POLICY & PRACTICE

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Super-Antibiotic Research Funded

The Biomedical Advanced Research and Development Authority (BARDA) has contracted with Achaogen Inc. for the company to develop an antibiotic that appears to work against two bioterrorism agents and some antibiotic-resistant infections. The agreement will run for 2-5 years and will pay the company up to $64 million to continue work on ACHN-490, which has shown promise in early clinical trials. The agent acts against plague and tularemia bacteria, which could be used as bioterrorism agents. It also could be effective against hospital-related infections, such as pneumonia resulting from prolonged use of a ventilator and urinary tract infections from catheter use, according to a BARDA announcement. The contract is the first under a BARDA program to develop broad-spectrum antimicrobials.

First EHR Certifying Bodies Named

A nonprofit organization dedicated to health information technology and a software-testing lab have been chosen as the first two bodies to officially test and certify electronic health record (EHR) systems for the federal government. The Certification Commission for Health Information Technology and the Drummond Group can immediately begin certifying EHR systems as HHS-compliant, the Department of Health and Human Services said in an announcement. Legislation approved in 2009 created incentives up to $64,000 for health providers to transition from paper to certified EHRs. Now that HHS has named the certifying organizations, vendors can start applying for certification of their EHR systems and physicians soon should be able to purchase certified products, the HHS said.

Outcomes Research Funded

HHS will provide grants totaling nearly $17 million for "patient-centered outcomes research" (PCOR), which focuses on treatments and strategies that might improve health outcomes from the patient's point of view. Most of the announced grants will support outcomes research in primary care, HHS said. As part of the grant program, five health organizations will attempt to show that providers and academic institutions can partner on PCOR. Each organization– in Illinois, California, New York, Massachusetts, and Oregon – will receive about $2 million over 3 years to create a national network for evaluating the patient-centered approach in patient populations that are not always adequately represented in other studies, according to HHS. "Patient-centered outcomes research can improve health outcomes by developing and disseminating evidence-based information to patients, providers and decision-makers about the effectiveness of different treatments," said HHS Secretary Kathleen Sebelius in a statement.

AMA Opposes Tax Change

The American Medical Association and 90 medical organizations, including the American Academy of Family Physicians and the American College of Physicians, have written to the Depart-

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Table 7. Number (%) of patients with 3 or more step progression on ETDRS scale at endpoint

	Lantus (%)	NPH (%)	Difference*,† (SE)	95% CI for difference
Per-protocol	53/374 (14.2%)	57/363 (15.7%)	-2.0% (2.6%)	-7.0% to +3.1%
Intent-to-Treat	63/502 (12.5%)	71/487 (14.6%)	- 2.1% (2.1%)	-6.3% to +2.1%

*Difference = Lantus – NPH

†using a generalized linear model (SAS GENMOD) with treatment and baseline HbA1c strata (cutoff 9.0%) as the classified independent variables, and with binomial distribution and identity link function

- *Insulin initiation and intensification of glucose control*

Intensification or rapid improvement in glucose control has been associated with a transitory, reversible ophthalmologic refraction disorder, worsening of diabetic retinopathy, and acute painful peripheral neuropathy. However, long-term glycemic control decreases the risk of diabetic retinopathy and neuropathy.

- *Lipodystrophy*

Long-term use of insulin, including LANTUS, can cause lipodystrophy at the site of repeated insulin injections. Lipodystrophy includes lipohypertrophy (thickening of adipose tissue) and lipoatrophy (thinning of adipose tissue), and may affect insulin absorption. Rotate insulin injection or infusion sites within the same region to reduce the risk of lipodystrophy. *[See Dosage and Administration (2.1)].*

- *Weight gain*

Weight gain can occur with insulin therapy, including LANTUS, and has been attributed to the anabolic effects of insulin and the decrease in glucosuria.

- *Peripheral Edema*

Insulin, including LANTUS, may cause sodium retention and edema, particularly if previously poor metabolic control is improved by intensified insulin therapy.

- *Allergic Reactions*

Local Allergy

As with any insulin therapy, patients taking LANTUS may experience injection site reactions, including redness, pain, itching, urticaria, edema, and inflammation. In clinical studies in adult patients, there was a higher incidence of treatment-emergent injection site pain in LANTUS-treated patients (2.7%) compared to NPH insulin-treated patients (0.7%). The reports of pain at the injection site did not result in discontinuation of therapy.

Rotation of the injection site within a given area from one injection to the next may help to reduce or prevent these reactions. In some instances, these reactions may be related to factors other than insulin, such as irritants in a skin cleansing agent or poor injection technique. Most minor reactions to insulin usually resolve in a few days to a few weeks.

