Learning objectives

- Estimate the prevalence of medication errors in the United States according to the Institute of Medicine’s 1999 report.
- Identify the responsibilities of a dentist or dental health care attendant when an adverse event occurs.
- Define the following terms:
  - Sentinel event.
  - Root-cause analysis.
  - Adverse event.
  - Medical error.
  - Near-miss.
  - Medication error.
- Name three organizations that collect adverse event reports.
- Name three databases of adverse event reporting.
- Describe the objectives and sequence of events in a root-cause analysis.
- Define a dental device and explain its risk potential.
- List examples of the most common dental-related adverse events.

Introduction

As a dental health care professional, you have a responsibility to be aware of the risk of medical errors as well as learn strategies to minimize that potential risk. Medical errors can occur at any point in treatment, even in preventive care, and do not always result in patient injury or death. Dental professionals who suspect the occurrence of an adverse reaction to a drug or dental device have an obligation to communicate that information to the broader medical and dental community, including, in the case of a serious adverse event, the Food and Drug Administration (FDA).

This course introduces you to the subject of medical errors.

Part I: Medical errors: The scope of the problem

The November 1999 report of the Institute of Medicine (IOM), entitled To Err Is Human: Building A Safer Health System, focused a great deal of attention on the issue of medical errors and patient safety. The report indicated that as many as 44,000 to 98,000 people die in hospitals each year as the result of medical errors. Even using the lower estimate, this would make medical errors the eighth leading cause of death in this country – higher than motor vehicle accidents (43,458), breast cancer (42,297), or AIDS (16,516). About 7,000 people per year are estimated to die from medication errors alone – about 16 percent more deaths than the number attributable to work-related injuries.

The following section of the course, excerpted from the Agency of Healthcare Research and Quality (AHRQ) web site, part of the U.S. Department of Health and Human Services, briefly summarizes findings from recent research and the seminal 1999 Report. To read about the report in more detail, see an eight-page summary at http://www.iom.edu/Object.File/Master/4/117/ToErr-8pager.pdf, or review the full text at http://www.nap.edu/books/0309068371/html/.

Where errors occur

Errors occur not only in hospitals but also in other health care settings, such as physicians’ offices, dental offices, nursing homes, pharmacies, urgent care centers and care delivered in the home. Unfortunately, very little data exist on the extent of the problem outside of hospitals. The IOM report indicated, however, that many errors are likely to occur outside the hospital. For example, in a recent investigation of pharmacists, the Massachusetts State Board of Registration in Pharmacy estimated that 2.4 million prescriptions are filled improperly each year in the state.

Costs

Medical errors carry a high financial cost. The IOM report estimates that medical errors cost the nation approximately $37.6 billion each year; about $17 billion of those costs are associated with preventable errors. About half of the expenditures for preventable medical errors are for direct health care costs.
Not a new issue

The serious problem of medical errors is not new, but in the past, the problem has not gotten the attention it deserved. A body of research describing the problem of medical errors began to emerge in the early 1990s with landmark research conducted by Lucian Leape, M.D., and David Bates, M.D., and supported by the Agency for Health Care Policy and Research, now the Agency for Healthcare Research and Quality (AHRQ).

Public fears

While there has been no unified effort to address the problem of medical errors and patient safety, awareness of the issue has been growing. Americans have a very real fear of medical errors. According to a national poll conducted by the National Patient Safety Foundation:

- Forty-two percent of respondents had been affected by a medical error, either personally or through a friend or relative.
- Thirty-two percent of the respondents indicated that the error had a permanent negative effect on the patient’s health.

Overall, the respondents to this survey thought the health care system was “moderately safe” (rated a 4.9 on a 1 to 7 scale, where 1 is not safe at all and 7 is very safe).

Another survey, conducted by the American Society of Health-System Pharmacists, found that Americans are “very concerned” about:

- Being given the wrong medicine (61 percent).
- Being given two or more medicines that interact in a negative way (58 percent).
- Complications from a medical procedure (56 percent).

Most people believe that medical errors are the result of the failures of individual providers. When asked in a survey about possible solutions to medical errors:

- Seventy-five percent of respondents thought it would be most effective to “keep health professionals with bad track records from providing care.”
- Sixty-nine percent thought the problem could be solved through “better training of health professionals.”

This fear of medical errors was borne out by the interest and attention that the IOM report generated. According to a survey by the Kaiser Family Foundation, 51 percent of Americans followed closely the release of the IOM report on medical errors.

It’s a systems problem

The IOM emphasized that most of the medical errors are system-related and not attributable to individual negligence or misconduct. The key to reducing medical errors is to focus on improving the systems of delivering care and not to blame individuals. Health care professionals are simply human and, like everyone else, they make mistakes. But research has shown that system improvements can reduce the error rates and improve the quality of health care:

- A 1999 study indicated that including a pharmacist on medical rounds reduced the errors related to medication ordering by 66 percent, from 10.4 per 1,000 patient days to 3.5 per 1,000 patient days.
- The specialty of anesthesia has reduced its error rate by nearly sevenfold, from 25 to 50 per million to 5.4 per million, by using standardized guidelines and protocols, standardizing equipment, etc.
- One hospital in the Department of Veterans Affairs uses hand-held, wireless computer technology and bar-coding, which has cut overall hospital medication error rates by 70 percent. This system is soon to be implemented in all VA hospitals.

