New Trial Empowers Patients in Their End-of-Life Care

At the Medical College of Virginia in Richmond, researchers have just launched a clinical trial randomizing terminally ill cancer patients to traditional fee-for-service care or to an indemnity arm in which they'll be given $18,000 to spend on chemotherapy, other palliative care, or whatever they want.

The unusual trial, ultimately involving up to 120 patients, will include a cost analysis, but that is not its primary goal. "Our main concern is how to get patients involved in their own medical decisions at the end of life," said Thomas Smith, M.D., director of cancer education at the college's Massey Cancer Center, and a speaker at the American Society of Clinical Oncology meeting in Philadelphia in May.

"(But) our intent is not to withdraw hope," Smith stressed in a phone interview following the ASCO conference. "We are trying to encourage better use of hospices . . . to improve the quality of life."

The cost for palliative chemotherapies ranges from $8,000 to $29,000. The $18,000 figure was selected, Smith said, as the average cost for 6 months of standard chemotherapy, which the insurer — in this case, Trigon Blue Cross, Blue Shield — will provide. Patients on the indemnity arm of the trial who want chemotherapy must pay for it out of the $18,000.

Once the trial is over, Smith said, the hope is that "we'll find out what's most important to patients" and patients will have more control over their medical care.

Cost Issues

As a medical oncologist, Smith told ASCO participants that cost issues are playing an ever-increasing role in medical care. For example, Medicaid caps imposed by the state of Virginia provide a lump sum of $140 million annually for all patients' needs, Smith said, even though the medical college handles most of the Medicaid cases in central Virginia. "If I give a patient more chemotherapy (than average)," he said, "this means our hospital can give less care in other areas such as in the emergency room and well-child care." But if money is saved, Smith added, "there is no guarantee that the savings will be used for cancer patients."

Another problem in assessing whether the benefits justify the costs of cancer treatments, Smith said, is that some cancer treatments that "cost more up front may be a good buy down the road."

Providing the patients' perspective on these issues during the ASCO forum were Amy Langer, executive director of the National Alliance of Breast Cancer Organizations, New York, and Ellen Stovall, executive director of the National Coalition for Cancer Survivorship, Silver Spring, Md. Elizabeth Brown, M.D., director of technology assessment at Aetna Life and Casualty, Hartford, Conn., gave the perspective of a third party payor.

From the patient's viewpoint, assessing the outcomes or benefits of a particular cancer therapy is nothing new and "not all that impressive," according to Langer, an 11-year breast cancer survivor. A "cure" today in breast cancer is still "dying of something else," she said, and among women with the disease there is "uneven knowledge," resulting in unequal outcomes. "The system favors the 'information seeker' who plays an aggressive role in her treatment, Langer said.

But while breast cancer is a popular target for treatment guidelines, Langer added, there has been no real evaluation of which treatments works best. Moreover, the extent to which these guidelines "may be set in stone is of concern"
to patients who fear guidelines may lag behind evolving, state-of-the-art treatments.

Brown, who described her job as evaluating new drugs and procedures for Aetna, said that Aetna’s reliance on outcomes data evaluating factors that drive medical costs is fairly new, and factors into a definition of medical necessity both safety and effectiveness of a therapy. “Instead of relying on the therapeutic outcome of a technology,” Brown said, “we now cover it if it affects the management of a patient.”

Gray Areas

On the sensitive issue of clinical trials coverage, Brown said that Aetna routinely covers any phase III trial sponsored by the National Cancer Institute, and “does not automatically deny coverage” for earlier phase I and phase II trials. But gray areas include patients who are treated off-label, she admitted.

Also raised as a touchy subject: coverage for cancer patients who have made up their minds that a treatment is beneficial without the scientific underpinnings of a clinical trial. The most dramatic example of this, Langer said, is high-dose chemotherapy combined with autologous bone marrow transplantation for advanced breast cancer. “Breast cancer patients have gotten the message that you should either have aggressive therapy or choose not to fight your disease,” Langer said. “This is the wrong message . . . and comes back to [having a better] doctor and patient interaction.”

Brown agreed. She said that insurers, including Aetna, have covered ABMT for breast cancer because of fears that they will wind up in court and lose. But for insurers to say to women “you can’t do this unless you are in a clinical trial” won’t work, she said. “We need the support of the oncology community.”

— Susan Jenks

Stat Bite

Testicular Cancer Incidence by Race/Ethnicity

Testicular cancer, unlike most cancers in the United States, occurs predominantly in young men. Incidence rates vary widely among U.S. racial and ethnic populations: The rate for non-Hispanic white men is almost seven times the rate for black men, and rates for Hispanics and Asian groups fall between these two extremes. As a result of a chemotherapy treatment breakthrough in the 1970s, most cases are curable, and the overall mortality rate for this cancer is only about 10% of the incidence rate.

Age-adjusted incidence rate per 100,000 (1988–1992)

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