Preface

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Editors

"Look around, look around, how lucky we are to be alive right now…" This is the hopeful lyric that suffuses the smash hit musical, *Hamilton*. Despite its structure as a tragedy, where the eponymous hero dies in a duel with Aaron Burr, despite all the political infighting, jealousy, back-stabbing, and imperfections of that age, this tour de force is a testament to the optimism that embodies the American ideal.

While laboratory medicine lacks the music, choreography, and staging of a Broadway production, it is nevertheless a time for optimism in our field. True, we are equally beset by politics, jealousies, and vigorous debates, and we are still far from the ideals that laboratory medicine should achieve. But we are so lucky to be alive right now, and see so much progress, and work with so many individuals who are full of energy, generosity, and optimism.

Two years ago, when we first edited an issue of *Clinics in Laboratory Medicine*, the dawn of the Risk Management age was upon us. Laboratories were facing a new frontier: one built on new guidelines (Clinical and Laboratory Standards Institute [CLSI]'s EP23), new approaches (Risk Management), and new tools (Failure Modes and Effects Analysis). It seemed like a daunting task.

In the last 2 years, that challenge has only become more daunting and difficult.

When the Centers for Medicaid and Medicare Services released its guidelines for Individualized Quality Control Plans (IQCP), it became apparent the bar had been moved… but it was lowered, not raised. Instead of asking laboratories to embrace the procedures and power of the Risk Management tools used in industry, labs only have to perform a truncated, qualitative, subjective process for hazard analysis. So much for implementing the Right QC for patient care!

But that is not the only risk that emerged in the last 2 years.

In 2014, the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) convened a meeting to revisit the 1999 Stockholm Consensus on Quality Specifications. What had transpired to require a review of this consensus? Not much, as it happens. It appears the metrology wing of laboratory medicine wanted to reverse the course of laboratory quality management and prioritize Measurement Uncertainty (MU) as the universal measure of quality. This began as a distinctly European perspective, but was embraced by International Organization for Standardization accreditation

Clin Lab Med 37 (2017) xiii–xvii
http://dx.doi.org/10.1016/j.cll.2016.12.001
0272-2712/17/

requirements, and therefore, it has been gaining prominence in the rest of the world. In the Clinical Laboratory Improvement Amendments part of the world, MU has not been adopted because it adds little practical value in laboratory quality management. However, related issues, such as goal setting models and requirements, will impact quality management practices worldwide.

In Milan, some major changes were proposed to the current status quo of quality management. (a) The "Ricos goals" (biological variability) that form the largest and most popularly adopted set of quality specifications and had been supported by numerous Spanish groups for the last 15 years would be absorbed into the EFLM/International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) bureaucracy, to be administered with more control, more rigor, and more requirements. (b) The Stockholm consensus hierarchy of five different levels of quality specifications would be replaced by a slimmer three-level consensus, in which regulatory requirements, expert group recommendations, and "state-of-the-art" were lumped into an equivalent but lesser category. (c) Finally, but most crucially, a new set of "Task-Finishing Groups" was created to address more contentious topics, such as Total Analytic Error as a measure of analytical quality and Allowable Total Error (ATE or TEa as it is popularly known) as a quality goal. The committee's mission included questioning whether the Total Error (TE) approach should continue to exist or preferably be replaced by MU. While that was apparently considered to be a footnote in the meeting, it is truly a radical proposal, and risks compromising the quality management improvements that have been accomplished over the past 40 years.

Much of the debate following the Milan conference has been aired online and in print. Nearly a dozen papers devoted to "MU vs TE" have been printed, primarily in *Clinical Chemistry and Laboratory Medicine*, the flagship journal of the IFCC. The presidents of EFLM have voiced their opinions that the "uncertainty model" should take priority over the "total error model," with little concern for practical issues such as the daily management of analytical quality in routine clinical laboratories, which operate in stark contrast to highly specialized metrology reference laboratories.

It seems necessary, now more than ever, to present a counterpoint. This issue of *Clinics in Laboratory Medicine* explains the continuing value of the TE concept, the use of TE goals to determine quality on the Sigma scale, and the practical usefulness and application of the "total error toolbox" for routine quality management in a medical laboratory.

ABOUT OUR CONTRIBUTORS

It falls to me, Sten Westgard, the most junior of all the editors, to serve as the narrator and introduce our cast of characters. Each has a special role to play in this issue. Each has helped move the plot forward for quality improvement.