Types of errors

The IOM defines medical error as “the failure to complete a planned action as intended or the use of a wrong plan to achieve an aim.” Most people believe that medical errors usually involve drugs, such as a patient getting the wrong prescription or dosage, or mishandled surgeries, such as amputation of the wrong limb. However, there are many other types of medical errors, including:

- Diagnostic error, such as misdiagnosis leading to an incorrect choice of therapy, failure to use an indicated diagnostic test, misinterpretation of test results and failure to act on abnormal results.
- Equipment failure, such as defibrillators with dead batteries or intravenous pumps whose valves are easily dislodged or bumped, causing increased doses of medication over too short a period.
- Infections, such as nosocomial and post-surgical wound infections.
- Blood transfusion-related injuries, such as giving a patient the blood of the incorrect type.
- Misinterpretation of other medical orders, such as failing to give a patient a salt-free meal as ordered by a physician.

Preventing errors

Research clearly shows that the majority of medical errors can be prevented:

- One of the landmark studies on medical errors indicated 70 percent of adverse events found in a review of 1,133 medical records were preventable; 6 percent were potentially preventable; and 24 percent were not preventable.
- A study released last year, based on a chart review of 15,000 surgical records in Colorado and Utah, found that 54 percent of surgical errors were preventable.

Other potential system improvements include:

- Use of information technology, such as hand-held bedside computers, to eliminate reliance on handwriting for ordering medications and other treatment needs.
- Avoidance of similar-sounding and look-alike names on packages of medication.
- Standardization of treatment policies and protocols to avoid confusion and reliance on memory, which is known to be fallible and responsible for many errors.

Definitions and context

The lack of standardized nomenclature and a universal taxonomy for medical errors complicates the development of a response to the issues outlined in the IOM report. A number of definitions have been applied to medical errors and patient safety. In To Err is Human, the IOM adopted the following definition:
An error is defined as the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim.

In an effort to thoroughly consider all of the relevant issues related to medical errors, the Quality Interagency Coordination Task Force expanded the IOM definition, as follows:
- An error is defined as the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim. Errors can include problems in practice, products, procedures and systems.
- The term “patient safety” as used here applies to initiatives designed to prevent adverse outcomes from medical errors.
- The enhancement of patient safety encompasses three complementary activities: preventing errors, making errors visible, and mitigating the effects of errors.

It is critical to recognize that not all bad outcomes for patients are due to medical errors. Patients may not be cured of their disease or disability despite the fact that they are provided the very best of care. Additionally, not all adverse events that are the result of medical care are, in fact, errors.

An adverse event may be defined as “an injury caused by medical management rather than by the underlying disease or condition of the patient,” or “an injury that was caused by medical management and that resulted in measurable disability” (Leape, 1991). Some adverse events, termed “unpreventable adverse events,” result from a complication that cannot be prevented given the current state of knowledge. Many drugs, even when used appropriately, have a chance of side effects, such as nausea from an antibiotic. The occurrence of nausea would be an adverse event, but it would not be considered a medical error to have given the antibiotic if the patient had an infection that was expected to respond to the chosen antibiotic.

Medical errors are adverse events that are preventable with our current state of medical knowledge.

Some adverse events are not preventable, and they reflect the risk associated with treatment, such as a life-threatening allergic reaction to a drug when the patient had no known allergies to it. However, the patient who receives an antibiotic to which he or she is known to be allergic, goes into anaphylactic shock and dies represents a preventable adverse event.

In this report, the consideration of errors is broadened beyond preventable adverse events that lead to actual patient harm to include “near-misses,” sometimes known as “close calls.” A “near-miss” is an event or situation that could have resulted in an accident, injury or illness, but did not, either by chance or through timely intervention. Experience in other industries, including aviation, manufacturing and nuclear energy, demonstrates that there is as much to learn from close calls as there is from incidents leading to actual harm.

**Part II: Advances in patient safety; from research to implementation**

As a result of the IOM report, several actions occurred to bring adverse event/medical error reporting systems into the forefront of public policy. President Clinton ordered the development of the Quality Interagency Coordination Task Force (QuIC) to recommend strategies for improving patient safety and health care quality. The QuIC report, in 2000, recommended many strategies, including the establishment of mandatory reporting systems in all 50 states.

To date, no national adverse event system exists, and there are no federal standards regarding state systems. Instead, states may opt to require hospitals to report adverse events, identify and define which events are reportable, and establish parameters surrounding the specific information for hospitals to report. State-level adverse event reporting systems collect data regarding adverse events that have taken place in hospitals and other health care settings. Reporting has the potential to serve two purposes: to hold individual hospitals accountable for performance and to provide information that could lead to improved patient safety.

**State adverse event reporting**

As of December 2008, 26 states had hospital adverse event reporting systems and another state had taken action to develop one, according to a study published at the time. The remaining states did not have adverse event reporting systems, although one state had passed legislation to authorize a system and was developing policies and procedures. Many of the states’ systems were relatively new, with 10 systems being operational for less than three years.

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**Figure 1 shows this set of possible outcomes of medical care.**

**Figure 1: Framework for Identifying Errors**

- **Patient Receives Treatment**
  - No Error Made → Good Outcome
  - Error Made
    - Minor
      - Caught → Close Call
      - Not Caught
    - Serious
      - Caught → Close Call
      - Not Caught → Patient Injury

- **Bad Outcome (unpreventable adverse event due to underlying disease)**
  - Minor or no injury (Preventable adverse event)
  - Patient Injury (Preventable adverse event)
**Terminology**

The following terms are used to identify and address harmful health care events:

- **Adverse event**: An adverse event is defined as:
  - Any harm (injury or illness) caused by medical care.
  - Any unfavorable and unintended sign, symptom or disease temporally associated with the use of a medicinal product, whether or not considered related to the product.
  - Identifying adverse events indicates that the care resulted in an undesirable clinical outcome and that the clinical outcome was not caused by an underlying disease, but does not imply an error, negligence, or poor quality care.