Systemic Allergy

Severe, life-threatening, generalized allergy, including anaphylaxis, generalized skin reactions, angioedema, bronchospasm, hypotension, and shock may occur with any insulin, including LANTUS and may be life threatening.

- *Antibody production*

All insulin products can elicit the formation of insulin antibodies. The presence of such insulin antibodies may increase or decrease the efficacy of insulin and may require adjustment of the insulin dose. In phase 3 clinical trials of LANTUS, increases in titers of antibodies to insulin were observed in NPH insulin and insulin glargine treatment groups with similar incidences.

6.2 Postmarketing experience

The following adverse reactions have been identified during post-approval use of LANTUS.

Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to estimate reliably their frequency or establish a causal relationship to drug exposure.

Medication errors have been reported in which other insulins, particularly short-acting insulins, have been accidentally administered instead of LANTUS *[See Patient Counseling Information (17) in the full prescribing information*]. To avoid medication errors between LANTUS and other insulins, patients should be instructed to always verify the insulin label before each injection.

7. DRUG INTERACTIONS

A number of drugs affect glucose metabolism and may require insulin dose adjustment and particularly close monitoring.

The following are examples of drugs that may increase the blood-glucose-lowering effect of insulins including LANTUS and, therefore, increase the susceptibility to hypoglycemia: oral anti-diabetic products, pramlintide, angiotensin converting enzyme (ACE) inhibitors, disopyramide, fibrates, fluoxetine, monoamine oxidase inhibitors, propoxyphene, pentoxifylline, salicylates, somatostatin analogs, and sulfonamide antibiotics.

The following are examples of drugs that may reduce the blood-glucose-lowering effect of insulins including LANTUS: corticosteroids, niacin, danazol, diuretics, sympathomimetic agents (e.g., epinephrine, albuterol, terbutaline), glucagon, isoniazid, phenothiazine derivatives, somatropin, thyroid hormones, estrogens, progestogens (e.g., in oral contraceptives), protease inhibitors and atypical antipsychotic medications (e.g. olanzapine and clozapine).

Beta-blockers, clonidine, lithium salts, and alcohol may either potentiate or weaken the blood-glucose-lowering effect of insulin. Pentamidine may cause hypoglycemia, which may sometimes be followed by hyperglycemia.

The signs of hypoglycemia may be reduced or absent in patients taking sympatholytic drugs such as beta-blockers, clonidine, guanethidine, and reserpine.

8. USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category C: Subcutaneous reproduction and teratology studies have been performed with insulin glargine and regular human insulin in rats and Himalayan rabbits. Insulin glargine was given to female rats before mating, during mating, and throughout pregnancy at doses up to 0.36 mg/kg/day, which is approximately 7 times the recommended human subcutaneous starting dose of 10 Units/day (0.008 mg/kg/day), based on mg/m^2. In rabbits, doses of 0.072 mg/kg/day, which is approximately 2 times the recommended human subcutaneous starting dose of 10 Units/day (0.008 mg/kg/day), based on mg/m^2, were administered during organogenesis. The effects of insulin glargine did not generally differ from those observed with regular human insulin in rats or rabbits. However, in rabbits, five fetuses from two litters of the high-dose group exhibited dilation of the cerebral ventricles. Fertility and early embryonic development appeared normal.

There are no well-controlled clinical studies of the use of LANTUS in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. It is essential for patients with diabetes or a history of gestational diabetes to maintain good metabolic control before conception and throughout pregnancy. Insulin requirements may decrease during the first trimester, generally increase during the second and third trimesters, and rapidly decline after delivery. Careful monitoring of glucose control is essential in these patients.

8.3 Nursing Mothers

It is unknown whether insulin glargine is excreted in human milk. Because many drugs, including human insulin, are excreted in human milk, caution should be exercised when LANTUS is administered to a nursing woman. Use of LANTUS is compatible with breastfeeding, but women with diabetes who are lactating may require adjustments of their insulin doses.

8.4 Pediatric Use

The safety and effectiveness of subcutaneous injections of LANTUS have been established in pediatric patients (age 6 to 15 years) with type 1 diabetes *[see Clinical Studies (14) in the full prescribing information]*. LANTUS has not been studied in pediatric patients younger than 6 years of age with type 1 diabetes. LANTUS has not been studied in pediatric patients with type 2 diabetes.

Based on the results of a study in pediatric patients, the dose recommendation when switching to LANTUS is the same as that described for adults *[see Dosage and Administration (2.3)* and *Clinical Studies (14) in the full prescribing information]*. As in adults, the dosage of LANTUS must be individualized in pediatric patients based on metabolic needs and frequent monitoring of blood glucose.

