Medicare set to monitor adverse effects of drugs

Aiming to uncover the long-term side effects of new drugs, the US Medicare program in May announced plans to create a database cataloging patients' prescriptions and health outcomes.

Medicare is a federal health insurance program for seniors and those with disabilities. Mark McClellan, administrator of the Center for Medicare and Medicaid Services, says the database will allow doctors to record the frequency of side effects and determine which patients are most likely to experience adverse reactions. The plan will take advantage of the large number of subscribers expected to participate in Medicare's new prescription drug plan. The center plans to consult with the US Food and Drug Administration and other organizations over the next few months to set program details.

Other organizations have announced similar schemes. The US National Institutes of Health has funded a plan to create a virtual data warehouse that would integrate the medical and pharmacy records of millions of patients across the country (*Nature Medicine* **11**, 465; 2005). The European Medicines Agency plans to create a similar database spanning its 42 national health authorities.

US academy sets rules for stem cell research

US scientists are set to adopt a new set of guidelines for stem cell research, released in April by the National Academy of Sciences.

The committee's report recommends that local and national oversight boards, which should include scientific, legal and ethical experts, be established to review stem cell research proposals. The guidelines also emphasize that egg and embryo donors should not be paid.

The report also calls for oversight of human-animal chimeras—animals that have been injected with human stem cells or vice versa. Animal stem cells should not be transplanted into early human embryos, or blastocysts, and animals with human embryonic stem cell implants should not be allowed to breed, it suggests.

The guidelines are similar to the self-imposed rules already in place at universities and institutes that conduct stem cell research. Although voluntary, they are expected to be widely adopted. The academy says the recommendations fill a regulatory gap left by the US government.

News briefs written by Emily Singer

UK okays screening for 'savior siblings'

Embryonic screening took a step forward in May when the British House of Lords ruled that parents of children with serious genetic disorders can select embryos that could help treat a sick child. The ruling follows a decision by the UK's Human Fertilization and Embryology Authority last November to allow screening for a genetic variation that can lead to early colon cancer (*Nat. Med.* **10**, **1266; 2004**).

Parent advocates have pushed for the ruling to permit screening for life-threatening conditions such as Huntington disease and cystic fibrosis. Critics say embryo selection could lead to 'designer babies' selected for appearance or intelligence.

The unanimous vote upholds a 2003 High Court ruling allowing a British family to use preimplantation genetic diagnosis to select a baby to help their six-year-old son, who has beta thalassemia, a rare and potentially fatal blood disorder. A baby of the same blood type could provide stem cells from its umbilical cord that would theoretically cure the afflicted boy.

Parents Raj and Shahana Hashmi had tried unsuccessfully to have a tissue-matched baby by natural means and have not had children since beginning fertility treatment in 2003. It is unclear whether they will continue the treatment.

US to investigate AIDS drug trials in foster kids

Allegations over improper conduct in pediatric HIV trials surfaced in May, with reports that foster children given experimental treatments may not have received the outside support they were promised. The charges follow similar accusations last year about trials in New York City foster children (*Nat. Med.* **11**, 5; 2005).

During the 1990s, the US National Institutes of Health sponsored dozens of trials to test the effectiveness in children of HIV drugs approved for adults. Foster care agencies participated in these trials to allow HIV-positive children in their care access to the newest treatments.

Some drugs increased the lifespan of the HIV-positive children, but a few studies also reported serious side effects. One study in Illinois found a higher death rate among children taking the anti-infective dapsone, although deaths were not directly linked to the medication.

US Department of Health and Human Services regulations mandate that foster children participating in risky drug trials be appointed independent advocates. But institutions in at least three states—Illinois, New York and Maryland—did not provide advocates, according to a report in the Associated Press. Some participating institutions have said that because the drugs had previously been tested in adults, they did not classify the pediatric trials as high risk. The Office for Human Research Protections is now investigating the matter.

Lizard spits up diabetes drug

The first of a new class of diabetes drugs derived from lizard spit will soon hit the shelves. The US Food and Drug Administration in late April approved the drug Byetta, a synthetic version of a peptide found in the saliva of Gila monsters. The drug has only been approved for use in patients with type 2 diabetes who take the oral drugs metformin or sulfonylurea, but not insulin, to control their blood sugar.

The drug, developed by Amylin Pharmaceuticals, Inc. in San Diego and Eli Lilly in Indianapolis, resembles the human hormone glucagon-like peptide-1. It stimulates the release of insulin, thereby slowing digestion and stabilizing blood sugar. Unlike many other drugs, Byetta stimulates insulin release only when glucose levels are high and stops its action when glucose levels are in the normal range, which means the drug carries a low risk for hypoglycemia (*Nat. Med.* **9**, 1228; 2004).

The lizard compound has a relatively long half-life of two hours, compared with the two-minute half-life of the human homolog, making it better suited for pharmaceutical use. But it also has potential drawbacks: it must be injected twice a day and must be refrigerated. About six million diabetics may qualify for Byetta; analysts estimate the drug could bring in $1 billion per year.