- **Corrective action plan**: Policy and procedural actions that hospitals prepare to respond to an adverse event and to prevent recurrence.

- **Medical error**: The failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim. Errors can include problems in practice, products, procedures, and systems.

- **Medication error**:
  - Medication administration:
    - Of a drug other than as prescribed or indicated.
    - Of a dose other than as prescribed or indicated.
    - To a patient who was not prescribed the drug.
    - At a time other than prescribed or indicated.
    - At a rate other than as prescribed or indicated.

**What is reportable?**

Reporting systems vary in terms of what events are reported, criteria used for selection, and type of information reported. As of this study, the following states had adverse event reporting systems in place:

- California.
- Colorado.
- Connecticut.
- District of Columbia.
- Florida.
- Georgia.
- Indiana.
- Kansas.
- Maine.
- Maryland.
- Massachusetts.
- Minnesota.
- New Jersey.
- Nevada.
- New York.
- Ohio.
- Oregon.

- Pennsylvania.
- Rhode Island.
- South Carolina.
- South Dakota.
- Tennessee.
- Utah.
- Vermont.
- Washington.
- Wyoming.

Check with your state department of health to determine the specific policies and procedures for serious reportable events in your state.

Each of the 26 states’ systems have different requirements regarding the information that must be included about the event itself, the patient involved in the event, the result of any root-cause analyses and any corrective action plans or risk-reduction strategies. State criteria for determining whether an event is reportable focus primarily on the level of harm caused to the patient. All states with systems ask hospitals to gauge whether harm was caused to the patient and to assess the severity of this harm when determining whether an event should be reported.

**Severity of harm**

Researchers studying state reporting systems developed five basic categories to classify these systems’ criteria for severity of harm to determine whether events are reportable. These categories include events resulting in death, even if the death is unrelated to the patient’s underlying condition, an unanticipated death or death as an outcome of any reportable adverse event. All states use this criterion for at least one reportable event. For example, some states require hospitals to report any death resulting from circumstances other than natural causes, such as accidents, abuse, negligence or suicide. The categories are:

- **Events resulting in long-term harm or permanent disability**.
  These events may include serious disability or loss of bodily function. Twenty-three states use this criterion for at least one reportable adverse event. For example, Maine requires hospitals to report any major permanent loss of function that is not present on admission.

- **Events resulting in harm and likely to require additional medical care**. These events may include unanticipated injury or life-threatening, serious or unforeseen complications. Twenty-four states use this criterion for at least one reportable adverse event. For example, Connecticut requires hospitals to report any incident in which a gas line designated for oxygen to be delivered to a patient contains the wrong gas.

- **Events not resulting in identifiable physical harm**. These events may not result in death or physical disability and may not require additional medical care. They are reportable because they happened and may reflect vulnerabilities in the hospital environment. Twenty-three states use this criterion for at least one reportable adverse event. For example, Tennessee requires
hospitals to report instances in which there is misappropriation of patient funds.

- **Near-misses.** These events are occurrences that could have resulted in an adverse event but the event was averted and the patient was not harmed. Only one state, Pennsylvania, uses this criterion. Staff from this state explained that by requiring hospitals to identify and report near-misses, the state has the opportunity to bring about changes to prevent an event from reaching a patient.
  - For example, Pennsylvania received a near-miss report about a patient who nearly died because of confusion over the meaning of the patient’s color-coded wristband. Some hospital staff believed that the patient’s wristband color meant “do not resuscitate,” when it actually meant something else.

**Sample state policies and procedures**

This section describes policies and procedures associated with reporting serious adverse events (also called “sentinel” events, by some agencies) using the state of Utah as an example. These policies, as well as those of other states, are based on guidelines originally developed by the Joint Commission on the Accreditation of Health Care Organizations (JCAHO) and the FDA, which established basic terminology and strategies to address and track medical error.

**Reporting sentinel events**

A sentinel event is an unexpected occurrence involving death or serious physical or psychological injury. Such events are called “sentinel” because they signal the need for immediate investigation and response. Some organizations and hospitals use the term serious adverse or serious reportable event to identify these cases. The terms “sentinel event” and “medical error” are not equivalent; not all sentinel events occur because of an error and not all errors result in sentinel events.

A sentinel event reporting program requires certain health care facilities to report serious patient injuries and to allow an independent, external review of and response to the thoroughness and credibility of the processes of investigating and responding to these events. The reporting under this rule helps the Department of Health and health care providers to understand patterns of failures in the health care system and to recommend statewide resolutions. It limits access to identifiable health information that facilities report to the Department of Health under this rule.

The JCAHO expects accredited organizations to define “sentinel event” for their own purposes, as well as establish their own mechanisms to identify, report and manage these events. In Utah, each facility must report to the state Department of Health all patient safety sentinel events within 72 hours of the facility’s determination that a patient safety event may have occurred, but in no event later than four hours prior to convening a formal root-cause analysis.