James O. Westgard, PhD, FACB is of course best known as the father figure of Quality Control, the originator of the eponymous "Westgard Rules" and a perennial paradigm pioneer. He brought no less than five revolutions to the laboratory medicine world, starting with the establishment of a series of Method Validation protocols, later officially codified by CLSI. Next, he introduced the concept of "Total Error" and "Total Allowable Error," a combination of the effects of imprecision and inaccuracy that was greeted as heresy at the time, but soon became the dominant paradigm for evaluating analytical error. It was only then that he completed the work that generated power function graphs and studied the different performance characteristics of various single and multirule QC procedures, one combination of which would eventually become known as the "Westgard Rules." Following that ground-breaking tool, he created

the Critical-Error graph and the OPSpecs chart, tools that allowed laboratories for the first time to optimize their QC procedures based on the observed analytical performance. In 2001, he adapted the Six Sigma approach, so popular and successful in manufacturing and industry, to the medical analytical testing process, allowing laboratories to objectively benchmark their performance against a universal standard. This of course is only a brief summary of his books, chapters, papers, workshops, and webinars. A listing of the awards he has received during his career would require an additional article in the issue, so we summarize it by saying, he has been and continues to be thoroughly recognized for his achievements. All this he accomplished while holding just one job for more than 40 years—a distinguished professor at the University of Wisconsin in Madison, at the Medical Technology School and the Hospital and Clinics.

About myself, the less said the better; I am my father's son, a dutiful apprentice to the master for nearly 25 years. When I give lectures, I often explain that I am not following in my father's footsteps, but instead, simply trying to make his footsteps as big as possible. I cannot express how grateful I am, how lucky I feel, to be working with my father and making a difference in so many labs around the world. And, if the previous paragraph wasn't clear enough, I am very proud of my father.

Dave Armbruster, PhD, DABCC, FACB is our coeditor. We recruited him primarily to get a more objective opinion on many of these articles (hoping he would rein in some of our worst tendencies), but also because he has an excellent editor's eye. Dave serves on several scientific committees for key professional organizations, such as the Joint Committee for Traceability in Laboratory Medicine, which maintains a database of reference materials and methods that are the foundation for good laboratory medicine. His perspective as a representative of the in vitro diagnostic device industry is also crucial, because the goals of achieving comparability and traceability, so essential to an uncertainty of measurement approach, require industry to cooperate in establishing harmonization and standardization of assays.

Elvar Theodorsson, MD, PhD, Full Professor in the Department of Clinical and Experimental Medicine of Linkoping University, is a polymath of laboratory medicine, with hundreds of papers published. He has a strong interest in the philosophical approaches of the models of measurement uncertainty and TE. His contribution to this issue addresses the areas of overlap and contrast between these two models and proposes a future where both models can be utilized, rather than a future in which one model eliminates the other.

Carmen Ricos, PhD is one of the leading scientists who launched the compilation of data on biological variation. With colleagues from the Sociedad Española de Bioquímica Clínica y Patología Molecular (SEQC), she helped create the first database of desirable imprecision, inaccuracy, and allowable TE based on within-subject biological variation. This database is often popularly referred to as the "Ricos Goals." Currently, Dr Ricós and her colleagues are continuing this within one of the Task and Force groups derived from the Milan Conference, using a recently developed critical appraisal to classify papers for the final display of the revised data. Together with her colleagues, Virtudes Alvarez, Joana Minchinela, Pilar Fernández-Calle, Carmen Perich, Beatriz Boned, Elizabet González, Margarita Simón, Jorge Díaz-Garzón, José Vicente García-Lario, Fernando Cava, Pilar Fernández-Fernández, Zoraida Corte, and Carmen Biosca (active members of the SEQC-Analytical Quality Commission, some of them since 1982), she provides us with an article with key insights into the practical use of biological variation data in the laboratory as well as an article on the unique "state-of-the-art" goal approach on which the Spanish societies collaborated to generate for External Quality Assurance in Spain, which not only provides

us with practical goals but also key information about which goals are practical to achieve for most laboratories.

Gerald A. Hoeltge, MD, FCAP is the checklist commissioner for the College of American Pathologists (CAP) Laboratory Accreditation Program. He provides us with the College's perspective in this issue. The CAP is the leading accreditation provider for full-service laboratories. Dr Hoeltge's narrative on IQCP and quality planning reflects the CAP's rigorous emphasis on laboratory quality. The CAP's implementation of IQCP is thus far the most detailed of all the regulators. It is setting the standard for IQCP implementation.

