POLICY & PRACTICE

Popularity of Biologics

Spending on injectable biologic drugs increased 34% in 2005, according to a report from Express Scripts, one of the country's largest pharmacy benefit managers. The report looked at spending through the pharmacy benefit for four injectable biologics—Enbrel (etanercept), Humira (adalimumab), Kineret (anakinra), and Remicade (infliximab)—but excluded spending on drugs administered in physician offices. The biggest factor in the increased spending was increased use of the drugs, such as earlier treatment of rheumatoid arthritis and longer duration of treatment. Utilization in this class was up nearly 25%, according to Express Scripts. In addition, uses for other indications, such as psoriasis, also drove up the utilization and spending.

Disparities Among Children

Children with juvenile rheumatoid arthritis who were covered by Medicaid had significantly lower health-related quality of life and higher levels of disability than children with the disease who had private insurance, according to a new study. The study, which was published in the June issue of Arthritis & Rheumatism, evaluated patients with juvenile rheumatoid arthritis being treated at the Cincinnati Children's Hospital Medical Center between July 2003 and March 2004. Of the 295 juvenile rheumatoid arthritis patients treated during that time, 40 (14%) were covered by Medicaid. Children in the two groups had about the same level of health care utilization, the researchers wrote. However, children with Medicaid received significantly fewer MRIs and were nearly twice as likely to visit the emergency department. The differences in disability and health-related quality of life may be due to nonadherence and poverty since patients had similar levels of health care utilization, the researchers wrote.

Harvard Launches Stem Cell Project

Scientists at Harvard University and Children's Hospital Boston have been given the green light to begin research using somatic cell nuclear transfer in an effort to develop treatments for diabetes, blood disorders, and neurodegenerative diseases. The research, which will involve human embryonic stem cells, will be privately funded because the federal government will not provide money for research using human embryonic stem cells derived after Aug. 9, 2001. The efforts were praised by the Coalition for the Advancement of Medical Research, which advocates for federal funding of stem cell research. "In the absence of federal support for and oversight of this type of research, CAMR is pleased that institutions like Harvard have taken the necessary steps to ensure that therapeutic cloning research happens in a manner fully consistent with the ethics and scientific standards in place for all research involving human subjects and tissues," CAMR President Sean Tipton said.

Women as Medical Subjects

More than 60% of women aged 50 years and older who have participated in a medical research study would "definitely" or "probably" do it again, according to a survey released by the Society for Women's Health Research. The group commissioned the national telephone survey of more than 1,000 women aged 50 years and older. A similar survey was conducted in 2003. Overall, 10% of women aged 50 years and older have participated in some type of medical research, the 2006 survey found, down slightly from 12% in 2003. However, a growing number of women said they aren't interested or don't believe in medical research in the 2006 survey. Nearly 16% of women surveyed cited lack of interest as a reason for not wanting to participate, compared with about 9% in the 2003 survey.

Survey: FDA Influenced by Politics

A majority of Americans—82%—believe the Food and Drug Administration is greatly influenced by politics when making decisions about the safety and efficacy of new prescription drugs, according to a Wall Street Journal online Harris Interactive poll. The finding was similar across parties, with 87% of Democrats, 77% of Republicans, and 88% of Independents saying they thought that politics outweighed science greatly or to some extent in decision making. The survey of more than 2,300 adults was conducted in mid-May. In addition, almost 60% said the agency is doing a fair or poor job in ensuring the safety and efficacy of new drugs. Only 36% said the FDA was doing an excellent or good job. That is a reversal from 2 years ago, when 56% had a positive view and 37% a negative view of the FDA. Opinions have not changed much on the agency's performance in bringing innovative drugs to market quickly. In 2004, 62% said the FDA was not doing well on that front, compared with 70% in the latest poll.

ICD-10 Fraud Concerns

The Blue Cross and Blue Shield Association and the Medical Group Management Association are among those objecting to the planned implementation of ICD-10, the newest version of the comprehensive list of diagnostic billing codes used by health care providers. A bill currently being considered in the House would require payers to switch from the current ICD-9 codes to ICD-10 by Oct. 1, 2009. Blue Cross/Blue Shield argued in a statement that the deadline should be pushed back to 2012 "because much has to be done before a switch to ICD-10 can be started . . . and providers need time to automate their offices and be trained." The Blues are particularly concerned because the switch comes at the same time that Medicare is shrinking the number of its claims processors—many of which are Blues plans—from 50 to 15.