Patient safety sentinel events include:

- **Surgical events:**
  - Surgery performed on the wrong body part.
  - Surgery performed on the wrong patient.
  - Incorrect surgical procedure performed on a patient.
  - Retention of a foreign object in a patient after surgery or other procedure, except for:

**Root-cause analysis**

- Root-cause analysis is a process for identifying the basic or causal factor(s) that underlie variation in performance, resulting in the occurrence or possible occurrence of a patient safety sentinel event. A thorough root-cause analysis should inquire into all associated aspects of the event and include the following points:
  - What factor or factors relate most directly to the sentinel event, and what systems and processes are associated with it?
  - What about the underlying systems and processes allowed the event, and how can they be made more foolproof?
  - What other areas of risk exist and could potentially contribute to a similar event?
  - What improvements, if any, in systems and processes could be implemented to reduce the likelihood of such an event in the future?
Finally, individuals are assigned responsibility for implementing necessary improvements. Once in place, these changes should be evaluated to determine their degree of efficacy.

According to the state procedure in Utah, the facility shall conduct a root-cause analysis which is “timely, thorough and credible” to determine whether reasonable system changes would likely prevent a patient safety sentinel event in similar circumstances.

The root-cause analysis must:
- Focus primarily on systems and processes, not individual performance.
- Progress from specific, direct causes in clinical processes to contributing causes in organizational processes.
- Seek to determine related and underlying causes for identified causes.
- Identify changes which could be made in systems and processes, through either redesign or development of new systems or processes, that would reduce the risk of such events occurring in the future.
- Inquires into all areas appropriate to the specific type of event.

The Department of Health will determine the root-cause analysis to be thorough if it:
- Involves a complete review of the patient safety sentinel event including interviews with all readily identifiable witnesses and participants and a review of all related documentation.
- Identifies the human and other factors in the chain of events leading to the final patient safety sentinel event, and the process and system limitations related to their occurrence.
- Searches readily retrievable records to analyze the underlying systems and processes to determine where redesign might reduce risk.
- Focus primarily on systems and processes, not individual performance.
- Progress from specific, direct causes in clinical processes to contributing causes in organizational processes.
- Seek to determine related and underlying causes for identified causes.
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- Searches readily retrievable records to analyze the underlying systems and processes to determine where redesign might reduce risk.
- Inquires into all areas appropriate to the specific type of event.

**Action plan**

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

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

Within 60 calendar days of determination of the patient safety sentinel event, the incident facility in Utah shall submit a final report with an action plan that:
- Identifies changes that can be implemented to reduce risk, or formulates a rationale for not implementing changes.
- Where improvement actions are planned, identifies who is responsible for implementation, when the action will be implemented (including any pilot testing), and how the effectiveness of the actions will be evaluated.

The incident facility shall provide a final report to the facility’s administration and the Utah Department of Health in a department-approved paper or electronic format that includes:
- Facility information.
- Patient information.
- Event information.
- Type of occurrence.
- Analysis.
- Corrective action.

**Serious adverse events**

What the JCAHO and many hospitals call a “sentinel event” is typically referred to as a “serious adverse event” by the FDA. They define an adverse event as any undesirable experience associated with the use of a medical product in a patient. The event is serious and should be reported when the patient outcome is:

- **Death:** Report if the patient’s death is suspected as being a direct outcome of the adverse event.
- **Life-threatening:** Report if the patient was at substantial risk of dying at the time of the adverse event or it is suspected that the use or continued use of the product would result in the patient’s death. Examples: Pacemaker failure; gastrointestinal hemorrhage; bone marrow suppression; infusion pump failure which permits uncontrolled free flow resulting in excessive drug dosing.
- **Hospitalization (initial or prolonged):** Report if admission to the hospital or prolongation of a hospital stay results because of the adverse event. Examples: Anaphylaxis; pseudo membranous colitis; or bleeding causing or prolonging hospitalization.
- **Disability:** Report if the adverse event resulted in a significant, persistent or permanent change, impairment, damage or disruption in the patient’s body function/structure, physical activities or quality of life. Examples: Cerebrovascular accident due to drug-induced hypercoagulability; toxicity; peripheral neuropathy.
- **Congenital anomaly:** Report if there are suspicions that exposure to a medical product prior to conception or during pregnancy resulted in an adverse outcome in the child. **Examples:** Vaginal cancer in female offspring from diethylstilbestrol during pregnancy; malformation in the offspring caused by thalidomide.

- **Requires intervention to prevent permanent impairment or damage:** Report if you suspect that the use of a medical product may result in a condition that required medical or surgical intervention to preclude permanent impairment or damage to a patient.

### Food and Drug Administration (FDA) Adverse Event Reporting program (AERP) and MedWatch

MedWatch, the FDA Safety Information and Adverse Event Reporting program, relies on the responsibility of health care providers to identify and report adverse events and determine which of those events are related to the use of medical products. Through the MedWatch program, health professionals can report serious adverse events and product problems that occur with such medical products as drugs, biologics, medical and radiation-emitting devices, and special nutritional products. AERS is to improve the public health by providing the best available tools for storing and analyzing safety reports. As a result, the FDA sends out a “Dear Health Care Professional” letter, or re-evaluating procedures for this mandatory reporting process.

### Post-marketing reporting of adverse events

The FDA has the regulatory responsibility for ensuring the safety of all marketed medical products. Health professionals are critical to this process. It is important for all health professionals to be aware that some reporting is mandated by federal law and regulation while other reporting, although considered vital, is strictly voluntary.

### Reporting to the FDA

Report serious adverse events for human medical products, including potential and actual product use errors, product quality problems, and therapeutic inequivalence/failure online at https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm. Reporting channels also include a toll-free number (1-800-FDA-1088). A one-page paper form can also be returned to the FDA by prepaid mail or fax (1-800-FDA-0178).

