



Today, laboratories often take for granted that new analytical systems provide the quality needed for patient care. But what quality is that?

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Education

PhD and MS degrees, Analytical Chemistry, UW-Madison;
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Personal

Collector of 16th- to 18th-century Scandinavian maps;
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("rose painting").

Furniture refinisher and repairman for wife's antique business.
Proud grandfather of four.

Westgard's trilogy for analytical QM

In the lead-up to a recent meeting, COLA featured a series of interviews with James Westgard, PhD, who recently published the 3rd edition of *Basic Method Validation*. This book is part of a series on analytical quality management that also includes *Basic QC Practices* and *Basic Planning for Quality*. MLO was curious as to how Dr. Westgard happened to develop these training materials.

Method validation. I trained as an analytical chemist, graduated from UW in 1968, and began working in the clinical laboratories at the UW Medical School. Clinical chemistry provided real-world experience in applying concepts and principles of chemical analysis. My first real-world problem was to evaluate the performance of a new continuous-flow multichannel analyzer. At that time, there was no standardized approach (this was before the days of NCCLS/CLSI). There were some important gaps in knowledge — one being the application of statistics to method validation (MV) data. Investigation of that problem by "data simulation" led to one of my first papers (together with Marion Hunt) on the "Use and Interpretation of Common Statistics in Method Comparison Studies," which recently was identified as a "Citation Classic" by the *Journal of Clinical Chemistry* (March 2008, page 612). That knowledge was also the basis for a series of educational papers on method evaluation first published in 1978 in the *Journal of the American Society for Medical Technology* and, later, as the monograph *Method Evaluation*. That material has been updated over the years, and the 3rd edition of *Basic Method Validation*, published by Westgard QC, is actually the fourth publication (counting ASMT).

Quality control. Once a new method has been evaluated, found acceptable, and is to be implemented for routine operation, quality control (QC) is the next step in analytical quality management (QM). In a sense, the purpose of QC is the same — to assess if method performance is acceptable, but the process is more difficult because only two or three samples are used for analysis. The initial investigation of QC was patterned after the MV work, using data simulation to determine the performance of different QC rules. I was lucky to spend a sabbatical year in Uppsala, Sweden. There, I had access to and the support of some of the world's leading scientists in computer simulation of laboratory processes, so this was a much more advanced study for me. That work eventually led to the multirule Shewhart Chart that, today, is commonly known as "Westgard Rules."

QC planning. Analytical methods were improving dramatically, and newer systems were much more stable and precise. It became obvious that the different QC procedures were appropriate for different analytic systems and also for different tests on those systems. So, the next step was to figure out how much QC was needed based on the quality required for a test, and the precision and accuracy observed for a method. A QC-planning-and-selection process was developed that wove together the concepts from MV and performance information on QC rules to identify the specific control rules and the number of control measurements needed. This is the subject of *Basic Planning for Quality* as is a more advanced book, *Assuring the Right Quality Right*.

Back to basics. There is an ongoing need for education and training in analytical quality management. That is why Westgard QC is dedicated to providing these materials. This is made possible by my son, Sten, who has developed the Westgard.com website, and who is the editor and producer of all of our educational materials and online courses. Today, laboratories often take for granted that new analytical systems provide the quality needed for patient care. But what quality is that? If we do not know or have not defined that quality, then we may be assuming rather than assuring, the quality of laboratory tests. □