ASCO's Clinical Practice Committee

Sick Sigmas

By Michael N. Neuss, MD

We have heard it so many times, it hardly seems worth mentioning. If you do not write it down, it did not happen. If you cannot measure it, you cannot judge achievement or improvement. And it does seem obvious that without measurement, there is really no basis to claim that high-quality care is being provided to our patients who, in the face of the serious diseases we treat, deserve the best. It seems clear that “the best” has to reflect two somewhat opposing factors. First, one has to consider global disease circumstances and recognize the standard of care for that circumstance—for example, that one should recommend and use hormonal adjuvant therapy in node-positive hormone receptor–positive patients with breast cancer as part of their care. Second, one has to respect and react to patient individuality, both in terms of comorbidities and, at least as importantly, to each individual's autonomy and right to consent, or deny consent, for a particular treatment.

To put this slightly differently, one has to reach a minimal level of achievement while providing appropriate exceptions to standard care as dictated by patient wish and medical circumstance. The Greek sigma is used as a symbol of both: when capitalized, Σ , to indicate a sum, and when in lower case, σ , to indicate variation, specifically the standard variation within a distribution of results. Both are parts of the Deming Six Sigma cycle, which assumes that all mistakes lead to a defective result. The “six” itself implies an error rate only beyond six standard deviations from the mean, which with a normal (Gaussian) distribution is a rate of two defects per billion opportunities.

According to Trusko et al,¹ health care operates at the four-sigma level, with an error rate of 63 per one million opportunities. Therefore, in a surgical procedure involving 1,200 steps, only five of 10,000 patients enjoy defect-free care. However, mistakes are not all of equal importance (using a dirty syringe and transmitting hepatitis clearly is not equivalent to using cloth when paper tape is specified), and taking care of living, breathing, healing patients allows for both correction of error and recovery.

In addition, there is not just one unique and correct pattern of care that is defined by an isolated variable. An 89-year-old with multi-infarct dementia and ischemic cardiomyopathy with two isolated brain metastases of remotely diagnosed lung cancer may be less of a surgical candidate than an otherwise healthy 24-year-old athlete with four brain metastases of testis cancer. We know this, and we bristle when someone else,

particularly someone with no medical training, tells us that we, despite personal discussion and review with radiologists, neurosurgeons, patients, and their families, are varying from the standard pathway for treating brain metastases no matter how much we agree in general with the expert guideline developed by specialists from the National Comprehensive Cancer Network (http://www.nccn.org/professionals/physician_gls/PDF/cns.pdf).²

This is not to deny that we also admit that variation in care as currently delivered seems excessive and at a minimum provides room for improvement. In results from the spring 2009 American Society of Clinical Oncology Quality Oncology Practice Initiative (QOPI), for example, in the three-step process of identification, characterization, and intervention for patients with moderate or severe pain, QOPI results show that this occurred overall 71% of the time in 17,600 patients. However, some practices were never able to do this, and others succeeded with 100% of patients.

Fortunately, those results are not the whole story. That is, we as oncologists are able to do some things in high agreement with practice guideline recommendations. As measured for patients with breast cancer, of the 733 patients age 70 years or younger with greater than T1c hormone receptor–negative nonmetastatic disease, spring 2009 QOPI results demonstrate that chemotherapy was recommended for 95%. And of the nearly 3,000 patients who were hormone receptor positive, hormonal therapy was recommended in 98%.

We have a clear path to improvement. We can start with Six Sigma and incorporate measurement, learning, change, and remeasurement into our practices. And we can remain true to patients by promoting their engagement in the process of consent while considering their health status and wishes. The QOPI model incorporates all of these features, and if you are not one of the 500 practices who have been involved with us, we invite you to learn more.³

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