### Reporting required by law or regulation

Reporting by individual health care providers is essentially voluntary. However, manufacturers and distributors of FDA-approved pharmaceuticals (drugs and biologics) and medical devices, plus pharmaceutical packers and device user facilities, all have mandatory reporting requirements.

### Mandatory device reporting

User facilities such as hospitals and nursing homes are legally required to report suspected medical device-related deaths to both FDA and the manufacturer, if known, and serious injuries to the manufacturer or to FDA, if the manufacturer is unknown. Health professionals within user-facilities should familiarize themselves with their institution’s procedures for this mandatory reporting process.

### Reporting by health professionals

Any post-marketing surveillance program depends on health professionals to report serious adverse events observed in the course of their everyday clinical work. The MedWatch program has two interconnected goals: To educate both health care providers and their patients about the importance of reporting serious adverse events to the FDA, and to facilitate that reporting. Health professionals are welcome to report any adverse event that they judge to be clinically significant. Suspicion that a medical product may be related to a serious event is sufficient reason to submit a report. Proof of causality is not necessary.

Given the clinical importance of post-marketing surveillance, all health care providers (physicians, pharmacists, nurses, dentists and others) should look upon adverse event reporting as part of their professional responsibility. The American Medical Association and American Dental Association advocate (respectively) physician and dentist participation in adverse event reporting systems. Health professionals can use the voluntary MedWatch form to report adverse events or product problems related to any medical product, with the exception of those occurring with vaccines. All unsolicited reports from health professionals received by FDA via either the voluntary or mandatory route are called spontaneous reports. A spontaneous report is a clinical observation that originates outside of a formal study. The combination of adverse event information generated by all reporting makes up the database upon which post-marketing surveillance depends.

### Medical error/adverse event databases

Currently, several databases collect information on specific types or errors, such as the Centers for Disease Control (CDC) hospital-acquired infections reporting systems, FDA's adverse drug and device event reporting systems, and the JCAHO's sentinel event system. Others collect information on errors that occur in a particular health care system, such as the Veterans Administration (VA) error reporting system. As previously mentioned, many states keep data collection systems for the facilities within their boundaries.

The FDA's Adverse Event Reporting System (AERS) is a computerized information database designed to support the FDA's post-marketing safety surveillance program for all approved drug and therapeutic biologic products. AERS collects information about adverse events, medication errors and product problems that occur after the administration of approved drug and therapeutic biologic products. Quarterly (noncumulative) data files since January 2004 are available for downloading on the AERS website. The ultimate goal of AERS is to improve the public health by providing the best available tools for storing and analyzing safety reports. As a result, the FDA may take regulatory actions to improve product safety and protect the public health, such as updating a product's labeling information, sending out a “Dear Health Care Professional” letter, or re-evaluating an approval decision.
The Manufacturer and User Facility Device Experience Database (MAUDE) represent reports of adverse events involving medical devices. The data consists of voluntary reports since June 1993, user facility reports since 1991, distributor reports since 1993, and manufacturer reports since August 1996. An online search of MAUDE is available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM, allowing you to search for information on medical devices that may have malfunctioned or caused a death or serious injury. MAUDE is scheduled to be updated quarterly, and the search page reflects the date of the most recent update.

**FDA reports**

The FDA receives three main types of reports:
1. Reports involving suspected serious adverse events associated with drugs, either prescription or OTC, biologic products, medical devices, cosmetics and special nutritional products such as dietary supplements, medical foods and infant formulas.
2. Reports suggesting manufacturing, counterfeit or other quality problems with drugs or devices.
3. Reports of medication and device use errors, for example, wrong drug or dosage errors that may be caused by product name, packaging or labeling confusion.

Reporting update: The Office of Management and Budget has reauthorized Form FDA 3500 and Form FDA 3500A through Dec. 31, 2011. The updated forms are being revised for the Web and will be provided when available at http://www.fda.gov/medwatch/getforms.htm.

**TABLE 1: Medical device reporting (MDR) requirements**

<table>
<thead>
<tr>
<th>User facility:</th>
<th>Manufacturer:</th>
</tr>
</thead>
<tbody>
<tr>
<td>● Deaths (to FDA and manufacturer within 10 days).</td>
<td>● Deaths, serious injuries, malfunctions (to FDA within 30 calendar days of becoming aware of event).</td>
</tr>
<tr>
<td>● Serious injuries/illnesses (to manufacturer within 10 days; to FDA if manufacturer unknown, also within 10 days).</td>
<td>● Five-day report to FDA if become aware of event(s) necessitating “remedial action to prevent an unreasonable risk of substantial harm to the public health” or reportable event for which FDA has requested five-day report.</td>
</tr>
<tr>
<td>● Semiannual reports (to FDA) of all reports sent to FDA and/or manufacturer (due Jan. 1 and July 1).</td>
<td>● Annual certification of number of reports.</td>
</tr>
</tbody>
</table>

**Distributor:**

- Deaths (to FDA and manufacturer within 10 days).
- Serious injuries/illnesses (to FDA and manufacturer within 10 days).
- Malfunctions (to FDA and manufacturer within 10 days).

**TABLE 2: Adverse event (AE) reporting requirements for pharmaceuticals**

**15-day alert reports:** Each AE, both serious and unexpected (i.e., not in the product’s current labeling), must be reported to the FDA within 15 working days.

**Periodic AE reports:** All non-15-day AE reports must be reported periodically (quarterly for the first three years after approval, then annually).

**Other:** The frequency of reports of AEs that are both serious and expected; therapeutic failures must be periodically monitored; and any significant increase must be reported within 15 days.

