CHAPTER I
DENTAL OFFICE – PREVENTING MEDICAL ERRORS
(2 CE HOURS)

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, defines concepts and issues associated with medical errors and reviews findings from recent studies, including the seminal 1999 Institute of Medicine (IOM) Report, entitled, To Err Is Human: Building A Safer Health System, which defined the issue and urged a variety of strategies to address and prevent medical errors.

Part II: Advances in patient safety; from research to implementation, discusses attempts to develop a unified reporting system for adverse events and describes some of the policies and procedures currently in place to report adverse events, faulty equipment, and adverse reactions to drugs, dental materials and devices.

Part III: Adverse events in dentistry, reviews recent research in dental-related adverse events, highlighting findings from the analysis of databases compiled by the FDA’s MedWatch or similar programs in other countries.

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/4/1177/ToErr-Spager.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 systems-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 postsurgical 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 medical 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 handheld 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.

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

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.
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 temporarily 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.
  - Of an improperly prepared drug.
  - By a means other than as prescribed or indicated.
  - Administration of a medication to which the patient has a known allergy or drug interaction to the prescribed medication.

- **Near-miss**: An event or a situation that did not produce patient harm, but only because of intervening factors, such as patient health or timely intervention. Also known as a “close call.”

- **Never event**: An event or a situation that should never occur in a health care setting. The National Quality Forum initially used the term “never events” to describe its list of serious events but began in 2005 to refer to the list as “serious reportable events.”

- **Patient safety**: Freedom from accidental or preventable injuries caused by medical care.

- **Risk reduction strategies**: Interventions, actions and strategies designed to reduce the risk of recurrence of the event. Typically part of a corrective action plan.

- **Root-cause analysis**: A focused review of systems and processes to identify the basic or contributing factors that cause adverse events.

- **Serious reportable or adverse event**: May be referred to as a “sentinel” event (see below).

- **Sentinel event**: An unexpected occurrence involving death or serious physical or psychological injury.

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. The incident prompted the state to issue an advisory on the risks associated with using specific colors to convey clinical information.

States and accrediting agencies require hospitals and health care organizations to establish internal processes to identify adverse events, conduct root-cause analyses, identify and document areas of risk, and implement a plan of risk-reduction measures to correct system failures. Many of these policies have been adopted by state agencies for reporting purposes. If your practice is ICAHO-accredited (see below), or if you live in a mandatory reporting state, you will need to be familiar with the specific adverse event reporting procedures in place for your organization and/or state.

Sample state policies and procedures

This section describes policies and procedures associated with reporting serious adverse events.
Patient safety sentinel events include:

- Event later than four hours prior to convening a patient safety event may have occurred, but in no event later than four hours prior to convening a patient safety event. 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:
    - Objects intentionally implanted as a part of a planned intervention.
    - Objects present prior to surgery that were intentionally left in place.
    - Broken microneedles.
  - Intraoperative or immediately post-operative death of a patient who the facility classified prior to surgery as Anesthesia Surgical Assessment Class I. “Intraoperative” means literally during surgery. “Immediately post-operative” means within 24 hours after surgery, or other invasive procedure was completed, or after induction of anesthesia if surgery not completed.
  - Product or device events.
    - Patient death or disability arising from the use of contaminated drugs, devices or biologics provided by the facility.
    - Patient death or disability associated with the use or function of a device in patient care in which the device is used for an off-label use, except where the off-label use is pursuant to informed consent.
  - Patient death or disability associated with intravascular air embolism that occurs while being cared for in the facility, except for intravascular air emboli associated with neurosurgical procedures.
  - Patient protection events.
  - Care management events.
    - Patient death or major permanent loss of function arising from a medication error.
    - Patient death or major permanent loss of function arising from a hemolytic reaction due to the administration of ABO/HLA incompatible blood or blood products.
    - Patient death or major permanent loss of function arising from hypoglycemia, the onset of hypoglycemia which occurs while the patient is being cared for in the facility.
  - Environmental events.
  - Criminal events.

**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.

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.
- Inquires into all areas appropriate to the specific type of event.
- Makes reasonable attempts to identify and analyze trends of similar events that have occurred at the facility in the past.
- Identifies risk points and their potential contributions to this type of event.
- Determines potential improvement in processes or systems that would tend to decrease the likelihood of such events in the future, or determining, after analysis, that no such improvement opportunities exist.

The Department of Health shall determine the root-cause analysis to be credible if it:

- Is led by someone with training in root-cause analysis processes and who was not involved in the patient safety sentinel event.
- Involves, if necessary, consultation with either internal or external experts in the processes in question who were not involved in the patient safety sentinel event.
- Includes participation by the leadership of the organization and by the individuals most closely involved in the processes and systems under review.
- Is internally consistent, i.e., not contradicting itself or leaving obvious questions unanswered.
- Provides an explanation for all findings of “not applicable” or “no problem.”
- Includes consideration of relevant, available literature.

The report shall be submitted in a department-approved format and shall include at a minimum:

- Facility information.
- Patient information.
- Event information.
- Type of occurrence.
- Analysis.
- Corrective action.
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:

- Type of harm.
- Contributing factors.
- Actions taken.

If the department representative identifies problems with the processes that limit the thoroughness or credibility of the findings and recommendations and that have not been corrected after reporting them to the designated responsible individual, the representative may submit a separate written dissenting report to the administrator of the incident facility, and the department.

The incident facility may seek review of the dissenting report by filing a request for agency as allowed by the Utah Administrative Procedures Act and Department rule. If a dissenting report is not challenged or is upheld on review:

- The facility shall include it in the facility’s records of the root-cause analysis.
- The department may forward it, together with the records of the root-cause analysis.
- The department may forward it to the appropriate state agencies.

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 (e.g., medical foods, dietary supplements and infant formulas). Use the MedWatch website to voluntarily report a serious adverse event, product quality problem or report adverse events that they judge to be clinically significant.

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. Suggestion 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 ICAHO’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.ht.

Health professionals working in a hospital or other user facility (nursing home, ambulatory surgical facility, outpatient treatment facility and outpatient diagnostic facility) should be aware of the legal requirements for medical device-related reporting by user facilities mandated by the Safe Medical Devices Act of 1990 (SMDA) (see TABLE 1, below).

