

# Existing Reporting Systems

**This document provides an overview of the following existing medical care reporting systems:**

- ❶ State Adverse Event Tracking
- ❷ Food and Drug Administration (FDA)
  - Spontaneous reporting systems—for drugs and therapeutic biological products
    - MedWatch
    - Adverse Event Reporting System (AERS)
    - Center for Biologics Evaluation and Research (CBER) Error and Accident Reporting System (CEARS)
    - Drug Quality Reporting System (DQRS)
  - Spontaneous reporting systems—for blood and blood components
  - Spontaneous reporting systems—for vaccines
    - Vaccine Adverse Event Reporting System (VAERS)
  - Spontaneous reporting systems—for devices
    - Manufacturer and User Device Experience (MAUDE) Database
- ❸ The Joint Commission on the Accreditation of Health Care Organizations (JCAHO) Sentinel Event Reporting
- ❹ USP-ISMP Medication Error Reporting (MER) Program
- ❺ MedMARx
- ❻ ECRI Medical Device Safety Reports (MDSR)

## ① State Adverse Event Tracking

A February 2000 survey of states by the National Academy for State Health Policy explored current state activities to assess and address the issue of medical error reporting. The principal purpose of the survey was to determine the extent to which states require reporting of serious adverse events attributable to errors in hospital settings. A secondary purpose was to collect more general information on similar reporting requirements in other settings of care, exclusive of nursing facilities.

The survey was mailed to state licensure and certification contacts in all 50 states and the District of Columbia with a copy to state public health officers. All 50 states and the District of Columbia responded to the survey. The results provide a snapshot of activities that states are undertaking to track and reduce medical errors and adverse events.

Among the survey's findings:

- The survey confirmed the lack of universal use or interpretation of the terms “medical error” and “adverse event” as employed by the Institute of Medicine’s report. No states have a definition of medical error. Two states use the term “adverse event.” Six states have a standard definition of a term that is similar to adverse event, but the term and the definition vary among the states. Seven states report they do not have a standard definition of adverse event but, instead, specify which types of events must be reported.
- Fifteen states (Colorado, Florida, Kansas, Massachusetts, Nebraska, New Jersey, New York, Ohio, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, and Washington) require mandatory reporting from general and acute care hospitals of adverse events, as defined by the IOM or by the state in a way that encompasses part or all of the IOM definition. An adverse event is defined by the IOM as an injury caused by medical management rather than the underlying disease or condition of the patient.
- Six states (Georgia, New Mexico, North Carolina, Oregon, Wyoming, and D.C.) have voluntary reporting systems for medical errors or adverse events.
- Six additional states (Iowa, Kentucky, Maine, Missouri, North Dakota, and New Hampshire) have pending legislation to require reporting of medical errors or adverse events.
- While 12 of the 15 states that require mandatory reporting from hospitals do so for unexpected patient deaths, much variation exists in the other types of events that must be reported, including major loss of function, wrong site surgery, and medication errors.
- Of the 15 states that require mandatory reporting from hospitals, 13 also require reporting from freestanding ambulatory care settings, and 12 require reporting from psychiatric hospitals.

- Most states that require mandatory reporting indicate that they protect at least some reports from legal discovery, although states vary in the types of information and reports that are protected. Five states protect data in the case of a request under the Freedom of Information Act.
- Seven states protect access to person-level reports, the most frequent method of protecting reports. Five states provide a promise of confidentiality, the second most frequent response. Various other methods of protecting data include removing certain identifying information, anonymous reporting, and destroying reports once data are extracted.
- The most frequent use of data from reports is aggregating data to identify trends, reported in ten states with mandatory reporting. Nine states administer sanctions and assure corrective action; eight states issue public reports.
- States cite under-reporting and inadequate resources as their two greatest concerns with their reporting systems.
- Using medical error reporting data to improve public safety is still an issue with which states are grappling; two states are using data to develop quality improvement projects. Many others noted this area as one of their greatest technical assistance needs.

The survey provides a snapshot of what states are doing to track and reduce medical errors and adverse events. The National Academy for State Health Policy will conduct phone interviews, site visits, and expert meetings in the coming months to assist states as they explore the issues involved in reducing errors and improving patient safety.