**Scientific literature:** A 15-day report based on scientific literature (case reports; results from a formal clinical trial; epidemiology-based studies or “analyses of experience in a monitored series of patients”).

**Post-marketing studies:** No requirement for a 15-day report on an AE acquired from a post-marketing study unless manufacturer concludes pharmaceutical causation for AE is a “reasonable possibility.”

**What is a product problem?**

Product problems should be reported to the FDA when there is a concern about the quality, authenticity, performance or safety of any medication or device.

Problems with product quality may occur during manufacturing, shipping, or storage. They include:
- Suspected counterfeit product.
- Product contamination.
Adverse reactions to dental materials

Two major studies, the first in the U.S., the second in Europe, recently reviewed adverse reactions to dental materials. Dental materials are the most commonly used biomaterials in the human body, and a wide range of materials used within dental practices pose a potential risk to patients as well as an occupational risk to dental professionals.

Given the complexity and range of materials employed in dentistry, some adverse reactions are unavoidable. Dental device defects, malfunctions, poor use instructions and misuse result in thousands of injuries a year. Dental devices include products, such as implants or floss, that are specifically used in dentistry or oral health care, but not general-use items, such as gloves or scalpels, which are used by other doctors.

Because dental materials are classified as medical devices in many countries (like the U.S.), most materials are thoroughly tested before common use. Such testing, however, cannot identify rare issues. While dental ingredients have to comply with high safety standards, a small number of people may be sensitive to certain types of dental materials. All dental materials, including fillings, dentures, crowns, orthodontic appliances and impression materials have the potential to cause an adverse reaction. Sometimes even contact with toothpastes can affect a small number of people.

Adverse reactions associated with dental materials range from contact dermatitis to life-threatening anaphylaxis. They are primarily either irritant or allergic in nature, although specialist diagnosis from patch or prick tests is required to confidently distinguish between them. The most commonly reported reaction, in association with protective gloves, is irritant contact dermatitis. This is a nonimmunologic inflammation caused by direct damage to the protective layer of the skin, which can result from inadequate hand-care regime, friction, sweating or extreme humidity conditions. Irritant reactions typically elicit mild localized reactions, which clear within hours.

Allergic reactions can be localized or systemic, depending on the type of immune response elicited. They are seen as two main reaction types; delayed (Type IV) hypersensitivity reaction, or immediate (Type I) hypersensitivity reaction. Type IV reactions are predominantly seen as hand dermatitis in dental personnel and oral lichenoid reactions in patients. Oral lichenoid reactions are localized white lesions (lichen planus) located in the oral cavity often adjacent to restorative materials. A wide range of chemicals and procedures carried out in dentistry can trigger this reaction. Type I reactions are seen as contact urticaria, a wheal and flare response to allergens. The consequences of this response type are potentially more serious as reactions are not always localized and can involve internal organs such as the gastrointestinal and respiratory tract, which can culminate in anaphylactic shock.

Both studies assessed the extent, type and severity of adverse reactions associated with dental materials. The first study discusses the frequency and risk of aspiration or ingestion of foreign materials in dental practice.

Aspiration and ingestion in dental practice

A review of incidents over a period of 10 years at a dental education facility examined the risk of aspiration or ingestion of dental foreign objects during dental procedures, in part to determine which dental procedures were most likely to involve aspiration or ingestion. All patients experienced loss of dental instruments or material behind the posterior pharynx, totaling 36 reports in the 10-year period. Of these, 25 involved ingesting a dental foreign object.

Items included one dental implant screwdriver, one bur, 13 single-unit crowns, two pieces of orthodontic wire, one implant, one 3 x 3-inch piece of gauze, three cast onlay restorations, one orthodontic/pediatric appliance, one clasp from a removable denture, one cast post and core, and one ultrasonic scaler tip.

Adverse outcomes totaled eight in prosthodontics, three in orthodontic/pediatric dentistry, five in restorative dentistry, five in oral and maxillofacial surgery, one in endodontics, one in dental hygiene, two in special care dentistry and one in periodontics. Data suggests incidents in special care or pediatrics are a relatively rare occurrence, contrary to popular belief. While ingestion or aspiration can be very dangerous, there are also cases where material has gone undetected until identified by radiographs.

Fixed prosthodontic therapy was associated with the highest number of adverse outcomes, causing ingestion more than aspiration. Dental procedures involving single-tooth cast or prefabricated restorations involving cementation, such as procedures involving cementation of permanent crowns and/or placement of cast post and core and onlays, have a higher likelihood of aspiration or ingestion. During cementation, when the crown is “wet” from the application of cement, it may be more difficult to hold or retrieve the material if it drops into the patient’s mouth.

Research findings encourage the use of preventive measures such as rubber dams or gauze throat screens or floss ligatures. Some doctors tether small instruments or clasps using floss. Even so, physical barrier methods cannot completely prevent aspiration or ingestion. It may also reduce incidents if patients are not reclined far back in the chair for certain procedures, such as try-in phases for fixed prosthesis.

Part III: Adverse events in dentistry

This section highlights recent research findings regarding cases and characteristics of dental-related adverse events around the world. The generated from spontaneous reports is determined by the quality of the submitted information, dental health professionals can play a major role in improving the public health.

Program success depends on participation

The effectiveness of a national post-marketing surveillance program is directly dependent on the active participation of health professionals including dentists. By viewing adverse event reporting as a professional responsibility and recognizing that the quality of data

Defective components.
Poor packaging or product mix-up.
Questionable stability.