Erna Lenters-Westra, PhD is an HbA1c Research Coordinator at Isala Klinieken in the Netherlands. Her publications have, over the past decade, concentrated on benchmarking the performance of HbA1c assays. Along with her colleague, Emma English of the University of Nottingham, she participated in the IFCC Task Force on HbA1c standardization. Dr English is also part of the IFCC Committee on Education in the Use of Biomarkers in Diabetes. Together, they contribute an article that discusses the real-world application of TE goals as a way to not only evaluate the acceptability of methods but also drive the standardization, harmonization, and performance improvement of assays. HbA1c is one of the best success stories of standardization, harmonization, and performance improvement of assays, and their discussion reveals which parts of the success can be generalized to other assays and which parts of the success are unique to the nature of the HbA1c assay itself.

Navapun Charuruks, MD, a Diplomate of the Thai Board of Clinical Pathology, the Division Director of the Laboratory for Bumrungrad International Hospital in Bangkok, Thailand, is a tireless driver for laboratory improvement. For several years, she has been implementing Sigma-metrics to evaluate performance and optimize QC. But in her article, she demonstrates it is possible to apply Sigma-metrics not only to the analytical performance of laboratory assays but also to preanalytical and postanalytical processes as well. Thus, her article provides us with a Six Sigma perspective on the Total Testing Process and allows us, possibly for the first time, to make some true apples-to-apples comparisons among the error rates of the different testing phases.

Jamuna Jairaman, Senior Manager, Allied Health Support at Sunway Medical Centre in Selangor, Malaysia, has been implementing Sigma-metrics in her laboratory for nearly a decade. Together with colleagues, Zarinah Sakiman and Lee Suan Li, she contributes an article that compares the Sigma-metric approach to those other current contemporary approaches, MU and IQCP. The experience of Sunway Medical Centre in implementing all three approaches reveals some of the strengths and weaknesses of each technique.

Harold Harrison, MD, PhD is the Director of Clinical Pathology for Geisinger Medical Center in Danville, Pennsylvania. For more than five years, he has guided the implementation of Sigma-metrics across the entire Geisinger Health System, expanding its scope to cover not only chemistry but also hematology and coagulation assays. With years of data, he has enabled Geisinger Medical Laboratories to get a precise view of their long-term performance and comparability.

Joseph Litten, PhD, is the Technical and Development Manager of the Valley Health System in Virginia. A pioneer in the field of performance measurement, he began using Sigma-metrics to assess performance and compare vendors long before any other laboratory in the United States was doing so. His laboratory may have the longest continuously evaluated Sigma-metric performance data in the United States, more than six years of data. He has used that data to not only assess but also improve laboratory operations. His contribution to this issue discusses his monitoring of

performance beyond the Sigma-metric and includes outliers, trouble-shooting, error types, and more.

Mario Plebani, MD is the Editor-in-Chief of *Clinical Chemistry and Laboratory Medicine* and perhaps the most-published laboratory professional in the world, with well over 1400 abstracts, books, and chapters to his name. He is a leading figure in the field of preanalytical and postanalytical error, having authored the groundbreaking studies on error rates in the laboratory. He has too many titles, committee chairmanships, and keynotes to mention here. Together with his colleague, Laura Sciacovelli, PhD, the Quality Manager at the Department of Laboratory Medicine of the University Hospital of Padova, Italy, they present an update of the project of the Working Group of the IFCC, "Laboratory errors and patient safety" and EFLM, "Performance specifications for the extra-analytical phases," to create a comprehensive set of quality indicators (QIs) that cover the preanalytical, postanalytical, and intra-analytical phases of the laboratory testing cycle. This represents decades of efforts to standardize QIs so that laboratories around the world can track their error rates in a comparable way.

It is with great pleasure that we, along with our colleagues, present this issue of *Clinics in Laboratory Medicine*, with the hope that we provide the reader with not only a stimulating discussion of about the debate on quality in the laboratory but also a meaningful series of real-world scenarios demonstrating that successful quality management can be accomplished at present with the tools at hand.

Look around, look around, there's plenty to be proud of in our labs right now. How lucky we are to have these colleagues, their examples, and practical tools to help us optimize and improve our performance.

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