Source: *State Reporting of Medical Errors and Adverse Events: Results of a 50-State Survey—Executive Summary*, April 2000, a publication of the National Academy for State Health Policy.

## ② Food and Drug Administration (FDA)

A vital part of FDA's mission is to ensure that medical products currently available in the United States are safe and effective. The Agency monitors marketed human medical products for unexpected adverse events. FDA surveillance programs alert the Agency to potential threats to the public health and help Agency experts identify the need for preventive actions, such as changes in product labeling information and, rarely, reevaluation of an approval decision. Reports submitted to FDA are one part of the surveillance system for monitoring adverse events associated with medical products after their approval (referred to as “postmarketing surveillance”).

The various approaches the Agency is using for postmarketing surveillance are described briefly in the following pages. The program descriptions are grouped according to the type of product being monitored and the Center doing the monitoring.

### Spontaneous reporting systems — for drugs and therapeutic biological products

FDA receives spontaneous reports of *suspected* adverse events from manufacturers (required by law and regulation to report to FDA), from user facilities, and from healthcare professionals or consumers. Through a program called MEDWATCH, the FDA Medical Products Reporting Program, healthcare professionals and consumers are encouraged to report serious adverse events and product problems to the FDA, the manufacturer, or both. MEDWATCH has established four methods for the public to report to FDA: phone (via a toll-free number), fax, direct mail (using a postage-paid form), and Internet (via the interactive form on the MEDWATCH website). All MEDWATCH reports are expeditiously transferred to the appropriate Center (i.e., Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research, Center for Devices and Radiological Health) for evaluation and entry into one of the following database systems. (see sample forms for voluntary and mandatory reporting at the end of this section)

### *Adverse Event Reporting System (AERS)*

FDA's adverse event database for drugs and therapeutic biological products, the Adverse Event Reporting System (AERS), contains approximately 2 million reports. In FY 1998, more than 230,000 reports of suspected adverse events were received by AERS.

The FDA evaluates spontaneous reporting data from AERS to identify any serious, rare, or unexpected adverse events or an increased incidence of events. When a signal of a potential adverse reaction is detected, safety evaluators consult with product reviewers, medical officers, and epidemiologists to review available data and consider further options. Focused studies may be undertaken using various epidemiological and analytical databases and other resources. Based on the results of these studies and evaluations, FDA may decide to disseminate risk information, such as Dear Healthcare Professional letters, and may initiate regulatory action.

The Agency recognizes that surveillance should focus particularly on medical products in the immediate postmarketing period and is refining its programs to ensure that these products receive special attention.

*Center for Biologics Evaluation and Research (CBER) Error and Accidents Reporting System (CEARS)*

Errors and accidents in the manufacture of biological products are required to be reported to FDA by the product manufacturer. An error or accident is a deviation from current good manufacturing practice (CGMP) regulations, applicable standards, or established specifications, or an unexpected, unforeseen event that may affect the safety, purity, or potency of a biological product, or otherwise cause the product to be in violation of the FD&C Act or the Public Health Service Act. Among other examples, reportable errors and accidents may relate to labeling, storage and distribution, or testing of a biological product.

FDA receives approximately 13,000 reports per year from biological product manufacturers. In the past 2 years, there has been a significant increase in reports submitted by the non-blood industry, including the manufacturers of vaccines, therapeutics, in vitro diagnostics, and plasma derivatives. FDA reviews and evaluates reports of errors and accidents to determine if a recall is needed. Approximately 13 percent of the reports received in fiscal year 1998 were forwarded to the appropriate district office for follow-up and evaluation as potential recall situations. Error and accident reports are coded based on the type of error or accident and entered into a database. Quarterly and annual summary reports are prepared from these data. District offices can access the error and accident database through the CBER CEARS to aid in preparation for inspections.