Device malfunctions.
Labeling concerns.
as physician, dentist, nurse practitioner, chiropractor and optometrist offices.

Reports included individual filings, such as those submitted by health care providers and consumers through MedWatch (Forms 3500 and 3500A), as well as mandatory filings submitted by manufacturers and user facilities, and summary reports from Alternative Summary Reporting (ASR) and the MAUDE databases. The U.S. study analyzed data regarding types of events (death, injury, malfunction), types of devices, and patient or dental professional effects. Most reports were filed by dentists (76 percent), followed by dental assistants (4 percent).

Out of 272,241 reports in about a three-year period (1996-1999), 10.5 percent involved dental devices, with nearly 100 percent of injuries associated with surgical devices. The most commonly cited dental devices were endosseous implants (90 percent), temporomandibular joint implants, bone plates and bone augmentation materials. In total, there were about 18,000 (64 percent) injuries, with nearly 10,000 device malfunctions (35 percent). Over three-fourths (77 percent) of the device-related problems were associated with implant failure (52 percent, with many relating to osseointegration), surgical procedures (13 percent) and infections (12 percent).

Powered devices (hand-pieces, bone saws, and drills) accounted for 33 percent of adverse events, including malfunctions of devices such as radiographic units, dental units, dental handpieces and drills, bone saws and drills, and ultrasonic scalers.

While surgical and powered devices were frequently associated with patient problems, injuries were also associated with cements, saliva ejectors and dental adhesives. Clearly any dental device can be a hazard if it is inhaled or ingested. Other device categories commonly listed included cements, sealants and filling materials; dental needles; orthodontic devices (including brackets, elastics, wires, etc.); dental burs and dental cutting instruments; and endodontic files and filling materials.

The European study, published in the July 2004 Journal of Dentistry, also collected incidents of “adverse reactions,” defined as a side effect or other unexpected or unusual response to contact with a dental material. Post-market monitoring programs in Norway, Sweden and the United Kingdom (UK) collected reports with incidents totaling over 3,000. Both studies concluded that frequency of adverse biological reactions is difficult to accurately assess, but the literature review suggests the risk of an adverse reaction to a dental material may range anywhere from 1: 10,000 to 1: 100. Dental restorations often have multiple components that make them difficult to associate with specific adverse reactions.

In the European study, some sectors of the population have expressed concern about the use of mercury in dental amalgam. UK data showed the presence of a metal restoration was most commonly cited as the reason for an adverse reaction, with 140 out of the 193 metal adverse reactions associated with amalgam. The Norwegian study reported 60-70 percent of reports per year associated with amalgam, with intraoral reactions noted in one in three reports (lichenoid reactions were the most common). In Sweden, composites were named 52 percent of the time. Additionally UK occupational reactions showed a high frequency of reactions to rubber products, the bulk of which were associated with latex gloves (395 out of 547 cases).

**Getting the word out**

In cases where the FDA’s analysis of post-market surveillance highlights a problem, the FDA publishes a notice to potential users. In December 2007, the FDA informed dentists, oral surgeons, dental hygienists and other health care professionals about serious patient injuries, including third-degree burns, associated with the use of poorly maintained electric dental handpieces during dental procedures. The notice is reprinted below.

**Preventing burns from electric dental handpieces**

FDA is warning dental professionals about serious patient injuries caused by poorly maintained electric dental handpieces. Some patients have experienced third-degree burns that needed plastic surgery. The burns have occurred during tooth extraction, when cutting teeth and bone, and during other surgical procedures, but overheating could happen during any dental procedure.

The problem occurs if an electric handpiece is worn or clogged. In that case, the motor sends increased power to the handpiece head to maintain performance, which generates heat at the head or the attachment. All of this can happen very quickly. And it can happen without warning, because the patient is anesthetized so he or she can’t feel the burn and the operator is protected from the heat by the handpiece housing.

Burns are less likely to occur with air-driven handpieces, because if there is a problem such as worn gears or a dull bur, the handpiece will perform sluggishly, and this alerts the operator to get it looked at.

Here’s what FDA recommends to prevent burns from electric handpieces. Essentially, it boils down to assuring proper maintenance. For example:

1. Maintain the handpiece according to the manufacturer’s instructions, and verify how often the device should be serviced.
2. Be sure that personnel are trained to clean and maintain the device, and that they track and record this.
3. Examine the handpiece before you use it, and be sure you’re not using a worn drill or bur.

Finally, it’s also important to understand that the problem of burns from electric handpieces occurs outside the dental area. Similar devices are used in orthopedics, ENT procedures and podiatry, and any of these devices can also cause burns. Rotary surgical handpieces can cause patient burns during orthopedic procedures, as reported in the July 2003 edition of FDA Patient Safety News (http://www.fda.gov/cdrh/psn/show17-burns.html). Dental offices may receive medical alerts from the FDA, pharmaceutical companies or device manufacturer when a product or interaction among products and/or services may be increase a patient’s risk of adverse dental events.

**Increased risk products and procedures**

Adverse events are sometimes associated with certain medications, products, or procedures. The following notice, issued by Novartis Pharmaceutical Corp. in 2005, is an example of a warning to dental professionals regarding increased risk of osteonecrosis of the jaw, resulting from a combination of invasive dental procedures and medication for cancer treatment.

**IMPORTANT DRUG PRECAUTION FOR DENTAL HEALTH PROFESSIONALS WITH PATIENTS BEING TREATED FOR CANCER**

Dear Doctor:

We are writing to inform you of an adverse event osteonecrosis of the jaw (ONJ) observed in cancer patients receiving treatment with
intravenous bisphosphonates, Aredia and Zometa, which may have an impact on the dental care of patients within your practice. While on treatment, invasive dental procedures should be avoided, if possible.