Under the SMDA, physicians’ offices are excluded from the user facility definition and thus exempt from mandatory reporting requirements. The FDA likewise excludes other groups that perform similar functions to physicians’ offices (e.g., dentists, optometrists, nurse practitioners) from mandatory reporting. However, health professionals within a user facility should familiarize themselves with their institution’s procedures for device-related reporting and actively participate in the program. Table 1 lists the medical device-related reporting required of user facilities, manufacturers and distributors.

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

| NB: Days refers to working days, unless otherwise specified |
| User facility: |
| ✤ Deaths (to FDA and manufacturer within 10 days), |
| ✤ Serious injuries/illnesses (to manufacturer within 10 days; to FDA if manufacturer unknown, also within 10 days), |
| ✤ Semiannual reports (to FDA) of all reports sent to FDA and/or manufacturer (due Jan. 1 and July 1), |
| Manufacturer: |
| ✤ Deaths, serious injuries, malfunctions (to FDA within 30 calendar days of becoming aware of event), |
| ✤ 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, |
| ✤ Annual certification of number of reports, |
| 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 unexpected; 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 experiences 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.”

In the case of over-the-counter (OTC) drugs, reports are only required on OTC products marketed under an approved new drug application (NDA), including those prescription drugs that undergo a switch to OTC status. Reports are not required for other OTC drugs (i.e., older drug ingredients that are marketed without an NDA), although voluntary reporting is encouraged.

Both prescription and OTC drugs require FDA safety and efficacy review prior to marketing, unlike dietary supplements (which include vitamins, minerals, amino acids, botanicals and other substances used to increase total dietary intake). By law, the manufacturers of these products do not have to prove safety or efficacy, so the onus is on the FDA to prove that a particular product is unsafe. As a result, direct-to-FDA voluntary health professional reporting of serious adverse events possibly associated with dietary supplements is particularly important.

**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.
- Defective components.
- Poor packaging or product mix-up.
- Questionable stability.
- Device malfunctions.
- Labeling concerns.

**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 generated...
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 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 claspers 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.

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 1 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 to dental materials. In the U.S., adverse-event reports associated with dental devices are collected by the FDA from device manufacturers, health care professionals and consumers. Initially, the 1976 Medical Device Amendments, which became effective in 1984, required device manufacturers to report deaths, serious injuries and malfunctions (a devise malfunction is failure to perform as intended). Six years later, in 1990, the Safe Medical Devices Act required mandatory reporting from user facilities, including hospitals, ambulatory surgical facilities, nursing homes, outpatient treatment and diagnostic facilities, as well 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 99 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’s FDA recommends to prevent burns from electric handpieces. Essentially, it boils down to assuring proper maintenance. For example:

- Maintain the handpiece according to the manufacturer’s instructions, and verify how often the device should be serviced.
- Be sure that personnel are trained to clean and maintain the device, and that they track and record this.
- 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.

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 postcard-paid FDA form 3500 [which may be downloaded from www.fda.gov/MedWatch/forms.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 increasing 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.

References

- Report of the Quality Interagency Coordinating Task Force (QuIC) to the President, February 2000
- Types of psychosocial job demands and adverse events due to dental mismanagement: a cross sectional study, by Akihiro Tanizumi, Katsura Urami and Hiroshi Onoue 2001 American Dental Association
- Aspiration and Ingestion in Dental Practice; a 10-Year Institutional Review, Journal of Dental Association
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Learning objectives

- Define domestic violence/intimate partner violence.
- Learn the different types of domestic violence/intimate partner violence.
- Review a study of domestic violence statistics.
- Identify the different theories as to the causes of domestic violence.
- Discuss the role of the medical/dental professional.
- Explain how to identify and respond to abuse victims.
- List the guidelines for assessment and documenting a patient file.
- Learn the applicable Florida Statutes 39, 415, 790 and 794.
- Discuss Florida statistics relating to domestic/intimate partner violence.
- Learn the federal and state domestic violence hot lines.

Introduction

Although most people believe domestic violence/intimate partner violence (IPV) is a substantial public health problem in the United States, few agree on its magnitude. Recognizing the need to better measure both the scope of the problem of IPV as well as resulting economic costs – in particular, those related to health care – Congress funded the Centers for Disease Control and Prevention (CDC) to conduct a study to obtain national estimates of the occurrence of IPV-related injuries, to estimate their costs to the health care system, and to recommend strategies to prevent IPV and its consequences.

Before we get started, let’s define domestic violence/intimate partner violence (IPV), particularly in the state of Florida. According to Florida Statute 741. 28 Domestic violence, the definition is as follows:

- “Domestic violence” means any assault, aggravated assault, battery, aggravated battery, sexual assault, sexual battery, stalking, aggravated stalking, kidnapping, false imprisonment, or any criminal offense resulting in physical injury or death of one family or household member by another family or household member.

Another definition goes into a little more depth in explaining domestic violence/intimate partner violence (IPV) and the behavior patterns that account for the multiple forms of abuse that victims are exposed to during their lifetime as follows:

- Domestic violence (also known as domestic abuse, spousal abuse or intimate partner violence) occurs when a family member, partner or ex-partner attempts to physically or psychologically dominate another. Domestic violence often refers to violence between spouses, or spousal abuse, but can also include cohabitants and nonmarried intimate partners. Domestic violence occurs in all cultures; people of all races, ethnicities, religions, sexes and classes can be perpetrators of domestic violence. Domestic violence is perpetrated by both men and women. Domestic violence has many forms, including physical violence, sexual abuse, emotional abuse, intimidation, economic deprivation and threats of violence. Violence can be criminal and includes physical assault (hitting, pushing, shoving, etc.), sexual abuse (unwanted or forced sexual activity) and stalking. Although emotional, psychological and financial abuses are not criminal behaviors, they are forms of abuse and can lead to criminal violence. There are a number of dimensions, including:

  - **Mode:** Physical, psychological, sexual and/or social.
  - **Frequency:** On/off, occasional and chronic.
  - **Severity:** In terms of both psychological or physical harm and the need for treatment.
  - **Transitory or permanent injury:** Mild, moderate, severe and up to homicide.

An important component of domestic violence, often ignored, is the realm of passive abuse, leading to violence. Passive abuse is covert, subtle and veiled. This includes victimization, procrastination, forgetfulness, ambiguity, neglect, spiritual and intellectual abuse.

Recent attention to domestic violence began in the women’s movement, particularly feminism and women’s rights, in the 1970s, as concern about wives being beaten by their husbands gained attention. Awareness and documentation of domestic violence differs from country to country. Estimates are that only about a third of cases of domestic violence are actually reported in the United States and the United Kingdom. According to the Centers for Disease Control, domestic violence is a serious, preventable public health problem affecting more than 32 million Americans, or more than 10 percent of the U.S. population.

