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ne year after the death of Terri Schiavo, the extraordinary publicity surrounding her case is affecting the conversations people are having, and the decisions they are making, about end-of-life care, experts say.

Terri Schiavo died on March 31, 2005, at age 41, nearly two weeks after doctors removed her feeding tube on orders of a state circuit court.

Her death came 15 years after she suffered a heart attack that left her permanently brain damaged. And it followed seven years of bitter court battles between her husband and her family—battles that prompted comment and intervention from the White House, Congress, and the Vatican.

Two organizations—the National Hospice and Palliative Care Organiza-

tion (NHPCO) and the US Living Will Registry—report significant increases over the past year in the numbers of people seeking information about end-of-life choices.

And nearly 30% of Americans have thought about their own mortality enough to make their wishes known through living wills—compared with just 12% in 1990, according to a recent poll by the Pew Research Center for the People & the Press.

While some of the change is attributed to the aging of America, the Schiavo story continues to motivate people to explore their end-of-life options, make decisions, and inform others of what those decisions are, those interviewed for this article said. “The Schiavo case is one of those situations that bring difficult discussions to people’s kitchen tables,” said NHPCO spokesman Jon Radulovic.

The organization has had more than two million visitors to its Caring Connections Web site—www.caring info.org—launched about a week before Terri Schiavo’s death, and more than one million people have downloaded the site’s specific advance directives forms, Mr. Radulovic said.

NHPCO also has seen a significant increase over the past year in calls to its toll-free help line—800-658-8898—started about 20 years ago. Before the Schiavo case, the line averaged 10 calls a day, said Kathy Brandt, NHPCO Vice President for Consumer Services and Professional Education.

Two weeks before Terri Schiavo died, calls increased to up to 1,200 a day, Ms. Brandt said, and the line continues to receive more than 100 calls a day.

“There was nothing we could have done to raise awareness the way this

whole unfortunate situation in Florida did,” Ms. Brandt said. And while most people called and said, “I don’t want to end up like her,” many said, “I want everything done for me.”

“Previous Survey

NHPCO had done a previous survey (continued on page 7)

assignment to the experimental rather than the standard arm. However, the heterogeneity of outcomes and the small magnitude of advantage suggest that, as a group, these trials satisfy the uncertainty principle.”

Also, there was no apparent publication bias—i.e., non-publication of trials with negative results.

A third study looked at similar parameters for trials sponsored by pharmaceutical companies. The report, which was not limited to cancer studies, included 30 industry-sponsored trials and found that those trials were more likely to have outcomes favoring the industry sponsor’s product than studies with other sponsors such as the NIH.

The odds ratio was 4.05 (4.05 positive result in industry-sponsored to 1.0 in other sponsored trials) with a 95% confidence interval of 2.98-5.51. The authors conclude that, “Systematic bias favors products which are made by the company funding the research.” The bibliography of the paper lists other studies that drew the same conclusion.

“Gradation of Results Testing the Uncertainty Principle

So we see a gradation of results that test the uncertainty principle. There clearly was no bias in the pediatric studies. Some bias was detected in the adult oncology studies, though not statistically significant enough to violate the uncertainty principle. And clear-cut bias was seen in the industry-sponsored trials.

There are a variety of explanations for these findings. One would expect large and very expensive RCTs sponsored by industry to be carefully chosen with “best bet” products. In other words, the dogs may have been screened out in Phase 1 and Phase 2 trials.

Few novel front-line agents have been tested in pediatric RCTs in the past 30 years because pediatric oncology is not a lucrative business for the pharmaceutical industry. Consequently, most pediatric RCTs have tested variations of regimens using the same agents in both arms of a study in which the differences are likely to be small and there is no inherent pressure to favor one regimen over another.

The result in non-industry trials for adult oncology patients is a bit in-between; the small, but measurable bias may be due to the admixture of some hot new agents.

Enthusiasm runs high in such instances, since for adult oncology, new agents with substantial effectiveness were rare in the time periods under study.

Less Neutral Explanations

There are less neutral explanations. It has been shown that industry trials are much less likely to be published, especially those with negative results.

So there may be a publication bias that reduced the number of negative trials. It is also possible that biased studies have used inappropriate or inadequate controls.

Another possibility explaining the bias is that the positive result, while statistically significant due to a very large study population, may be clinically unimportant.

Approval of a new agent by the FDA is the pot of gold for the industry, so a good strategy would be to invest in a very large trial that requires a smaller difference in outcome from controls to achieve statistical significance.

These observations affirm the fact that industry-sponsored trials are far more likely to favor their products, and that the bias may be intentional or not, nefarious or not. But that begs the question of who should bear responsibility for the integrity of the trials.

As a mentor once told me, you don’t condemn a lion for killing and eat-

ing a zebra; that’s what lions do for a living. Likewise, it is foolish to blame only industry for a bias toward their products; that’s what businesses do for a living. I do not exonerate industry—many of their current practices are marginally or even frankly unethical, in my view.

Focus Should Be on Us, Not Industry

But the focus should not be on industry, but on us, the oncologists who order the therapy and conduct the trials.