8.5 Geriatric Use

In controlled clinical studies comparing LANTUS to NPH insulin, 593 of 3890 patients (15%) with type 1 and type 2 diabetes were ≥65 years of age and 80 (2%) patients were ≥75 years of age. The only difference in safety or effectiveness in the subpopulation of patients ≥65 years of age compared to the entire study population was a higher incidence of cardiovascular events typically seen in an older population in both LANTUS and NPH insulin-treated patients.

Nevertheless, caution should be exercised when LANTUS is administered to geriatric patients. In elderly patients with diabetes, the initial dosing, dose increments, and maintenance dosage should be conservative to avoid hypoglycemic reactions. Hypoglycemia may be difficult to recognize in the elderly *[See Warnings and Precautions (5.3)]*.

10. OVERDOSAGE

An excess of insulin relative to food intake, energy expenditure, or both may lead to severe and sometimes prolonged and life-threatening hypoglycemia. Mild episodes of hypoglycemia can usually be treated with oral carbohydrates. Adjustments in drug dosage, meal patterns, or exercise may be needed.

More severe episodes of hypoglycemia with coma, seizure, or neurologic impairment may be treated with intramuscular/subcutaneous glucagon or concentrated intravenous glucose. After apparent clinical recovery from hypoglycemia, continued observation and additional carbohydrate intake may be necessary to avoid recurrence of hypoglycemia.

Rev. September 2009
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LANTUS®
(insulin glargine [rDNA origin] injection) solution for subcutaneous injection

INDEX OF ADVERTISERS

ACO Concept Generating Activity, Discussion

Accountable care organization allows groups of providers to work together to treat patients.

BY MARY ELLEN SCHNEIDER

Accountable care organizations are garnering a lot of attention as a way to reform how health care is paid for in the United States, but just about the only thing that experts can agree on right now is that the ACO concept is still in its infancy.

"This is sort of an evolving area of health policy, and it's not exactly clear that, when people are talking about ACOs, [everyone] has the same thing in mind," said Dr. Francis J. Crosson, senior fellow in the Kaiser Permanente Institute for Health Policy in Oakland, Calif., and a member of a task force on ACOs that was recently convened by the National Committee for Quality Assurance (NCQA).

In general, ACOs would allow primary care physicians, specialists, and hospitals to form a partnership to provide care to a group of patients. The idea is that all the providers would work together to improve quality and manage costs, and that they would share in any savings that were produced as a result. A few models already exist for both pediatric and adult populations.

While many hospitals are still just contemplating their potential role in an ACO, Nationwide Children's Hospital in Columbus, Ohio, is billing itself as the country's largest pediatric ACO. It offers one model for how to pursue this concept in the care of children.

Starting about 5 years ago, Nationwide officials partnered with the state of Ohio to assume financial risk in treating children who were covered by the Medicaid managed care program in central and southeast Ohio. To help run the program, they formed a nonprofit physician-hospital organization called Partners for Kids that includes not only Nationwide-employed physicians but also other physicians working in the community.

'This is sort of an evolving area of health policy, and it's not exactly clear that, when people are talking about ACOs, [everyone] has the same thing in mind.'

Under the arrangement, Partners for Kids receives a capitated fee to care for about 285,000 pediatric Medicaid recipients. The organization contracts with three Medicaid managed care plans that retain a percentage of the Medicaid premium to provide claims processing, member relations, and other medical management functions. The hospital and physicians assume the business risk for clinical and financial outcomes.

The idea was to move away from the conventional fee-for-service model while improving access for children who might otherwise have difficulty finding a physician, said Dr. Steve Allen, chief executive officer for Nationwide. For example, Partners for Kids pays primary care physicians in rural areas an increased fee to keep their panels open for these Medicaid patients.

"We saw this as an opportunity to change the paradigm so that we could improve access," Dr. Allen said.

Officials at Nationwide Children's Hospital have conducted an analysis of the current ACO landscape and found that about a dozen institutions around the country are planning to develop or have launched some type of a pediatric ACO, with sizes ranging from 30,000 patients to Nationwide's high of 285,000. Most of the more developed models are among integrated delivery systems, Dr. Allen said.

One integrated system looking to become an ACO is University Hospitals in northeast Ohio.

Participating in an ACO will mean shifting the system's focus from an acute, episodic care model to a prevention and wellness model, according to Dr. Eric Bieber, chief medical officer at University Hospitals Case Medical Center and Rainbow Babies and Children's Hospital.

"Health care in its present design is highly episodic. It doesn't relate one piece to the other," he said. Switching to an ACO model "is a transformational change in how care is going to be delivered."

There has been a lot of buzz around ACOs since the passage of the Affordable Care Act. The massive health reform law includes three sections with implications for forming ACOs. The section that has received the most attention is the Medicare shared-savings program, which will allow groups of providers to work together to treat patients and to share in any savings they achieve. That program is set to launch in January 2012. CMS is expected to put out its criteria for the shared-savings program sometime this fall.