Popular emphasis has tended to be on women as the victims of domestic violence. However, with the rise of the men’s movement, and particularly masculinity and men’s rights, there is now advocacy for men victimized by women. In a special report on violence-related injuries by the U.S. Department of Justice (in August 1997), hospital emergency room visits pertaining to domestic violence indicated that physically abused men represent just under one-sixth of the total patients admitted to a hospital reporting domestic violence as the cause of their injuries (see table 7 of the report). The report highlights that significantly more men than women did not disclose the identity of their attacker.

The term “intimate partner violence” (IPV) is often used synonymously. Family violence is a broader definition, often used to include child abuse, elder abuse and other violent acts between family members. Wife abuse, wife beating and battering are terms sometimes used, though with acknowledgment that many are not actually married to the abuser, but rather co-habiting or other arrangements. In more recent years, “battering” or “battered wife” have become less acceptable terminology because abuse can take other forms than physical abuse, and males are often victims of violence as well. Other forms of abuse may be constantly occurring, while physical abuse happens occasionally. These other forms of abuse have potential to lead to mental illness, self-harm and even attempts at suicide.

The U.S. Office on Violence Against Women (OVW) defines domestic violence as a “pattern of abusive behavior in any relationship that is used by one partner to gain or maintain power and control over another intimate partner.” The definition adds that domestic violence “can happen to anyone regardless of race, age, sexual orientation, religion or gender,” and that it can take many forms, including physical abuse, sexual abuse, emotional, economic and psychological abuse.

The Children and Family Court Advisory and Support Service in the United Kingdom in its Domestic Violence Policy uses domestic violence to refer to a range of violent and abusive behaviors, defining it as:

- Patterns of behavior characterized by the misuse of power and control by one person over another who are or have been in an intimate relationship. It can occur in mixed gender relationships and same gender relationships, and has profound consequences for the lives of children, individuals, families and communities. It may be physical, sexual, emotional and/or psychological. The latter may include intimidation, harassment, damage to property, threats and financial abuse.

Domestic violence can take the form of physical violence, including direct physical violence ranging from unwanted physical contact to rape and murder. Indirect physical violence may include destruction of objects, striking or throwing objects near the victim, or harm to pets. In addition to physical violence, spousal abuse often includes mental or emotional abuse, including verbal threats of physical violence to the victim, the self or others including children, ranging from explicit, detailed and impending to implicit and vague as to both content and time frame; and verbal violence, including threats, insults, put-downs, and attacks. Nonverbal threats may include gestures, facial expressions and body postures. Psychological abuse may also involve economic and/or social control, such as controlling the victim's money and other economic resources, preventing the victim from seeing friends and relatives, actively sabotaging the victim’s social relationships and isolating the victim from social contacts.

Physical violence

Physical violence is the intentional use of physical force with the potential for causing injury, harm, disability or death, for example, hitting, shoving, biting, restraint, kicking or use of a weapon.
At least 42 percent of women and 20 percent of men who were physically assaulted since age 18 sustained injuries during their most recent victimization. Most injuries were minor such as scratches, bruises and welts.

More severe physical consequences of IPV may occur depending on severity and frequency of abuse. These include:

- Bruises.
- Knife wounds.
- Pelvic pain.
- Headaches.
- Back pain.
- Broken bones.
- Gynecological disorders.
- Pregnancy difficulties like low birth weight babies and perinatal deaths.
- Sexually transmitted diseases including HIV/ AIDS.
- Central nervous system disorders.
- Gastrointestinal disorders.
- Sleep disturbances.
- Flashbacks.
- Replaying assault in mind.
- Heart or circulatory conditions.

**Sexual violence**

Sexual violence is divided into three categories:

1. Use of physical force to compel a person to engage in a sexual act against his or her will, regardless of whether the act is completed.
2. Attempted or completed sex act involving a person who is unable to understand the nature or condition of the act, unable to decline participation, or unable to communicate unwillingness to engage in the sexual act, e. g., because of underage immaturity, illness or disability.
3. The influence of alcohol or other drugs, or because of intimidation or pressure; and abusive sexual contact.

**Emotional abuse**

Emotional abuse (also called psychological abuse or mental abuse) can include humiliating the victim privately or publicly, controlling what the victim can and cannot do, withholding information from the victim, deliberately doing something to make the victim feel diminished or embarrassed, isolating the victim from friends and family, implicitly blackmailing the victim by harming others when the victim expresses independence or happiness, or denying the victim access to money or other basic resources and necessities.

Women who are being emotionally abused often feel as if they do not own themselves; rather, they may feel that their significant other has nearly total control over them. Women undergoing emotional abuse often suffer from depression, which puts them at increased risk for suicide, eating disorders, and drug and alcohol abuse.

**Economic abuse**

Economic abuse is when the abuser has complete control over the victim’s money and other economic resources. Usually, this involves putting the victim on a strict “allowance,” withholding money at will and forcing the victim to beg for the money until the abuser gives them some money. It is common for the victim to receive less money as the abuse continues. This also includes (but is not limited to) preventing the victim from finishing education or obtaining employment, or intentionally squandering or misusing communal resources.

**Stalking**

In addition, stalking is often included among the types of intimate partner violence. Stalking generally refers to repeated behavior that causes victims to feel a high level of fear.

**Domestic violence statistics**

Domestic violence occurs across the world in various cultures, and affects people across society, irrespective of economic status. In the United States, according to the Bureau of Justice Statistics, women are about six times as likely as men to experience intimate partner violence. The percent of women surveyed (national surveys) who were ever physically assaulted by an intimate partner showed these results:

- Barbados (30 percent).
- Canada (29 percent).
- Egypt (34 percent).
- New Zealand (35 percent).
- Switzerland (21 percent).
- United States (22 percent).

Some surveys in specific places report figures as high as 50-70 percent of women surveyed who say they had been physically assaulted by an intimate partner. Others, including surveys in the Philippines and Paraguay, report figures as low as 10 percent. The rate of intimate partner violence in the U.S. has declined since 1993. Almost always, surveys will undercount actual numbers. Results will also vary, depending on specific wording of survey questions, how the survey is conducted, the definition of abuse or domestic violence used, the willingness or unwillingness of victims to admit that they have been abused and other factors.