Unlike the lions and the medical products industry, our training, professional culture, societal standing, and sentiments are all geared to helping and representing the interests of the patient. In that capacity, we are duty-bound to do our very best to avoid bias, particularly bias that results in personal financial gain, in assessing and prescribing diagnostics and treatments.

So in the end, it is we who must be the guardians of that trust given to us by society in general and our patients in particular.

In my next column, I will expand on this theme and discuss recent reports calling for more stringent rules for eliminating conflicts of interest.

References


Ethnicity May Influence End-of-Life Care Preferences

By Heather Lindsey

Investigators and practitioners are striving to develop a better understanding of how people’s ethnicity and cultural background may affect their preferences for end-of-life care. For example, a new study (J Am Geriatr Soc 2006; 54:150-157) may provide some insight into the needs of various ethnic groups. However, more research to improve the understanding of diversity and end-of-life care is clearly needed, say the oncologists and palliative care and hospice experts interviewed for this article.

“As our country becomes more diversified, we need to assess more thoroughly peoples’ end-of-life differences and preferences,” said the lead author, Sonia A. Duffy, PhD, RN, a research investigator with the Center for Practice Management and Outcomes Research at the Veterans Affairs Ann Arbor Healthcare System and with the departments of Otalaryngology and Psychiatry at the University of Michigan Medical School. “Our medical system is based on Western cultural values.”

Added Michael H. Levy, MD, PhD, Vice-Chair of the Department of Medical Oncology and Director of Supportive Oncology at Fox Chase Cancer Center: “The issues of ethnicity and culture are critical if you look at an outcome measure of palliative care or end-of-life care being satisfactory to the patient and family. Effectiveness of care is control of symptoms, based on patient and family assessment, and therefore you need to know what the patient and family need, want, or expect.”

Dr. Duffy cautioned that even though this study finds some trends associated with different ethnicities, physicians and health care providers should be careful not to stereotype.

“Individual preferences supersede group norms,” Dr. Levy agreed.

10 Focus Groups

The study consisted of 73 people, who identified themselves as Arab Muslim, Arab Christian, Hispanic, black, or white, divided into 10 focus groups. They participated in exercises, scenarios, and discussions about end-of-life issues, and completed questionnaires that helped measure how closely they were connected with their cultural group. All participants were age 50 or older.

Arab Participants

Many of the Arabs in the study also expressed that they do not want heroic measures taken to prolong life. They tended to be against telling their family members bad news, but they wanted to know the news themselves.

Also of interest, said Dr. Duffy, was that Arab women noted that male health care providers often came into women’s rooms unannounced.

Hispanic Participants

Many Hispanic people in the study were strongly concerned about dying with dignity. They were receptive.

The National Hospice and Palliative Care Organization and the US Living Will Registry report significant increases over the past year in the numbers of people seeking information about end-of-life choices. And nearly 30% of Americans have thought about their own mortality enough to make their wishes known through living wills—compared with just 12% in 1990.
End-of-Life
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tive to hospice care and hospitals, but said it was important to avoid going to a nursing home.

They were more likely than other groups to want to control their place of death, to not want a feeding tube, and to not have do-not-resuscitate orders. Also of note, Hispanic men were not opposed to the idea of assisted suicide or rather, assisted dying, Dr. Duffy said.

Most Surprising Finding: Gender Differences Among Ethnic Groups

The most surprising finding was that there were gender differences among the various ethnic groups, Dr. Duffy said. For example, African American and Hispanic women were more in favor of end-of-life extending care while men did not want heroic measures performed.

Study Limitations

This study is based on focus groups, so it allows researchers only to develop a hypothesis on which to base a larger, more sophisticated study, commented Eduardo Bruera, MD, Professor and Chair of Palliative Care and Rehabilitation Medicine at the University of Texas M. D. Anderson Cancer Center.

"None of the results are conclusive," he said, adding that interpreting any of the findings as fact is potentially harmful.

“There is both the risk of neglecting the importance of culture and of overemphasizing it," he explained.

The researchers have asked members of the public who represent different ethnic groups about their attitudes surrounding end of life care, he said. “So it reflects the attitude and beliefs of healthy people, not those of cancer patients.”

In addition to ethnicity, end-of-life care preferences are going to vary according to social-economic status, educational level, age, gender, and religiosity, Dr. Bruera said. Once researchers are able to control for such variables, they will be able to understand the independent role that ethnicity may have.

It’s possible that researchers may find socioeconomic status or other factors to be more important than ethnicity, Dr. Bruera noted.

Black Men

Black men in the study indicated that they did not feel strongly about the importance of having family and friends take care of them, and they said they did not want to burden their loved ones. Black people in the study said they would prefer staying in an intensive care unit or nursing home, or to have hospice care, rather than being at home under the care of family.

Many black men expressed distrust of doctors, and some expressed concern related to past medical-related injustices experienced by black men.

 Caucasians

Caucasians generally didn’t want their families to take care of them, but they—like members of other racial and ethnic groups—want their families nearby as they live out their last days. Whites were open to hospice care, hospitals and nursing homes, but generally preferred to die at home.