—Mary Ellen Schneider

Ethicists Debate Ways to Solve U.S. Organ Shortage

BY TODD ZWILLICH
Contributing Writer

The growing gulf between patients requiring organ transplants and the number of persons willing to give them is spurring some ethicists to call for new—and sometimes radical—ways to encourage donations.

The proposals range from loosening current restrictions on qualified donors to far more drastic measures, including "organ conscription," which would require donations from all who die with adequately healthy body parts.

Some ethicists even are calling for debate on changing the legal definition of death to allow patients in permanent comas or vegetative states to become candidates for donation before cardiac death.

Transplant list wait times have increased dramatically in the United States. More than 92,200 persons were on U.S. waiting lists as of early May. That's nearly five times the number waiting a decade ago, according to the United Network for Organ Sharing, the nonprofit group that oversees organ allocation in the United States.

Despite the demand, numbers of donations have risen only slightly. Just over 28,000 Americans donated organs last year, up from 19,000 a decade ago, according to the network.

The shortage has led some experts to call for new incentives to encourage donations. One option would let prospective recipients move up on wait lists if members of their family donate. Another would require citizens to make an affirmative choice whether or not to donate before receiving a driver's license.

Federal law bans offering money or other inducements in exchange for organs. But policy makers should consider altering the law to allow for new incentives, said Robert Veatch, Ph.D., a professor at the Kennedy Institute of Ethics at Georgetown University, Washington.

Dr. Veatch calls an organ conscription policy the "nuclear option." But he has called for experimentation with policy that many officials consider nearly as radical: cash payments for organs.

"There are too many people dying. I think its time to begin limited experiments with cash payments," he said at a meeting of the President's Council on Bioethics.

But a cash-payment system of organ procurement is strongly opposed by both liberal and conservative ethicists, and also by a host of medical groups. Dr. Francis L. Delmonico, a transplant surgeon at Massachusetts General Hospital and a professor of surgery at Harvard, both in Boston, warned that groups including the National Kidney Foundation, the American Society of Transplant Surgeons, and the Organ Procurement and Transplantation Network/United Network for Organ Sharing, would offer "staunch opposition" to any congressional attempt to legalize a market in human organs.

"That [waiting] list is growing because of inadequate medical care, and it's not just solvable by buying organs," Dr. Delmonico, also president of the board for OPTN/UNOS, said.

Others warn that assigning organs market value would undermine human dignity. "Isn't there really something disquieting about entering into a society in which certain parts of the body are treated as alienable things like automobiles?" asked council member Dr. Leon R. Kass, a University of Chicago ethicist who is also a vocal opponent of embryonic stem cell research.

Still, Dr. Veatch predicted that a policy of limited payments, forced donation decisions, and waiting list incentives could boost U.S. donations by up to 75%. ■

AHIC Calls for Pilot Tests on Secure Electronic Messaging

Public and private payers may soon be testing reimbursement strategies for secure electronic messaging between clinicians and patients, if the American Health Information Community has anything to say about it.

The group, which advises Health and Human Services Secretary Mike Leavitt on health information technology (IT) interoperability issues, voted to urge payers to pilot-test secure messaging to evaluate possible forms of reimbursement, physician work-flow issues, and the impact on patient involvement in their care.

The widespread use of secure systems that allow patients and physicians to communicate by e-mail has the potential to improve quality and lower costs, Dr. Douglas E. Henley, executive vice president for the American Academy of Family Physicians, said at a teleconference of the American Health Information Community (AHIC).

AHIC also voted to recommend that the Healthcare Information Technology Standards Panel work on defining standards for secure messaging that will be interoperable with electronic health records.

And in an effort to ensure that access to secure messaging is available to all patients and clinicians, AHIC is asking officials at the Health and Human Services Department to look at how to address the gaps in access to computers and the Internet for poor and underserved populations and the safety net providers that provide their care. AHIC also recommended that the federal government work with state agencies and professional societies to develop new licensing alternatives that address the ability to provide electronic care delivery across state lines through secure messaging systems.

—Mary Ellen Schneider