In May 2007, researchers with the Centers for Disease Control reported on rates of self-reported violence among intimate partners using data from a 2001 study. In the study, almost one-quarter of participants reported some violence in their relationships. Half of these involved one-sided (“nonreciprocal”) attacks and half involved both assaults and counterassaults (“reciprocal violence”). Women reported committing one-sided attacks more than twice as often as men (70 percent versus 29 percent).

In all cases of intimate partner violence, women were more likely to be injured than men were, but 25 percent of men in relationships with two-sided violence reported injury compared to 20 percent of women reporting injury in relationships with one-sided violence. Women were more likely to be injured in nonreciprocal violence.

While much attention has been focused on domestic violence against women, men’s rights activists argue that domestic violence against men is a social problem that is also worthy of attention. Each year, 834,000 men are raped or physically assaulted by intimate partners an average of 3.5 times a year, for a total of 2.9 million assaults a year (4.9 million for women).

Men in intimate relationships with other men are more likely to be raped or assaulted than men in heterosexual relationships. According to the 2000 CDC/Justice study, “Approximately 23 percent of the men who had lived with a man as a couple reported being raped, physically assaulted and/or stalked by a male cohabitant, while 7.4 percent of the men who had married or lived with a woman as a couple reported such violence by a wife or female cohabitant. These findings, combined with those presented (in the 2007 report), provide further evidence that intimate partner violence is perpetrated primarily by men, whether against male or female intimates.”

**Violence against children**

When it comes to domestic violence towards children involving physical abuse, research in the UK by the NSPCC indicated that “most violence occurred at home” (78 per cent). Forty to 60 percent of men and women who abuse other adults also abuse their children. Girls whose fathers batter their mothers are 6.5 times more likely to be sexually abused by their fathers than are girls from nonviolent homes.

**Violence against teens**

Teen dating violence is a pattern of controlling behavior by one of the two teens in the relationship. While there are many similarities to “traditional” domestic violence, there are also some differences. Teens are much more likely than adults to become isolated from their peers as the result of controlling behavior by their boyfriend/girlfriend. Also, for many teens, the abusive relationship may be their first dating experience, and they have never had a normal dating experience with which to compare it.

**2005 World Health Organization multicountry study**

The World Conference on Human Rights, held in Vienna in 1993, and the Declaration on the Elimination of Violence against Women in the same year, concluded that civil society and governments have acknowledged that violence against women is a public health and human rights concern. Work in this area has resulted in the establishment of international standards, but the task of documenting the magnitude of violence against women and producing reliable, comparative data to guide policy and monitor implementation has been exceedingly difficult.

The World Health Organization’s Multicountry Study on Women’s Health and Domestic Violence against Women 2005 is a response to this difficulty. Published in 2005, it is a groundbreaking study that analyzed data from 10 countries and sheds new light on the prevalence of violence against women. The findings will be used to inform a more effective response from government, including the health, justice and social service sectors, as a step towards fulfilling
the state’s obligation to eliminate violence against women under international human rights laws.

**Types of domestic violence**
The form and characteristics of domestic violence and abuse may vary in other ways. Michael P. Johnson (1995, 2006) argues for three major types of intimate partner violence. The typology is supported by subsequent research and evaluation by Johnson and his colleagues, as well as independent researchers. Distinctions need to be made regarding types of violence, motives of the perpetrators, and the social and cultural context. Violence by a man against his wife or intimate partner is often done as a way for men to control “their woman.” Other types of intimate partner violence also occur, including violence between gay and lesbian couples, and by women against their male partners. Distinctions are not based on single incidents, but rather on patterns across numerous incidents and motives of the perpetrator. Types of violence identified by Johnson:

- Common couple violence (CCV) is not connected to general control behavior, but arises in a single argument where one or both partners physically lash out at the other.
- Intimate terrorism is one element in a general pattern of control by one partner over the other. Intimate terrorism is more common than common couple violence, more likely to escalate over time, not as likely to be mutual, and more likely to involve serious injury.
- Violent resistance (VR), sometimes thought of as “self-defense,” is violence perpetrated usually by women against their abusive partners.
- Mutual violent control (MVC) is a rare type of intimate partner violence and occurs when both partners act in a violent manner, battling for control.
- Another type is situational couple violence, which arises out of conflicts that escalate to arguments and then to violence. It is not connected to a general pattern of control. Although it occurs less frequently in relationships and is less serious than intimate terrorism, in some cases it can be frequent and/or quite serious, even life-threatening. This is probably the most common type of intimate partner violence and dominates general surveys, student samples and even marriage counseling samples.

Types of male batterers identified by Holtzworth-Munroe and Stuart (1994) include “family-only,” which primarily fall into the CCV type, who are generally less violent and less likely to perpetrate psychological and sexual abuse. IT batterers include two types, “generally-violent-antisocial” and “dysphoric-borderline.” The first type includes men with general psychopathic and violent tendencies. The second type is men who are emotionally dependent on the relationship. Support for this typology has been found in subsequent evaluations. Others, such as the CDC, divide domestic violence into two types: reciprocal violence, in which both partners are violent, and nonreciprocal violence, in which one partner is violent.

**Theories**
There are many different theories as to the causes of domestic violence. These include psychological theories that consider personality traits and mental characteristics of the offender, as well as social theories that consider external factors in the offender’s environment, such as family structure, stress, social learning. As with many phenomena regarding human experience, no single approach appears to cover all cases.

**Psychological theories**
Psychological theories focus on personality traits and mental characteristics of the offender. Personality traits include sudden bursts of anger, poor impulse control and poor self-esteem. Various theories suggest that psychopathy and other personality disorders are factors, and that abuse experienced as a child leads some people to be more violent as adults. Studies have found high incidence of psychopathy among abusers. Dutton has suggested a psychological profile of men who abuse their wives, arguing that they have borderline personalities (between psychotics and neurotics), which are developed early in life. Gelles suggests that psychological theories are limited, and points out that other researchers have found that only 10 percent (or less) fit this psychological profile. He argues that social factors are important, while personality traits, mental illness or psychopathy are lesser factors.

It should be noted that borderline personality disorder as used in this context is outdated. While it was originally believed that a person’s psychological state was between neurotic and psychotic, it is now recognized that BPD is the most severe and intransigent of the personality disorders.

**Social theories**
Social theories look at external factors in the offender’s environment, such as family structure, stress, social learning, and includes rational choice theories.