*Drug Quality Reporting System (DQRS)*

Manufacturers of prescription medical products are required to submit adverse event reports to the FDA. In addition, drug and biological product manufacturers must submit either error and accident reports or drug quality reports when deviations from current good manufacturing practice (CGMP) regulations occur. The Drug Quality Reporting System (DQRS) receives reports of deviations from CGMPs that occur during the manufacturing, shipping, or storage of prescription or over-the-counter drug products. Despite FDA's surveillance activities and enforcement of CGMPs, some drug quality defects will occur and may occasionally pose a threat. Drug quality concerns include a number of hazards, which may be due to improper formulation, packaging, or labeling.

Information reported to the DQRS is currently entered by a contractor and retrieved using an on-line system. The system is being evaluated for possible integration with AERS (see previous page). In fiscal year 1998, some 2,500 reports were received, resulting in the initiation of 11 recalls. Most of the recalls were due to labeling violations.

### *Medication Error Reports*

FDA receives medication error reports from consumers and health professionals on marketed human drugs (including prescription drugs, generic drugs, and over-the-counter drugs) and non-vaccine biological products and devices. Medication errors can occur when prescribing, repackaging, dispensing, or administering a product. Common causes of medication errors include poor communication, patient misunderstanding, and ambiguities in product names or directions for use.

In 1992, the FDA began monitoring medication error reports that are forwarded to FDA from the United States Pharmacopeia (USP) and the Institute for Safe Medication Practices (ISMP). The Agency also reviews MEDWATCH reports for possible medication errors. Currently, medication errors are reported to the FDA as manufacturer reports (adverse events resulting in serious injury and for which a medication error may be a component), direct contact reports (MEDWATCH), or reports from USP, or ISMP.

FDA maintains a central database within the DQRS and AERS for all reports involving a medication error or potential medication error. The database contains some 7,000 reports. Unlike reports of adverse events, which always involve patient injury, medication error reports can be reported as errors with no patient injury, errors with patient injury, and potential errors (e.g., the report of a confusing product name).

FDA reviews and acts on medication errors that relate to product labeling and/or packaging. The Agency puts substantial effort into reviewing case reports to identify serious or potentially serious outcomes that might be avoided by modifying the labeling or packaging. Each report is analyzed to determine causality. Categorizing medication errors helps the Agency perform trend analyses and make recommendations to the reviewing divisions for potential regulatory action.

### Spontaneous reporting systems — for blood and blood components

The blood bank and source plasma industry submits the majority of error and accident reports received by the Center for Biologics. Most of these reports relate to donor suitability. A proposed rule that published in 1997 would expand the reporting requirement for licensed facilities to include unlicensed blood establishments and transfusion services.<sup>1</sup>

When a blood transfusion (or blood collection) complication is confirmed to be fatal, it must be reported to FDA within 7 days. This information is used for risk assessment and communication of risk to blood establishments, transfusion services, and physicians. Note that adverse events associated with therapeutic plasma-derivative products (such as hemoglobin) are reported in the same way as adverse events associated with drugs and other therapeutic biological products.

---

<sup>1</sup> This proposed rule was published in the *Federal Register* on September 23, 1997, 62 FR 49642.

## Spontaneous reporting systems — for vaccines

### *Vaccine Adverse Event Reporting System (VAERS)*

Postmarketing surveillance for vaccines is handled by the Vaccine Adverse Event Reporting System (VAERS), which is independent of other FDA spontaneous reporting systems. Established in 1990, VAERS is jointly managed by FDA (the Center for Biologics' Division of Biostatistics and Epidemiology) and Centers for Disease Control and Prevention (Vaccine Safety Activity, National Immunization Program). Representatives of both agencies oversee data processing and database management performed by a contractor.

VAERS receives 11,000 to 12,000 reports per year. Approximately 15 percent of the reports describe a *serious* event, defined as either fatal, life-threatening, or resulting in hospitalization or permanent disability. Selected reports of serious events and all reports of fatalities are followed up individually by a health professional. Autopsy reports, as well as other medical records, are retrieved when available. Medical staff carefully monitor trends in adverse event reporting for vaccines, with particular attention to newly licensed vaccines. In addition to monitoring reports according to vaccine type, reports are monitored according to the vaccine lot.

