PRESIDENT'S MESSAGE

Comparative Effectiveness—Is It in the Genes?

BY GEORGE KOVACH, MD

With the Affordable Care Act intact, one of the elements addressing the cost of healthcare is the concept of "comparative effectiveness." The basic idea of comparative effectiveness is to evaluate a treatment or procedure in order to rank its effectiveness and value (benefit and cost). This ranking would then provide the healthcare provider and payers the necessary information for selecting the "best treatment," thus avoiding unnecessary testing or treatment. There are a few caveats, however. For example, which value takes precedence—cost or benefit? How do you define "benefit" and who is doing the defining? Those pesky details!

Treatment benefit in oncology patients is very complex, since the majority of patients will ultimately succumb to their disease. What is the definition of treatment benefit—cure or prolonged survival with minimal treatment-induced morbidity? As a result of better understanding of the molecular biology of cancer, newer agents are being developed that provide survival benefits but at a significant cost. Increased use of these high-cost new agents may bring longer patient survival but accompanying this success are increases in the cost of healthcare.

In oncology, the side effects of treatment are associated with significant costs. Avoiding or minimizing these side effects would mean lower costs and better patient quality of life—truly a value. Does this fall under the definition of treatment benefit?

The effectiveness part of the equation is no less complex. Chemotherapy treatments are based on clinical trials without—in most cases—a predictability of response in the individual patient; thus, many treatments are administered with responses below 50 percent. This low response rate is not unique to oncology. For example, certain antidepressants (SSRIs) have a failure rate of about 38 percent, and the failure rate with arthritis drugs is nearly 50 percent. Put another way, 90 percent of drugs work in 30–50 percent of individuals. With annual global drug sales of $770 billion in 2008 (IMS Health), this translates into $350 billion spent annually on ineffective medicines! How can we improve?

As we better understand the molecular biology of cancer, specific "targets" are being identified and used in treatment. Hormone receptors and HER-2-neu have played a significant role in the appropriate treatment of breast cancer. Receptors such as CD-20 and others have improved the treatment of lymphoma, and the BCR-ABL-targeted therapy has led to a paradigm shift in the treatment and outcome of CML.

Genomics and molecular testing are becoming increasingly important in treatment decisions. OncotypeDx™ gene expression assay is used in determining the efficacy of chemotherapy in breast cancer treatment. KRAS mutation testing for colorectal cancer, ALK-4 testing in non-small cell lung cancer, and BRAF mutation testing in melanoma are only the beginning. Targeted therapies are beginning to change how we treat cancer, allowing us to individualize therapy and thus avoid unnecessary and ineffective treatments.

Pharmacogenomics, a branch of pharmacology studying the effect of genetics in drug response, is recognized as a method of predicting efficacy and potential side effects of a therapeutic agent, offering truly personalized therapy.

Adoption of these new technologies will require research and education, such as ACCC's Molecular Testing in the Community Oncology Setting education project, in order to effectively incorporate them into day-to-day practice as a standard of care, and to support adoption by CMS and private payers.

These are key steps toward realizing true comparative effectiveness.

Coming in Your 2012 *ONCOLOGY ISSUES*

- A Model AYA Survivorship Program
- Making the Case for Dedicated QI Staff
- Integrating Quality Improvement & Quality Measurement into Clinical Practice
- Cancer Center Registry: Employee vs. Independent Contractor
- Oncology Distress Screening
- A Model Arts in Oncology Program
- Physician-Hospital Alignment: Bringing Together the PSA and MSA
- New Cancer Center Design—Non-moving Patient and LEAN Design
- Developing a Centralized Process to Review and Tracking Clinical Studies
- A One-Day Cancer College
- Managing Through Change—A Community Hospital's Acquisition of a Private Oncology Practice