**Resource theory**
Resource theory was suggested by William Goode (1971). Most affected are women who are dependent on their spouse for economic well-being. Having children to take care of, should they leave the marriage, increases the financial burden and makes it all the more difficult for them to leave. Dependency means that they have fewer options and few resources to help them cope with or change their spouse’s behavior. Couples that share power equally experience lower incidence of conflict, and when conflict does arise, are less likely to resort to violence. If one spouse desires control and power in the relationship, the spouse may resort to abuse. This may include coercion and threats, intimidation, emotional abuse, economic abuse, isolation, making light of the situation and blaming the spouse, using children (threatening to take them away), and behaving as “master of the castle.”

**Social stress**
Stress may be increased when a person is living in a family situation with increased pressures. Social stresses, due to inadequate finances or other such problems in a family, may further increase tensions. Violence is not always caused by stress, but may be one way that some (but not all) people respond to stress. Families and couples in poverty may be more likely to experience domestic violence, due to increased stress and conflicts about finances and other aspects. Some speculate that poverty may hinder a man’s ability to live up to his idea of “successful manhood”; thus, he fears losing honor and respect. Theory suggests that when he is unable to economically support his wife and maintain control, he may turn to misogyny, substance abuse and crime as ways to express masculinity.

**Social learning theory**
Social learning theory suggests that people learn from observing and modeling after others’ behavior. With positive reinforcement, the behavior continues. If one observes violent behavior, one is more likely to imitate it. If there are no negative consequences (e.g., victim accepts the violence, with submission), then the behavior will likely continue. Often, violence is transmitted from generation to generation in a cyclical manner.

**Power and control**
In some relationships, violence arises out of a perceived need for power and control, a form of bullying and social learning of abuse. Abusers’ efforts to dominate their partners have been attributed to low self-esteem or feelings of inadequacy, unresolved childhood conflicts, the stress of poverty, hostility and resentment toward women (misogyny), hostility and resentment toward men (misandry), personality disorders, genetic tendencies and sociocultural influences, among other possible causative factors. Most authorities seem to agree that abusive personalities result from a combination of several factors, to varying degrees.

Another view of domestic violence is that it is a strategy to gain or maintain power and control over the victim. This view is in alignment with Bancroft’s “cost-benefit” theory that abuse rewards the perpetrator in ways other than, or in addition to, simply exercising power over his or her target(s). He cites evidence in support of his argument that, in most cases, abusers are quite capable of exercising control over themselves but choose not to do so for various reasons. An alternative view is that abuse arises from powerlessness and externalizing/projecting this and attempting to exercise control of the victim. It is an attempt to “gain or maintain power and control over the victim,” but even in achieving
Questions of power and control are integral
to the widely utilized Duluth Domestic Abuse
Intervention Project. The project included
developing the “power and control wheel”to
illustrate this: it has power and control at the
center, surrounded by spokes (to show the
techniques used), which include:
- Coercion and threats.
- Intimidation.
- Emotional abuse.
- Isolation.
- Minimizing, denying and blaming.
- Using children.
- Economic abuse.
- Male privilege.

The model attempts to address abuse by one-
sidedly challenging the misuse of power by the
“perpetrator.” Critics of this model suggest that
the one-sided focus is problematic as resolution
can only be achieved when all participants
acknowledge their responsibilities, and identify
and respect mutual purpose.

The power wheel model is not intended to
assign personal responsibility, enhance respect
for mutual purpose or assist victims and
perpetrators in resolving their differences. It is an
informational tool designed to help individuals
understand the dynamics of power operating in
abusive situations and identify various methods
of abuse.

**Alcohol-related and nonalcohol-related
violence**

Other factors associated with domestic violence
include heavy alcohol consumption, mental
illness, classism and various political and legal
characteristics such as authoritarianism and
dehumanization.

**Prescription drugs**

It is also important to this topic to understand
the paradoxical effects of some sedative drugs.
Serious complications can occur in conjunction
with the use of sedatives creating the opposite
effect as to that intended. Malcolm Lader at the
Institute of Psychiatry in London estimates the
incidence of these adverse reactions at about 5
percent, even in short-term use of the drugs. The
paradoxical reactions may consist of depression,
with or without suicidal tendencies; and phobias,
aggressiveness, violent behavior and symptoms
sometimes misdiagnosed as psychosis. The
contribution of these reactions is one possible
component.

**Sex and gender**

Modes of abuse are stereotyped by some to
be gendered, females tending to use more
psychological and men more physical forms. The
visibility of these differs markedly. However,
experts who work with victims of domestic
violence have noted that physical abuse is almost
invariably preceded by psychological abuse.
Police and hospital admission records indicate
that a higher percentage of females than males
seek treatment and report such crimes. Unless or
until more women identify themselves and go on
record as having been abused by female partners
and in a manner whereby the nature and extent
of their injuries can be clinically assessed, men
will continue to be identified as the most frequent
perpetrators of physical and emotional violence.

**Cycle of violence**

Frequently, domestic violence is used to describe
specific violent and overtly abusive incidents, and
legal definitions will tend to take this perspective.
However, when violent and abusive behaviors
happen within a relationship, the effects of those
behaviors continue after these overt incidents
are over. Advocates and counselors will refer
to domestic violence as a pattern of behaviors,
including those listed above. Lenore Walker
presented the model of a cycle of violence which
consists of three basic phases:

1. **Honeymoon phase**
   This phase is characterized by affection,
apology and an apparent end to the
violence. During this stage, the batterer
feels overwhelming feelings of remorse and
sadness. Some batterers walk away from
the situation, while others shower their victims
with love and affection.

2. **Tension-building phase**
   This phase is characterized by poor
communication, tension and fear of causing
outbursts. During this stage, the victims try
to calm the batterer down to avoid any major
violent confrontations.

3. **Acting-out phase**
   This phase is characterized by outbursts
of violent, abusive incidents. During this
stage, the batterer attempts to dominate his/
her partner (victim) with the use of domestic
violence.

Although it is easy to see the outbursts of the
acting-out phase as abuse, even the more pleasant
behaviors of the honeymoon phase serve to
perpetuate the abuse.

Many domestic violence advocates believe that
the cycle of violence theory is limited and does
not reflect the realities of many men and women
experiencing domestic violence.

**Gender differences**

The role of gender is a controversial topic related
to the discussion of domestic violence.