## Spontaneous reporting systems — for devices

### *Manufacturer and User Device Experience (MAUDE) Database*

In 1984, FDA implemented the Medical Device Reporting (MDR) program, which required manufacturers to report device-related adverse events to FDA. In 1990, the Safe Medical Device Act (SMDA) amendments expanded FDA's authority by requiring that user facilities (e.g., hospitals and nursing homes) report device-related serious injuries to the manufacturer and device-related deaths to the manufacturer and directly to FDA. The Agency receives approximately 80,000 to 85,000 device-related adverse event reports every year. The bulk of the reports are from manufacturers, with user facilities submitting only about 5,000 of this total. The Manufacturer and User Device Experience (MAUDE) database, established in 1995 to support the SMDA, contains approximately 300,000 reports.

When received, reports are first triaged by medical professionals. In general, the criteria for taking action relate to the unexpectedness and seriousness of the event, the vulnerability of the population affected, and the preventability of the event. Reports that involve pediatric death, explosion, and/or multiple injuries from one device, are sent immediately to supervisors of the report review staff for evaluation and further action, if necessary. All reports are entered into the MAUDE database, subjected to a quality control procedure, and then sent to the clinical analysts for review within 48 hours of receipt. Clinical analysts review and assess the adverse event reports. Each analyst is responsible for products within a specific medical specialty or for products that have common design or material features. Here, as with drugs and biological products, the

analysts' experience and familiarity with the products play a significant role in the evaluation of these reports.

Source: *Managing the Risk of Medical Product Use: Creating a Risk Management Framework*, U.S. Department of Health and Human Services, Food and Drug Administration, May 1999

### ③ **The Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) Sentinel Event Reporting System**

The Joint Commission evaluates and accredits nearly 20,000 health care organizations and programs in the United States, including hospitals, health care networks, managed care organizations, and health care organizations that provide home care, long term care, behavioral health care, laboratory, and ambulatory care services. The Joint Commission is an independent, not-for-profit organization.

JCAHO initiated a sentinel event reporting system for hospitals in 1996. Sentinel events subject to reporting are those that have resulted in an unanticipated death or major permanent loss of function not related to the natural course of the patient's illness or underlying condition, or an event that meets one of the following criteria (even if the outcome was not death or major permanent loss of function): suicide of a patient in a setting where the patient receives around-the-clock care; infant abduction or discharge to the wrong facility; rape; hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities; or surgery on the wrong patient or wrong body part (see sample form for reporting sentinel events at the end of this section). JCAHO requires that an organization experiencing a sentinel event conduct a root cause analysis, a process for identifying the basic or causal factor of the event.

In support of its mission to improve the quality of health care provided to the public, the Joint Commission includes the review of organizations' activities in response to sentinel events in its accreditation process, including all full accreditation surveys and random unannounced surveys.

Accredited organizations are expected to identify and respond appropriately to all sentinel events (as defined by the organization in accordance with the preceding paragraph) occurring in the organization or associated with services that the organization provides, or provides for. Appropriate response includes conducting a timely, thorough, and credible root cause analysis, implementing improvements to reduce risk, and monitoring the effectiveness of those improvements.

Root cause analysis is a process for identifying the causal factors that underlie variation in performance, including the occurrence or possible occurrence of a sentinel event. A root cause analysis focuses primarily on systems and processes, not individual performance. It progresses from special causes in clinical processes to common causes in organizational processes and identifies potential improvements in processes or systems that would tend to decrease the likelihood of such events in the future, or determines, after analysis, that no such improvement opportunities exist.

The product of the root cause analysis is an action plan that identifies the strategies that the organization intends to implement to reduce the risk of similar events occurring in the

future. The plan should address responsibility for implementation, oversight, pilot testing as appropriate, time lines, and strategies for measuring the effectiveness of the actions.

When conducting an accreditation survey, the Joint Commission seeks to evaluate the organization's compliance with the applicable standards and to score those standards based on performance throughout the organization, over time (e.g., the preceding 12 months for a full accreditation survey). For this reason, surveyors are instructed not to seek out specific sentinel events beyond those already known to the Joint Commission. During a full accreditation survey, the surveyor will assess the organization's compliance with sentinel event-related standards by:

- reviewing documents that describe the organization's process for responding to a sentinel event
- interviewing the organization's leaders and staff about their expectations and responsibilities for identifying, reporting, and responding to sentinel events
- asking for an example of a sentinel event that has occurred in the past year to assess the adequacy of the organization's process for responding to a sentinel event. Additional examples may be reviewed if needed to more fully assess the organization's understanding of, and ability to conduct, root cause analysis. In selecting an example, the organization may choose a "closed case" or a "near miss" to demonstrate its process for responding to a sentinel event.