The prescribing information recommends that cancer patients:
● Receive a dental examination prior to initiating therapy with intravenous bisphosphonates (Aredia and Zometa).
● Avoid invasive dental procedures while receiving bisphosphonate treatment.

For patients who develop ONJ while on bisphosphonate therapy, dental surgery may exacerbate the condition. Clinical judgment by the treating physician should guide the management plan of each patient based on individual benefit/risk assessment.

**Precautions**

- Osteonecrosis of the jaw.
- Osteonecrosis of the jaw (ONJ) has been reported in patients with cancer receiving treatment regimens including bisphosphonates. Many of these patients were also receiving chemotherapy and corticosteroids. The majority of reported cases have been associated with dental procedures such as tooth extraction. Many had signs of local infection including osteomyelitis.

A dental examination with appropriate preventive dentistry should be considered prior to treatment with bisphosphonates in patients with concomitant risk factors (e.g. cancer, chemotherapy, corticosteroids, poor oral hygiene).

While on treatment, these patients should avoid invasive dental procedures if possible. For patients who develop ONJ while on bisphosphonate therapy, dental surgery may exacerbate the condition. For patients requiring dental procedures, there are no data available to suggest whether discontinuation of bisphosphonate treatment reduces the risk of ONJ. Clinical judgment of the treating physician should guide the management plan of each patient based on individual benefit/risk assessment.

ONJ is a complex problem with multiple risk factors. Typical signs and symptoms of ONJ include, but are not limited to: pain, swelling or infection of the gums; loosening of the teeth; poor healing of the gums; numbness or a feeling of heaviness in the jaw; drainage; and exposed bone. The seriousness of ONJ ranges from patient being asymptomatic to requiring sections of the jaw to be removed.

Dentists, oral surgeons, periodontists, prosthodontists, dental hygienists and other dental health professionals can play a vital role in identifying ONJ and other oral complications of cancer and cancer therapy.

For more information about dental treatment for cancer patients receiving bisphosphonate therapy, please refer to:
● “Expert Panel Recommendations for the Prevention, Diagnosis and Treatment of Osteonecrosis of the Jaws: June 2004.”
● Revised package inserts on complete prescribing information for both Aredia and Zometa.
● Patient brochure, “Taking Care of Yourself While Living With Cancer: Dental Health and Osteonecrosis of the Jaw,” which you can share with patients who request more information on the topic (ONC-8155-01).

Please copy this information and share it with other dental health professionals in your practice, including dental hygienists. Additional copies of the patient brochure are available at no charge by calling Novartis at [1-800-521-9445] using the order number provided above.

Health care professionals are strongly encouraged to submit a report of any serious adverse events that occur with the use of Aredia or Zometa to Novartis Pharmaceuticals Corp. at [1-800-882-6577] or fax [1-888-299-4565] or to the FDA's MedWatch Adverse Event Reporting program online [at www.fda.gov/MedWatch/report.htm], by phone [1-800-FDA-1088], or by returning the postage-paid FDA form 3500 [which may be downloaded from www.fda.gov/MedWatch/getforms.htm] by mail [to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787] or fax [1-800-FDA-0178].

Please contact Novartis Oncology Medical Services at [1-888-669-6682] if you have questions.

**Job demands and adverse events**

A Japanese study, published in BMC Oral Health in 2007, attempts to shed more light on how adverse events can occur, and suggests that increase risk of adverse events may be associated with certain psychosocial job demands. This study examined the relationship between certain job demands and the risk of adverse dental events. Its purpose was to ascertain the impact of dental mismanagement on dental outcomes. The authors hypothesized that some job demands make a dentist more likely to cause adverse events, but no studies had investigated the relationship. Adverse events in the study were defined as any injury or complication in a patient due to dental mismanagement. The outcome was defined according to “whether the respondent’s patients experienced one of the following adverse events at least once during the previous one year: dropping of dental instrument or broken injection needle, soft tissue or nerve injury (numbness), accidental bleeding, loss of a tooth root into the maxillary sinus, and emphysema.”

The study found adverse events occurred with greater frequency among dental practitioners who felt stressed by a “harsh” work environment, including psychosocial demands such as having to work fast, having to use a high degree of precision, having to remember a lot of things, and having emotionally demanding work which requires hiding emotion. The number of patients seen per day was positively associated with adverse events, although working hours were not. A supportive environment may mediate this effect.
DENTAL OFFICE – PREVENTING MEDICAL ERRORS

Final Examination Questions
Select the best answer for each question and mark your answers online at Dental.EliteCME.com.

1. Medical errors always result in patient injury or death.
   ○ True
   ○ False

2. The key to reducing medical errors is to focus on improving the systems of delivering care and not to blame individuals.
   ○ True
   ○ False

3. Research clearly shows that the majority of medical errors cannot be prevented.
   ○ True
   ○ False

4. Near-misses are occurrences that could have resulted in an adverse event, but the event was averted and the patient was not harmed.
   ○ True
   ○ False

5. Root-cause analysis is the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim.
   ○ True
   ○ False

References
- An overview of the current status of national reporting systems for adverse reactions to dental material, Journal of Dentistry, Volume 32, Issue 5, July 2004, Pages 155-158, by Richard van Noort, Nils R. Gjerde, Andreas Schedel, Lars Bjorkman, and Anders Bjerlum, Department of Adult Dental Care, University of Sheffield