Erin Pizze, the founder of an early women’s
shelter in Chiswick, London, has expressed her
dismay at how she believes the issue has become
a gender-political football, and expressed an
unpopular view in her book, “Prone to Violence,”
that some women in the refuge system had a
predisposition to seek abusive relationships. She
also expressed the view that domestic violence
can occur against any vulnerable intimates,
regardless of their gender.

A Freudian concept, repetition compulsion, has
also come up in modern psychology as a possible
cause of a woman who was abused in childhood
seeking an abusive man (or vice versa),
theoretically as a misguided way to “master” their
traumatic experience.

There continues to be discussion about whether
men are more abusive than women, whether
men’s abuse of women is worse than women’s
abuse of men, and whether abused men should
be provided the same resources and shelters that
years of advocacy, money-raising, and funding
has gained for women victims.

Martin S. Fiebert of the Department of
Psychology at California State University, Long
Beach, provides an analysis of 219 scholarly
investigations: 170 empirical studies and 49
analyses, which he believes demonstrate women
are as physically aggressive, or more aggressive,
than men are. In a Los Angeles Times article
about male victims of domestic violence, Fiebert
suggests that “… consensus in the field is that
women are as likely as men to strike their partner
but that – as expected – women are more likely
to be injured than men. ” However, he noted, men
are seriously injured in 38 percent of the cases in
which “extreme aggression” is used. No statistic
was given to shed light on how often “extreme
aggression” occurs with women as the aggressor.
The article goes on to say, “We’ve all learned
to be wary of statistics, and Fiebert says studies
abound on the subject. He notes, however, that
those suggesting men are also frequent abuse
victims should not be used to minimize the threat
that women face from abusive boyfriends or
spouses.”

In a meta-analysis, John Archer, Ph. D., from the
Department of Psychology, University of Central
Lancashire, UK, writes:

“The present analyses indicate that men are
among those who are likely to be on the
receiving end of acts of physical aggression.
The extent to which this involves mutual
combat or the male equivalent to ‘battered
women’ is at present unresolved. Both
situations are causes for concern. Straus
(1997) has warned of the dangers involved
– especially for women – when physical
agression becomes a routine response to
relationship conflict. ‘Battered men’ – those
subjected to systematic and prolonged
violence – are likely to suffer physical and
psychological consequences, together with
specific problems associated with a lack
of recognition of their plight (George and
George, 1998). Seeking to address these
problems need not detract from continuing
to address the problem of ‘battered women.’”

Donald G. Dutton and Tonia L. Nicholls, from
the Department of Psychology at the University
of British Columbia also undertook a meta-
analysis of data in 2005. They concluded:

“Clearly, shelter houses full of battered
women demonstrate the need for their
continued existence. Moreover, outside
of North American and Northern Europe,
gender inequality is still the norm (Archer, in
press). However, within those countries that have been most progressive about women’s equality, female violence has increased as male violence has decreased (Archer, in press). There is not one solution for every domestically violent situation; some require incarceration of a terrorist perpetrator, others can be dealt with through court-mandated treatment, still others may benefit from couples therapy. However, feminist-inspired intervention standards that preclude therapists in many states from doing effective therapy with male batterers are one outcome of this paradigm. The failure to recognize female threat to husbands, female partners or children is another (Straus et al., 1980 found 10 percent higher rates of child abuse reported by mothers than by fathers). "The one-size-fits-all policy driven by a simplistic notion that intimate violence is a recapitulation of class war does not most effectively deal with this serious problem or represent the variety of spousal violence patterns revealed by research. At some point, one has to ask whether feminists are more interested in diminishing violence within a population or promoting a political ideology. If they are interested in diminishing violence, it should be diminished for all members of a population and by the most effective and utilitarian means possible. This would mean an intervention/treatment approach based on other successful approaches from criminology and psychology.

Theories that women are as violent as men have been dubbed “gender symmetry” theories. In the most serious violence, the men do dominate. For example, in 1999 in the U.S., 1,218 women and 424 men were killed by an intimate partner, regardless of which partner started the violence and of the gender of the partner. On the other hand, Michael Kimmel of the State University of New York at Stony Brook found that men are more violent inside and outside of the home than women are.

A problem in conducting studies that seek to describe violence in terms of gender is the amount of silence, fear and shame those results from abuse within families and relationships. Another is that abusive patterns can tend to seem normal to those who have lived in them for a length of time. Similarly, subtle forms of abuse can be quite transparent even as they set the stage for further abuse seeming normal. Finally, inconsistent definition of what domestic violence makes definite conclusions difficult to reach when compiling the available studies.

Both men and women have been arrested and convicted of assaulting their partners in both heterosexual and homosexual relationships. The bulk of these arrests have been men being arrested for assaulting women. However, in the case of reciprocal violence, frequently only the male perpetrator is arrested. Determining how many instances of domestic violence actually involve male victims is difficult. Male domestic violence victims may be reluctant to help

for a number of reasons. Another study has demonstrated a high degree of acceptance by women of aggression against men.

Murders of female intimate partners by men have dropped, but not nearly as dramatically. Men kill their female intimate partners at about four times the rate that women kill their male intimate partners. Research by Jacoblyn Campbell, PhD, RN FAAN has found that at least two-thirds of women killed by their intimate partners were battered by those men prior to the murder. She also found that when males are killed by female intimates, the women in those relationships had been abused by their male partner about 75 percent of the time.

Some researchers have found a relationship between the availability of domestic violence services, improved laws and enforcement regarding domestic violence and increased access to divorce, and higher earnings for women with declines in intimate partner homicide. However, both men and women are far less likely to be abused when married to each other. The bulk of injuries from domestic violence involves colhabitation or the distresses of relationship breakups.

Gender roles and expectations can and do play a role in abusive situations, and exploring these roles and expectations can be helpful in addressing abusive situations, as do factors like race, class, religion, sexuality and philosophy. None of these factors cause one to abuse or another to be abused.

Concerns about social programs dealing with violence

In 1997, the Canadian Advertising Foundation ruled that a National Ad campaign that featured Nicole Brown Simpson’s sister Denise, with the slogan entitled, “Stop violence against Women” was in fact portraying only men as aggressors, and that it was not providing a balanced message and was in fact contributing to gender stereotyping (The murder of Nicole Simpson also included the murder of Ronald Goldman).

Domestic violence in same-sex relationships

Domestic violence also occurs in same-sex relationships. In an effort to be more inclusive, many organizations have made an effort to use gender-neutral terms when referring to perpetrators and victims.