Surveyors also review the effectiveness and sustainability of organizational improvements in systems and processes in response to sentinel events previously evaluated under the Joint Commission's Sentinel Event Policy.

Each health care organization is encouraged, but not required, to report to the Joint Commission any sentinel event meeting the above criteria for reviewable sentinel events. Alternatively, the Joint Commission may become aware of a sentinel event by some other means such as communication from a patient, family member, or employee of the organization, or through the media.

If the Joint Commission becomes aware (either through voluntary self-reporting or otherwise) of a sentinel event meeting the criteria of events subject to reporting that has occurred in an accredited organization, the organization is expected to

- prepare a thorough and credible root cause analysis and action plan within 45 calendar days of the event or of becoming aware of the event; and
- submit to the Joint Commission its root cause analysis and action plan, or otherwise provide for Joint Commission evaluation of its response to the sentinel event under an approved protocol, within 45 calendar days of the known occurrence of the event.

The Joint Commission will then determine whether the root cause analysis and action plan are acceptable. If the root cause analysis or action plan is not acceptable, the organization is at risk for being placed on Accreditation Watch by the Accreditation Committee. An organization which experiences a sentinel event that does not meet the criteria for review under the Sentinel Event Policy is expected to complete a root cause

analysis. However, the root cause analysis need not be made available to the Joint Commission.

Source: The Joint Commission Internet site, [www.jcaho.org](http://www.jcaho.org), Sentinel Event Policy and Procedures, Revised June 2, 2000

#### ④ **USP-ISMP Medication Errors Reporting (MER) Program**

The Medication Errors Reporting (MER) program is a voluntary medication error reporting system that was organized as a grass roots program by the Institute for Safe Medication Practices (ISMP) in 1975. Since 1991 the program has been owned and administered by U.S. Pharmacopeia (USP). ISMP is a nonprofit organization that works closely with healthcare practitioners and institutions, regulatory agencies, professional organizations and the pharmaceutical industry to provide education about adverse drug events and their prevention. USP is a nonprofit, volunteer-based, private organization that establishes legally recognized standards of identity, quality, strength, purity, packaging, and labeling of medication and develops information for their appropriate use.

The MER program receives reports that are voluntarily and confidentially submitted by frontline practitioners via mail, telephone, or the Internet (see sample form for reporting medication errors at the end of this section). Reporters are informed that a copy of the report is routinely sent to ISMP, the U.S. Food and Drug Administration (FDA), and the pharmaceutical companies whose products are mentioned in reports. With permission, the reporter's name is disclosed to ISMP so it can initiate contact if necessary to clarify a report. ISMP provides an independent review of the reports. Information from the reports may be used by USP to impact on drug standards.

Errors or near-errors reported through the program include administering the wrong drug, strength, or dose, confusion over look-alike/sound-alike drugs, incorrect route of administration, miscalculations, misuse of medical equipment, and errors in prescribing and transcribing. Case studies are published by ISMP to alert healthcare professionals about the need for practice changes and to alert industry and regulatory professionals about pharmaceutical labeling, packaging, and nomenclature that may foster errors by their design.

Source: The Institute for Safe Medication Practices Internet site, [www.ismp.org](http://www.ismp.org)

## ⑤ MedMARx

U.S. Pharmacopeia's (USP) MedMARx program is a national, Internet-based, interactive medication error prevention tool that enables hospitals using MedMARx to anonymously report and track medication errors in a national, standardized format, and to identify processes that result in improved medication use systems and higher quality patient care. Approximately 250 subscribing hospitals use this system, including institutions of the Department of Veterans Affairs, the Department of Defense, and community health facilities.

Employees of hospitals that subscribe to the program may report a medication error anonymously to MedMARx by completing a standardized report. Hospital management is then able to retrieve compiled data on its own facility and also obtain non-identified comparative information on other participating hospitals.

