biologic variation must be statistically incorporated into the evaluation of laboratory results to identify a physiologic change. Traditional methods compare the difference in two values with the standard deviation (SD) of the biologic variation to indicate whether a "true" physiologic change has occurred.

Using a mathematical model, the BUSM researchers evaluated multiple paired sets of patient data, rather than a single pair, and found a substantial decrease in the difference between values necessary to achieve a given confidence interval, thereby improving the sensitivity of the evaluation.

"Our results show that we can obtain better predictions with what will

happen with a patient, such as return to the hospital because of heart failure for example, at a lower cost," said study author Martin Kroll, MD, a professor of pathology and laboratory [medicine](#) at BUSM. "The study shows that the practice of using multiple patient samples results in enhanced power to detect true changes in patient physiology," he added.

According to the researcher this approach has the potential to contribute to the personalization of health care delivery by redefining common thresholds in clinical patient management. "The decision to treat a patient with a more aggressive therapeutic regimen may be reconsidered when a test can show that a small but highly statistically significant change has taken place," explained Kroll. "Such a result may lead to the postponement of switching to a new therapeutic regimen until the next testing time, where the initial small but significant change in test values has grown to be both statistically and clinically relevant." Thus, a small difference in results may herald a true physiologic transition, a message that might easily be overlooked with older techniques.

The researcher believes testing multiple samples has the potential to fundamentally alter the way in which laboratory medicine is practiced. Greater research into the feasibility and cost of multiple testing paradigms in the clinical setting is recommended.

More information: www.archivesofpathology.org

Provided by Boston University Medical Center

Citation: Multiple patient samples of an analyte improve detection of changes in clinical status (2010, January 6) retrieved 19 April 2024 from <https://medicalxpress.com/news/2010-01-multiple-patient-samples-analyte-clinical.html>

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