
Office of Surveillance and Epidemiology

Contracts expand rapid evaluation of newly marketed drugs

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In the Office of Surveillance and Epidemiology, we have strengthened our ability evaluate the safety of newly marketed drugs faster and more effectively. In September, we awarded four contracts at \$1.6 million a year that give us access to databases that include more than 20 million patients in different geographic areas and include special populations. These contracts provide for up to five years of access to data resources that can be used to:

- Conduct safety analyses to benefit the public health.
- Respond in a timely manner to urgent public safety concerns.
- Provide a mechanism for collaborative pharmacoepidemiological research designed to test hypotheses, particularly those arising from suspected adverse reactions reported to us.
- Enable our rapid access to U.S. population-based data sources to ensure public safety when necessary.

In the past, our collaboration with researchers who have pharmacoepidemiologic databases was through a cooperative agreement or grant mechanism. This same type of research collaboration to conduct pharmacoepidemiologic studies will now occur through a contract mechanism. This will give us more flexibility

and access to a wider range of data resources. The contractors and their unique resources are:

- *Kaiser Foundation Research Institute* has large, fully integrated databases, some dating back to 1981, representing all 6.1 million current Kaiser Permanente members in northern and southern California. The Kaiser databases are linked annually to state vital statistics and cancer registry files. . Electronic records will be fully implemented in 2006.
- *I3 Drug Safety* has access to claims data on a very large, geographically diverse, insured population having a total membership of 12 million (United Health Care). This contract also allows us to use i3 Drug Safety's new Web-based tool that allows us to quickly assess the feasibility of many drug safety studies relating to new molecular entities. Some laboratory data are also available.
- *Harvard Pilgrim Healthcare* represents a large experienced HMO research network of eight health plans geographically diversified within the states of Massachusetts, Maine, Minnesota, Washington, Colorado, Georgia and New Mexico having a total membership of 3.2 million. Electronic medical records are available for six of the eight sites.
- *Vanderbilt University* represents small but

ethnically diversified, state Medicaid populations who are medically at high risk, such as those with HIV infection, the poor, psychiatric patients and nursing home residents. These data represent 2.2 million recipients in Tennessee and Washington. This site includes

data as far back as 1974 in Tennessee and also has linked maternal-child, cancer registry and other encounter files.

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