The anonymous nature of MedMARx reporting removes the barrier to sharing medication error information among hospitals. While navigating the system, MedMARx users are completely anonymous to each other and to USP. Users can only view a report's data, not which facility submitted it. An e-mail based notice feature in MedMARx allows USP to communicate with users and users with USP via the facility identifier, while maintaining anonymity. This feature also allows USP to communicate with a single user or a group of users, for example, to issue alerts on a particular problem or request more information about a report.

MedMARx provides the user with a template of the Joint Commission's framework for conducting a root cause analysis. Any duplicate information that would have already been provided in a MedMARx report is automatically copied to this template and downloaded to a database provided for use on the user's hard drive. A through analysis can then be completed by risk management and stored off-line—not in the MedMARx system.

The information in the facility profile enables USP to characterize the subscribing hospitals and enables a hospital to find similar facilities against which to measure and compare its own experiences. USP encourages use of its program as an integral part of a hospital peer review program and quality improvement process.

MedMARx will not replace the USP Medication Errors Reporting Program. That program will continue to be available for spontaneous reporting by individual practitioners, especially those not in hospitals participating in MedMARx, but also by practitioners who practice in other settings.

Source: *Medication Errors, MedMARx and Hospitals*, presented by Diane Cousins, Vice President, Practitioner Reporting Programs, USP, at the American Society of Health-System Pharmacists Mid-Year Meeting—December 1998

## ⑥ Medical Device Safety Reports (MDSR)

MDSR is a repository of medical device incident and hazard information independently investigated by ECRI, a nonprofit international health services research agency and a Collaborating Center of the World Health Organization. ECRI provides information and technical assistance to the healthcare community, with a focus on healthcare technology, healthcare risk and quality management, and healthcare environmental management.

MDSR is not an alerting service, but a periodically updated review of the types of problems that have occurred with medical devices and lessons learned over the past three decades. It focuses on the steps that medical device users can take to prevent or reduce medical device risks to patient care and healthcare worker safety. Since 1968, ECRI has investigated thousands of such problems--more than any other organization or government agency. It does so on behalf of healthcare facilities, regulatory agencies, insurance companies, medical examiners, patients, and attorneys.

Reports can be submitted to ECRI by letter, telephone, or fax. ECRI acknowledges receipt of the report and informs the reporting party of its finding and opinions in cases for which they can provide guidance; otherwise, ECRI logs the report in its system and monitors the situation for developing trends of similar problems. As soon as members of ECRI's staff--clinical engineers and other technical specialists who have expertise in biomedical, electronic, chemical, radiologic, and computer technologies--determine that specific device hazards and problems may exist, ECRI informs the manufacturers and encourages them to respond constructively and correct the problem. The name of the reporting institution and of the person making the report is never revealed without permission.

ECRI has written more than 1,300 original case reports containing recommendations for prevention or remediation of medical device hazards. Some of these cases--usually the most critical or severe--are then published in the form of Hazard Reports or Use Experience Network™ Reports in ECRI's journal, *Health Devices*, which is widely known as the Consumer Reports of medical devices. ECRI also publishes information to help healthcare professionals avoid medical device injury and manage medical devices properly through Guidance Articles, Frequently Asked Questions, posters, and checklists in *Health Devices*.

A short description of each document type found in MDSR follows:

- Hazard Reports—A hazard is a possible source of peril, danger, or difficulty. ECRI publishes reports about medical device models in which they have identified a fault or design feature that might, under certain circumstances, place patients or users at risk.
- User Experience Network™ Reports—These reports describe common or nuisance problems that ECRI believes are unlikely to pose a significant hazard. Typically they

can be corrected with an available modification or revised operating or maintenance procedures.

- **Guidance Articles**—These articles provide in-depth guidance on such healthcare technology and patient safety issues as preventing and responding to surgical fires and electromagnetic interference and medical devices.
- **Frequently Asked Questions**—Hospitals and other healthcare practitioners and providers turn to ECRI's medical device and health services experts for answers to their day-to-day challenges. ECRI responses, when deemed helpful to the medical community as a whole, have been published in various formats over the years.
- **Posters and Checklists**—As part of ECRI's continuing mission to educate users about the safe use of medical devices, they have published posters and checklists that summarize basic safety precautions for common devices (e.g., electrosurgical units) or procedures (e.g., emergency defibrillation) with inherent risks to patients and/or healthcare workers.