ACOs may also end up being part of testing performed by the Center for Medicare and Medicaid Innovation, a new office created under the law. The innovation center has broad authority to test new payment ideas and will launch in January 2011.

Finally, the Affordable Care Act includes a pediatric ACO demonstration project that allows states to recognize pediatric medical providers as ACOs and to award incentive payments through Medicaid. That project is also expected to launch in January 2012.

Since the passage of the Affordable Care Act, there's been a "flurry of activity" going on around the country, similar to what happened in the early 1990s around the growth of HMOs and capitation, said Dr. Crosson of the Kaiser Permanente Institute. "All over the country, hospital boards are going off with their medical staffs and asking the question, 'Do we want to become an ACO?' "

In the near term, there is likely to be a range of ACO models, Dr. Crosson predicted. Some will be tightly constructed around integrated delivery systems in which physicians and hospitals are part of the same economic entity. Other will be looser models that bring together a group of physicians and hospitals that are financially separate from one another, he said.

The real question, Dr. Crosson noted, is not whether various models can be designed, but which ones will work best. And for that, he said, only time will tell. ■

Naseem S. Miller contributed to this report.

Continued from previous page

ment of the Treasury urging it not to allow trial lawyers to deduct court costs and other expenses. Making such a change to tax law could encourage trial lawyers to file more claims, the organizations claimed. "Even though a substantial majority of claims are dropped or decided in favor of physicians, the cost of defending against meritless claims averages over $22,000," their letter said. The organizations urged the treasury department to reconsider rumored plans to change current policy, which does not allow such tax deductions.

Workers' Premium Share Jumps

Workers who receive health insurance through their employers are paying nearly $4,000 in 2010 for family health coverage, an increase of 14% from 2009, according to a report by the Kaiser Family Foundation and the Health Research and Educational Trust. However, the total cost of coverage, including employers' contributions, hasn't climbed as much: Average total premiums for family coverage rose 3% in 2010 to $13,770, the survey found. Since 2005, workers' contributions to premiums have risen 47%, while overall premiums rose 27%, the organizations reported. Many companies have raised deductibles for workers: A total of 27% of workers now face annual deductibles of at least $1,000, compared with 22% who faced these high deductibles in 2009, the survey found. "If premiums and costs continue to be shifted to consumers, households will face difficult choices, like forgoing needed care or re-examining how they can best care for their families," Maulik Joshi, Dr.P.H., president of the Health Research and Educational Trust Association, said in a statement.

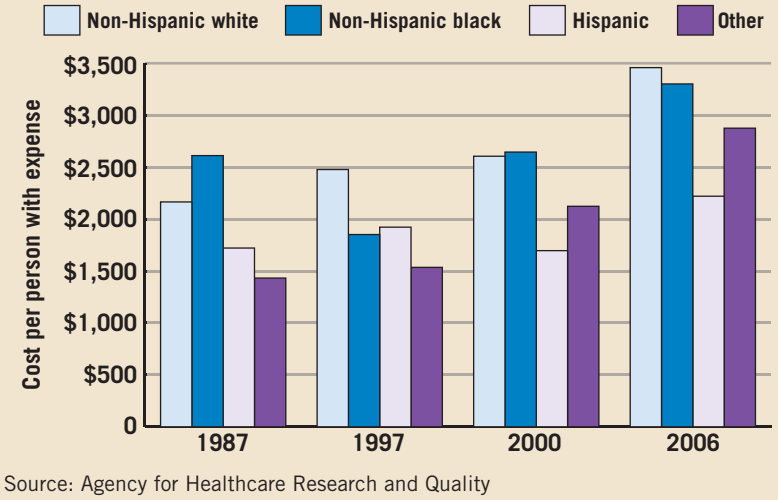
Prescription Drug Use Rises Again

The percentage of Americans who said they took at least one prescription drug in the past month increased from 44% to 48% from 1999 to 2008, according to a report from the Centers for Disease Control and Prevention. At the same time, the number of people who said they had taken two or more drugs in previous month increased from 25% to 31%, and the number of people who took five or more drugs increased from 6% to 11%, the report found. One out of every five children used one or more prescription drugs, as did 90% of adults aged 60 years and older. Women were more likely to have taken a prescription drug. Those who didn't have health insurance, prescription drug coverage, or a regular place to receive health care tended to take fewer prescriptions. The most commonly prescribed drugs included asthma medicines for children, central nervous system stimulants for adolescents, antidepressants for middle-aged adults, and cholesterol-lowering drugs for older Americans, the report found. The data came from the National Health and Nutrition Examination Survey.

—Jane Anderson

DATA WATCH

Annual Health Care Expenses Lowest for Hispanics



Source: Agency for Healthcare Research and Quality