It was important for them to have choices and an advance directive, and many were opposed to extensive measures to extend life. More so than the other groups, whites in the study were likely to want to know what to expect about pain and other effects of their condition.

Many end-of-life preferences were driven by religious beliefs, Dr. Duffy added. Consequently, involving clergy often becomes an important part of care.

Older Hispanic patients, especially immigrants, might not want to deal with decision-making surrounding a terminal illness, even though they are aware they are dying. Culturally, these individuals may prefer that their children take responsibility for such decisions.

Key Findings of the Study

■ Arab Americans were in favor of making peace on earth and were against assisted suicide, extending life artificially, nursing homes, and telling the patient “bad news.”
■ Hispanic and black women were against assisted suicide and in favor of extending life, whereas the men in these groups felt the opposite.
■ Hispanic women spoke of not wanting a feeding tube and would consider alternative medicine.
■ Blacks were least opposed to nursing homes. For whites, it was important to have choices.
■ When asked about discrimination related to end-of-life care, Muslim women spoke of cultural barriers, blacks spoke of inequities in the past, and whites spoke of age discrimination and abandonment when dying.


Still in Infancy

Literature about end-of-life care is in its infancy, said Joel Policzer, MD, Vice President and National Medical Director of VITAS Innovative Hospice Care in Miami, who is board certified in hospice and palliative medicine, internal medicine, hematology, and medical oncology. “I think, though, that the research will eventually show that how people deal with end-of-life care is heavily determined by the culture that one lives in.”

Using the Literature to Open up Discussion

The best use of available literature is to help practitioners ask patients the right questions, which will contribute to developing the best care for each person, Dr. Levy said.

The article by Dr. Duffy et al underscores the importance of being aware of cultural differences and could help guide people in the assessment of each patient and family, Dr. Levy said. “It gives you ideas of what types of questions you should ask before going ahead with specific care.”

Cultural information about end-of-life care allows health care practitioners to accept various choices, rather than predicting them, said Dr. Bruera. Because of the wide variations for end-of-life care preferences within ethnic groups, personalizing discussions about end-of-life care is crucial, he added.

Tailoring Care

While data on cultural preferences may be limited, when patients reach the end of life, conversations about care need to take place within the context of the cultural and ethnic background of the people involved, said Dr. Policzer, whose organization, VITAS, has end-of-life programs specifically tailored to various ethnic groups.

To help serve VITAS’s diverse population, the organization tries to ensure that staff are sensitive to and aware of cultural preferences without making generalizations about an individual, Dr. Policizer noted.

Among its many initiatives, the hospice has developed a program to certify its hospices across the country in providing care to the observant Jewish community. People within this group may believe that only God can determine the time of death, Dr. Policizer explained.

Therefore, the conversation about choices has to be put in that framework, and there often can be no discussion of anything perceived as humans’ hastening death.

Additionally, in the observant Jewish community, immediately after death, all rituals must be done by members of the community themselves, he noted. Once the death is determined, staff moves to the sidelines; the body can never be left alone and it cannot be touched by anyone outside the community until it is taken to the funeral home for proper washing and shrouding.

La Esperanza Eterna

Another formal VITAS initiative, La Esperanza Eterna (The Eternal Hope), is tailored to the Hispanic community in San Antonio, and offers educational end-of-life programs in Spanish.

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MedPAC Evaluates Access to Chemotherapy Services

The Medicare Payment Advisory Commission (MedPAC) has concluded that beneficiaries continue to have access to chemotherapy services. These findings were based on site visits to several oncology practices.

MedPAC found that physicians continue to treat Medicare patients and that beneficiaries as well as physicians reported no change in the quality of care. However, MedPAC staff did note that since 2004, some practices have had difficulty covering their costs for drugs and biologicals and as a result, they often send patients without supplemental insurance (Medigap) to hospital outpatient departments for cancer treatment.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) mandated MedPAC to study the effects of payment changes for Part D drugs and drug administration services on quality of care, patient services (continued on page 10)

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Older Hispanic patients, especially immigrants, might not want to deal with decision-making surrounding a terminal illness, even though they are aware they are dying, said Dr. Policzer.

Culturally, these individuals may prefer that their children take responsibility for such decisions. “Of course, this is a sweeping generalization, and there are variations within the Hispanic culture itself,” he said, adding that VITAS is also providing information about its programs directly to the African-American community through churches and their pastors. “If the church is not involved it’s often hard to get approval from the community as a whole, said Dr. Policizer, adding that this, again, is a generalization.

The African-American community tends to be matriarchal, he added. Consequently, the eldest daughter is often responsible for parents’ end-of-life care.

Expanding to Asian Populations

The hospice organization is also expanding its services to Asian populations throughout the United States.

VITAS has found that a great amount of respect is usually paid to the elderly among Asian populations and that decisions about end-of-life care are often made by a designated family member and not the patient. Care-giving may often take place at home because putting a family member in a facility can be considered insulting.

Such programs help practitioners go beyond their own culture and open up to the needs of their patients and families, Dr. Policzer said. “If the conversation is based on your own cultural values, you’re not serving the patient.”

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