Historically, domestic violence has been seen as a family issue, and little interest has been directed at violence in same-sex relationships. It has not been until recently, as the gay rights movement has brought the issues of gay and lesbian people into public attention, that research has started to be conducted on same-sex relationships. Several studies have indicated that partner abuse among same-sex couples (both female and male) is relatively similar in both prevalence and dynamics to that among opposite-sex couples. Gays and lesbians, however, face special obstacles in dealing with the issues that some researchers have labeled “the double closet.” A recent Canadian study by Mark W. Lehman suggests similarities include frequency (approximately one in every four couples); manifestations (emotional, physical, financial, etc. ); co-existent situations (unemployment, substance abuse, low self-esteem); victims’ reactions (fear, feelings of helplessness, hypervigilance); and reasons for staying (love can work it out, things will change, denial).

At the same time, significant differences, unique issues and deceptive myths are typically present. Lehman points to added discrimination and fear that gays and lesbians can face; dismissal by police and some social services; a lack of support from peers who would rather keep quiet about the problem in order not to attract negative attention toward the gay community; the impacts of HIV status or AIDS in keeping partners together due to health care insurance/access, or guilt; outing used as a weapon; and encountering supportive services that are targeted or structured for the needs of heterosexual women and which may not meet the needs of gay men or lesbians.

Diagnosis planning

The American Psychiatric Association planning and research committees for the forthcoming DSM-V (2012) have canvassed a series of new relational disorders that include marital conflict disorder without violence or marital abuse disorder (marital conflict disorder with violence). Couples with marital disorders sometimes come to clinical attention because the couple recognizes long-standing dissatisfaction with their marriage and come to the clinician on their own initiative or are referred by an astute health care professional. Secondly, there is serious violence in the marriage which is “usually the husband battering the wife.” In these cases, the emergency room or a legal authority often is the first to notify the clinician. Most importantly, marital violence “is a major risk-factor for serious injury and even death, and women in violent marriages are at much greater risk of being seriously injured or killed (National Advisory Council on Violence Against Women 2000).” The authors of this study add that “There is current considerable controversy over whether male-to-female marital violence is best regarded as a reflection of male psychopathology and control or whether there is an empirical base and clinical utility for conceptualizing these patterns as relational.”

Recommendations for clinicians making a diagnosis of marital relational disorder should include the assessment of actual or “potential” male violence as regularly as they assess the potential for suicide in depressed patients. Further, “clinicians should not relax their vigilance after a battered wife leaves her husband, because some data suggest that the period immediately following a marital separation is the period of greatest risk for the woman. Many men will stalk and batter their wives in an effort to get them to return or punish them for leaving. Initial assessments of the potential for violence in a marriage can be supplemented by standardized
interviews and questionnaires, which have been reliable and valid aids in exploring marital violence more systematically."

The authors conclude with what they call “very recent information” on the course of violent marriages that suggests that “over time, a husband’s battering may abate somewhat, but perhaps because he has successfully intimidated his wife. The risk of violence remains strong in a marriage in which it has been a feature in the past. Thus, treatment is essential here; the clinician cannot just wait and watch.” The most urgent clinical priority is the protection of the wife because she is the one most frequently at risk, and clinicians must be aware that supporting assertiveness by a battered wife may lead to more beatings, or even death.

**Response to domestic violence**

The response to domestic violence is typically a combined effort between law enforcement agencies, the courts, social service agencies and corrections/probation agencies. The role of each has evolved as domestic violence has been brought more into public view.

Domestic violence historically has been viewed as a private family matter that need not involve government or criminal justice intervention. Police officers were often reluctant to intervene by making an arrest, and often chose instead to simply counsel the couple or ask one of the parties to leave the residence for a period of time. The courts were reluctant to impose any significant sanctions on those convicted of domestic violence, largely because it was viewed as a misdemeanor offense.

Activism initiated by victim advocacy groups and feminist groups has led to a better understanding of the scope and effect of domestic violence on victims and families, and has brought about changes in the criminal justice system’s response.

Several projects have aided in filling the voids in the justice system as it pertains to the protection of victims. One such initiative, The Hope Card Project, makes an attempt to remedy several problems through the issuance of an ID card to victims of abuse. The card is used to identify both parties in a domestic violence protection order and provides additional resources to the victim through a voucher program for services. “There is no photograph on a protection order, so a photograph is a bonus, not a necessity. There are several methods used to obtain the photograph. Some jurisdictions have a photograph taken of the offender during the first hearing while both parties are present. Another method is for officers to take a photograph in the field or retrieve a booking photograph from their local jail. In a lot of cases, the victim brings a photograph and it is scanned. Lastly, the new online site has some state motor vehicle department photograph databases connected for that purpose.”

**Medical response – The role of the medical/dental professional**

Medical/dental professionals, who have contact with abuse victims through medical visits, have a role to play in helping domestic violence victims. Many cases of spousal abuse are handled solely by medical professionals and do not involve the police. Sometimes cases of spousal abuse are brought into the emergency room, while many other cases are handled by family physician or other primary care provider.

Doctors, dentists and other medical professionals are in a position to empower victims, give advice and refer them to appropriate services. Health care professionals in the United Kingdom, the United States and elsewhere have not always met this role, been uneven in quality of care, and in many cases have been unhelpful due to misunderstandings they have about domestic violence. Myths that have prevailed in the past and influenced how a doctor approaches a case where domestic violence may be involved include the belief that domestic violence is rare, that women are responsible for the violence, and it is inevitable. Washaw (1993) suggests that many doctors prefer not to get involved in people’s “private” lives. Clifton, Jacobs, and Tulloch (1996) found that training for general practitioners in the United States about domestic violence was very limited, or they had no training. Abbott and Williamson found that knowledge and understanding of domestic violence was very limited among health care professionals in a Midlands, United Kingdom, county, and that they don’t see themselves as being able to play a major role in helping women in regards to domestic violence. Furthermore, in the biomedical model of health care, injuries are often just treated and diagnosed without regard for the causes. As well, there is substantial reluctance for victims to come forward and broach the issue with their physicians. On average, women experience 35 incidents of domestic violence before seeking treatment.

A number of medications have been used for control of aggression. Good evidence exists on the efficacy of clozapine. Evidence also exists for SSRIs (selective serotonin re-uptake inhibitors), like Prozac, hormonal antiandrogenic agents, beta-blockers, quetiapine and aripiprazole. Lithium and anticonvulsants are widely used, but their efficacy is not strongly supported.