Source: The Medical Devices Safety Reports Internet site, [www.mdsr.ecri.org](http://www.mdsr.ecri.org)

## **Medical Event Reporting System for Transfusion Medicine**

The Medical Event Reporting System for Transfusion Medicine, MERS-TM, is a University of Texas-Southwestern- and Columbia-based, National Institutes of Health-funded project that seeks to stop blood- transfusion errors before they happen. With a \$4 million grant over the next four years, the research team is working with several affiliated organizations -- including Parkland Health & Hospital System, Carter Bloodcare and the American Red Cross -- to track transfusion error through a no-fault, standardized reporting system. After testing the model in a small prototype, the group recently began testing it nationally through organizations such as the Red Cross. The project has caught the attention of Congress and the Surgeon General. Another goal of the program is to standardize transfusion-reporting systems nationwide.

## **Austral-Asian Incident Monitoring System (AIMS)**

The meeting began with reports on various aspects of the host country's pacesetter national study, the Austral-Asian Incident Monitoring System (AIMS). Drs. Lynn Currie, William Runciman and John Russell described how the system is functioning, some key findings and consequent publications, and how results have led to recommendations and system changes. Since the start of AIMS in 1988, data collected by the Australian Patient Safety Foundation ("APSF," but not to be confused with the parent organization of this Newsletter) have so far been only from Australia, yet there has been some expansion to other countries and now the first applications of corrective strategies. The effort is now funded by the Australian Department of Health, which may represent a cultural change. Protection from discovery by federal legislation and confidentiality are responsible for practitioners' cooperation with reporting. More recently, pilot studies have been done in six other medical specialties and a dozen other countries have undertaken incident monitoring in some form based on AIMS.

Among the findings from AIMS are that problems in use of drugs appear in 8% of incidents, that endobronchial intubation is still the most frequently occurring problem leading to hypoxia, and that the most common cause of intraoperative hypertension is some type of drug administration problem. Stress, most often from self-generated haste, was seen as a contributing factor in 14% of incidents. A full third of critical incidents reported in anesthesia are related to equipment human-interface problems (only 8% were pure equipment failures, which has led recently to an industry/AIMS liaison allowing limited access to data by manufacturers).

About 20% to 30% of crisis situations would have been diagnosed sooner or managed better had a specific protocol been followed. This has led to the ABCD COVER algorithm, a plan for dealing step-by-step with untoward developments during an anesthetic. A new sub-algorithm, SCARE, has been developed: Scan every five minutes, Check on the unexpected, Alert/Ready if suspicion of a problem and turn to Emergency mode in a rapidly deteriorating situation.

The plan for the future is to include more specialties, hospitals and countries. Analysis of patient factors such as obesity are underway as is examination of preoperative assessment and preparation, the most commonly reported contributing factors in deaths in Australia. There is now also a study of clinical pathways underway.

Dr. Runciman listed several kinds of health care outcome and quality studies ongoing in Australia: incident reporting, M&M committee processes, and analysis of medical legal cases. Starting with six pilot studies funded by the federal government, there is now significant funding for incident monitoring in intensive care, general

practice and obstetrics. The federal government provides money to state governments with certain requirements. There is federal and state protection from access to data. Dr. Runciman said that all the systems are in place for AIMS: collection, analysis and feedback of reports. The net for capturing anesthesia incident information is very broad and includes any event that could have caused harm to someone or any complaint. Cases are sent to the APSF via a relay station in the National Bureau of Statistics, which removes identifiers. The database is accessible only on a local area network, with no access to the outside world. The data entry system allows for "parallel coding," i.e., very complex problems can be characterized. The classification is by "natural" categories, i.e., ones that describe the data as they are described by the reporter.

