The *Journal of Laboratory and Precision Medicine*'s special edition on Patient Based Quality Control

There is a trend in laboratory medicine towards increasing automation and centralization. While the trend towards increasing automation and centralization has been in process for several years, the primary focus has been on clinical chemistry and hematology laboratories. Automation's ceaseless march is now however also beginning to encircle microbiology and molecular pathology laboratories.

The main goals of increased laboratory automation is cost reduction, increased throughput and reduced analytical errors. Minimizing human interaction with patient samples has the effect of increasing throughput, while decreasing cost and preanalytic errors. As automation capacity and throughput has increased, traditional internal quality control (QC) practices have not advanced at the same rate. While efforts have been made to tailor QC frequency (1) a survey of large academic medical centers in the United States reveals wide variability in QC practices (2). Increased internal QC frequency still does not adequately account for the development and resolution of an error condition between QC events (3). For these and other reasons there is a growing interesting in developing QC strategies using patient results to monitor the analytic performance of automated analyzers in real-time.

In this special edition of the Journal of Laboratory and Precision Medicine, the use of patient results to monitor both preanalytic and analytic processes are described in a series of articles. In regards to the assessment of analytic processes, two separate articles by leading authorities in the growing field of patient based real-time quality control (PBRTQC) demonstrate the utility of such strategies.

On the topic of PBRTQC, Drs. Alexander Katayev and James Fleming detail the challenges of traditional QC techniques, and share their experiences with developing and implementing PBRTQC techniques in a multi-site commercial laboratory network. One of the most fascinating aspects of this article is their development of the "release from the back" approach to PBRTQC. Significantly, the authors also detail how PBRTQC decreased the false rejection of analytic runs, and substantially reduced the use of liquid QC materials.

In their article, "Optimization and validation of moving average quality control for the INR and aPTT coagulation tests" Dr. van Rossum *et al.* describe their work to develop PBRTQC strategies to monitor assays for prothrombin time/International Normalized Ratio (INR) and the activated Partial Thromboplastin Time. In addition to developing a PBRTQC metric for these two widespread coagulation tests, the authors also demonstrate how PBRTQC detected an analytic shift associated with a change of reagent lot number that was missed by their normal lot-to-lot validation strategies.

The use of patient data to query the analytic process is not limited to detecting errors in real-time. In, "Derivation of real metrics of long term patient and analytical variation of three hemoglobin A1c assays demonstrates both borderline and highly acceptable analytical performance" Dr. Cembrowski *et al.* demonstrate how the evaluation of sequential intra-patient hemoglobin A1c results can be used to evaluate long term assay imprecision. The implication being that assays with a larger intra-person variability due to assay imprecision decreases the reliability and interpretability of the hemoglobin A1c result.

The topic of using machine learning techniques in laboratory medicine is also of great interest and in this edition my co-author, Christopher Jackson and I, examine the use of neural networks to detect mislabeled samples in our article titled, "Development and characterization of neural network-based multianalyte delta checks." Delta checks are commonly used in laboratory medicine to detect mislabeled samples or analytic errors by comparing a patient's current laboratory values to those previously generated on the same patient. Delta checks commonly only examine a single analyte value at a time which limits their ability to detect mislabeled samples with high sensitivity and specificity. While commonly used, the ability of delta checks to detect mislabeled samples is infrequently tested, and here we demonstrate the performance specifications of the delta checks in use in our laboratory, as well as the improved performance that can be achieved by the use of multi-analyte delta checks developed through the use of neural networks.

Finally, I am excited to share an editorial article by Drs. Lim, Loh, and Badrick titled, "Asking why: moving beyond error detection to failure mode and effects analysis." The focus of error detection has long been on detecting an error when it occurs, but the authors of this editorial are advocating that it is not enough to simply detect an error, but that we also should

be taking error prevention and risk mitigation steps to minimize the risk of the same or similar error occurring in the future. To achieve this goal, the authors correctly point out that one of the costs of increased automation is a decreasing familiarity, or understanding of the automated instruments that enable the efficient delivery of accurate test results. The authors make the case for the application of the "Failure Mode and Effects Analysis (FMEA)" a quality tool that is widely applied in many industries including the aviation industry.

I hope that the reader will find this special edition of the *Journal of Laboratory and Precision Medicine* informative, and that new and instructive patient based quality control tools may be inspired by these articles.

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Footnote

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