Adverse Event Reporting System (AERS)
Office of Pharmacoepidemiology and Statistical Science
Brief Description with Caveats of System
July 18, 2005

The Adverse Events Reporting System (AERS) in the Office of Pharmacoepidemiology and Statistical Science (OPSS) was implemented to take advantage of up-to-date methods for data entry and database design. AERS contains all reports received since November 1, 1997.

Background

The AERS database is a computerized system for storing adverse events reported by health professionals and others. The system contains adverse events detected and reported after marketing of the drug.

AERS relies on health professionals to detect new clinical events, to attribute the appearance of the clinical event to the administration of a drug, and to report that clinical event. The information contained in these reports has not been scientifically or otherwise verified as to a cause and effect relationship and cannot be used to estimate incidence of adverse drug reactions.

The health professional may choose to report the adverse reaction to the FDA or to a drug firm, who must, by law, report to the FDA. Ninety percent of the FDA's reports are received from drug manufacturers. OPSS receives the remaining ten percent directly from other reporters (i.e. Health Professionals and consumers).

Individual Safety Reports (ISRs)

Data from all reports are entered into AERS and the report images are scanned into an Electronic Filing System (EFS). All reports are retrieved by accessing the Individual Safety Report (ISR) number.

Copies of individual case safety reports, which are summarized in this printout, may be obtained by submitting a separate Freedom of Information Act (FOIA) request. When requests are submitted for copies of report images, the ISR number should be listed in tabular format in ascending order as shown in the following example:

ISR NUMBER
3000913
3000917
3001581

There may be a $38.00/hour search and review time and a $ 0.10 page reproduction charge for ISRs. Please note that there will be redactions made to all potential personal identifiers on the report. Information on how to submit a FOIA request can be found at http://www.fda.gov/opacom/backgrounders/foiahand.html

Definitions of the FOI Report

Date	Date the report was received by the FDA.
ISR Number	Unique number for identifying an AERS report.
Report Type	The type of ISR received. Expedited (15-day) and periodic reports are from manufacturers; "direct" reports are voluntarily submitted to the FDA by non-manufacturers.

Report Type	Description
Expedited (15-day)	Mandatory reports received from the manufacturer informing the FDA of adverse events that are both serious and unexpected. By law, these reports must be delivered to the FDA, within 15 calendar days of the initial receipt by the manufacturer.
Periodic	These are mandatory reports that do not fall into the expedited category. These reports are delivered quarterly to the FDA.
Direct	These reports are from health professionals, private individuals or sources other than manufacturers.

Company Report Number	Manufacturer's unique report identifier.
Age	Numeric value of patient's age at event.
Gender	The gender of the patient (male, female, unknown, or Not specified).
Outcome	The results of the adverse event as. The following events are potential choices.

Outcome	DESCRIPTION
DE	Death
LT	Life-Threatening
HO	Hospitalization – Initial or Prolonged
DS	Disability
CA	Congenital Anomaly
RI	Required Intervention to prevent permanent impairment/damage
OT	Other

PT (Preferred Term)	The reported reaction, in medical terminology, describing the event. This is coded using the Medical Dictionary for Regulatory Activities (MedDRA).
Report Source	Identifies the initial source of the report. (I.e., Health Professional, Consumer, etc..)
Product	Name of drug.
Role	S = Suspect C = Concomitant PS = Primary Suspect SS = Secondary Suspect
*Suspect Drug	The drug that the initial reporter deemed most likely to be associated with the reactions.
Concomitant Drug	A list of any drugs taken at the same time as the suspect medication, but not suspected of causing the adverse event.
Manufacturer	The company that manufacturers the drug.
Route	Route of administration of the drug.
Dose	Quantity of drug administered in a 24-hour period.
Units	Modifies the dose with units of measurements (e.g., mg, IU, ml, etc.).
Duration	Number of days the drug was used.

CAVEATS:

There are some important things to remember when reviewing or analyzing data from AERS.

1. Reports contain only those reactions voluntarily submitted either directly to the FDA or to the drug manufacturer by consumers and/or members of the health profession and which have been entered into the AERS computerized filing system since November 1,1997.

2. The information contained in the reports has not been scientifically or otherwise verified.

3. For any given report, there is no certainty that the suspected drug caused the reaction. This is because physicians are encouraged to report suspected reactions. The event may have been related to the underlying disease for which the drug was given to concurrent drugs being taken or may have occurred by chance at the same time the suspected drug was taken.

4. Accumulated case reports cannot be used to calculate incidence or estimates of drug risk.

5. Numbers from these data must be carefully interpreted as reporting rates and not occurrence rates. True incidence rates cannot be determined from this database. Comparisons of drugs cannot be made from these data.