They have created various guidelines, protocols, checklists and manuals for feedback of findings. Dr. Runciman has been impressed with the power of this qualitative method (this issue was raised again later in the day). Some elements of AIMS that he believes have been important to its success are that it is confidential, provides rapid feedback, is non-threatening and is inexpensive relative to case review. He estimates that the cost is about \$30,000/year to operate the system in one hospital.

Via AIMS, problems heretofore unappreciated have been recognized, for instance, that infections related to failure to replace IV cannula collectively cause more morbidity than all anesthesia events combined. From other findings it has been computed that, to be cost-effective with respect to preventing overnight admissions for ambulatory day-of-surgery patient (assuming a 1/250 rule), a completely effective treatment for prevention of postoperative nausea and vomiting would have to cost less than \$2.00 per anesthetic.

Separate from AIMS, the Department of Health funded an analysis of 14,000 randomly collected case notes. Sixteen percent of admissions were found to be associated with adverse events, of which 80% were deemed preventable. This extrapolates to 250,000 adverse events a year and 14,000 preventable deaths, thought to account for 10% of acute-care hospital costs. While 50% of events were in association with surgery, less than 2% were associated with anesthesia.

During the discussion, it was asked why it isn't possible to have access to individual cases since this precludes the possibility of a deeper qualitative analysis. Dr. Runciman believes that absolute anonymity is so important that it is an over-riding consideration mitigating against allowing for follow-up. Dr. Grobee questioned if there could not be ways to allow for follow-up with reporters and still allow for anonymity.

Dr. Frederick Orkin postulated that much is lost by not having more data about the patient, e.g., risk factors. Dr. Runciman believes that qualitative analysis of these data can still be productive in the absence of having complete demographics of patients, i.e., the elements of detail about what happened are sufficient to point

toward designing solutions.

Dr. Russell reported on three examples of how AIMS data have been applied to change practice: To eliminate problems arising from soda lime dusting, they have worked with a manufacturer to create new procedures for loading absorbent, commonly supplied in bulk in Australia. The simple solution was to provide a larger container so the granules can be scooped instead of poured. They have been developing and testing this solution and are now publicizing findings.

Because AIMS identified that the greatest source of drug swaps and of drug-error related morbidity have involved relaxants and reversal agents, the U.S. color-coding standard was adopted. They have also introduced a special syringe with a colored plunger for these drugs. Introduction into practice began in 1994 and preliminary data suggest a sharp reduction in reported syringe swaps. But, he also believes that publicity from a symposium issue of the journal of the Australian Society of Anesthesiologists describing results of AIMS analyses, including drug swaps, may also have had an impact.

The analyses of endobronchial intubations, also reported in the symposium issue, do not appear to have been followed by a change in the rate of AIMS reports. In Australia, a mark is now placed on endotracheal tubes to indicate correct placement. But, power analysis suggests that about six years of new reports will be needed to study effects of this alteration in the tubes. This may be impractical unless there is an increasing rate of reporting.

### **Anaesthetic Incident Monitoring Study (AIMS) Pilot Project**

Modern anaesthesia is an extremely sophisticated and safe process, but from time to time incidents happen and anaesthetists need to be informed of how and why they occurred.

Anaesthetic incidents are reported to the Anaesthetic Incident Monitoring Study (AIMS), administered by the Australian Patient Safety Foundation (APSF) at Royal Adelaide Hospital. They put together an incidents profile and analysed them for common patterns.

Prior to the introduction of the Health Communication Network (HCN) project, the manual form of incident reporting took as long as six months. This HCN pilot study has linked ten hospitals and private group anaesthetists in five states by computer to the APSF office in Adelaide. The current hard copy report forms have been replaced with an electronic reporting and feedback facility. The electronic data interchange (EDI) service allows pilot participants to anonymously send their incident reports by PC modem to an electronic mailbox at APSF.

The project has already seen reporting time for anaesthetic incidents reduced dramatically. This has improved the overall efficiency of reply and feedback, and will make anaesthetic procedures even safer as potential problems will be addressed more quickly.

**Critical Incident Reporting System (CIRS)**

Critical incidents in daily anesthetic practice can be reported anonymously using the Critical Incident Reporting System (CIRS) form of the University of Basel, Switzerland.