**Law enforcement**

In the 1970s, it was widely believed that domestic disturbance calls were the most dangerous type for responding officers, who arrive to a highly emotionally charged situation. This belief was based on FBI statistics that turned out to be flawed, in that they grouped all types of disturbances together with domestic disturbances, such as brawls at a bar. Subsequent statistics and analysis have shown this belief to be false.

Statistics on incidents of domestic violence, published in the late 1970s, helped raise public awareness of the problem and increase activism. A study published in 1976 by the Police Foundation found that police had intervened at least once in the previous two years in 85 percent of spouse homicides. In the late 1970s and early 1980s, feminists and battered women’s advocacy groups called on police to take domestic violence more seriously and change intervention strategies. In some instances, these groups took legal action against police departments, including in Oakland, Calif., and New York City, to get them to make arrests in domestic violence cases. They claimed that police assigned low priority to domestic disturbance calls.

The Minneapolis Domestic Violence Experiment was a study done in 1981-1982, led by Lawrence W. Sherman, to evaluate the effectiveness of various police responses to domestic violence calls in Minneapolis, Minn., including sending the abuser away for eight hours, giving advice and mediation for disputes, and making an arrest. Arrest was found to be the most effective police response. The study found that arrest reduced the rate by half of re-offending against the same victim within the following six months. The results of the study received a great deal of attention from the news media, including The New York Times and prime-time news coverage on television. Many U.S. police departments responded to the study, adopting a mandatory arrest policy for spousal violence cases with probable cause. By 2005, 23 states and the District of Columbia had enacted mandatory arrest for domestic assault, without warrant, given that the officer has probable cause and regardless of whether or not the officer witnessed the crime. The Minneapolis study also influenced policy in other countries, including New Zealand, which adopted a pro-arrest policy for domestic violence cases.

However, the study was subject of much criticism, with concerns about its methodology, as well as its conclusions. The Minneapolis study was replicated in several other cities, beginning in 1986, with some of these studies producing different results. In the replication studies, arrest seemed to help in the short run in some cases, but those arrested experienced double the rate of violence over the course of one year. Criminologists do not fully understand the reasons why deterrent effects do not last over time. But they suggest that abusers may initially fear punishment, though many cases do not make it all the way through the criminal justice process. If the victim is uncooperative during investigation, the prosecutor may choose not to pursue the case. If the case is pursued through the criminal justice system, sometimes the resulting sentence is minor. Subsequently, any fear that the abuser has of punishment may have diminished.

**Domestic response of law enforcement today**

Each agency and jurisdiction within the United States has its own standard operating procedures when it comes to responding and handling domestic calls. Generally, it has been accepted that if the understood victim has visible (and recent) marks of abuse, the suspect is arrested and charged with the appropriate crime. However, that is a guideline and not a rule. Like any other call, domestic abuse lies in a gray area. Law enforcement officers have several things to consider when making a warrantless arrest;
Are there signs of physical abuse?
Were there witnesses?
Is it recent?
Was the victim assaulted by the alleged suspect?
Who is the primary aggressor?
Could the victim be lying?
Could the suspect be lying?

Along with protecting the victim, law enforcement officers have to ensure that the alleged abusers’ rights are not violated. Many times in cases of mutual combatants, it is departmental policy that both parties be arrested and the court system can establish truth at a later date. In some areas of the nation, this mutual combatant philosophy is being replaced by the primary abuser philosophy in which case if both parties have physical injuries, the law enforcement officer determines who the primary aggressor is and arrests only that one. This philosophy started gaining momentum when different government/private agencies started researching the effects. It was found that when both parties are arrested, it had an adverse affect on the victim. The victims were less likely to call or trust law enforcement during the next incident of domestic abuse.

**Intervention**

In 1981, the Duluth Domestic Abuse Intervention Project became the first multidisciplinary program designed to address the issue of domestic violence. This experiment, conducted in Duluth, Minn., was frequently referred to as the “Duluth Project.” It coordinated agencies dealing with domestic situations, drawing together diverse elements of the system, from police officers on the street to shelters for battered women and probation officers supervising offenders. This program has become a model for other jurisdictions seeking to deal more effectively with domestic violence. Corrections/probation agencies in many areas are supervising domestic violence offenders more closely, and are also paying closer attention to the victim’s needs and safety issues.

There has been controversy, as the Duluth framework depends on a strict “patriarchal violence” model and assumes that all violence in the home and elsewhere has a male perpetrator and female victim. Also, evidence of success of the model is limited with scholarly analysis and critique.

Many victims leave their abusers, only to return. Research has shown that a major factor in helping a victim to establish lasting independence from the abusive partner is her or his ability to get legal assistance. Economists at the Brennan Center for Justice analyzed Bureau of Justice Statistics data to determine what accounted for the nationwide reduction in reported abuse. Their findings revealed that one significant factor was the availability of legal services to assist abuse victims. Another major study by economists at Colgate University and the University of Arkansas flatly stated that the only public service that reduces domestic violence in the long term is legal aid. Legal assistance can provide essential safety planning, buttress a family’s economic position through child or spousal support, allay fears planted by the batterer about loss of custody, and help victims to secure needed government benefits.

**Identifying and responding to abuse can make a difference**

For more than two decades, the Family Violence Prevention Fund (FVPF) has worked to end violence against women and children around the world. Instrumental in developing the landmark Violence Against Women Act passed by Congress in 1994, the FVPF continues to ensure that violence prevention efforts become self-sustaining through public education, education for health care providers, prevention campaigns, public policy reform, model training, advocacy programs and organizing. They have partnered with the National Health Care Standards Campaign on Domestic Violence, a coalition of health care providers, public health and policy leaders, and domestic violence advocates from 15 states working to promote improved health care responses to victims of abuse to provide the following “Guidelines on Routine Screening.”

The health care system plays an important role in identifying and preventing public health problems. Models developed to identify other chronic health problems can effectively be applied to IPV. Routine inquiry, with a focus on early identification of all victims of IPV regardless of whether symptoms are immediately apparent, is a primary starting point for this improved approach to medical practice for IPV.

Regular, face-to-face screening of women by skillful health care providers markedly increases the identification of victims of IPV, as well as those who are at-risk for verbal, physical and sexual abuse. Routine inquiry of all patients, a common practice in pediatric settings, is a central and legitimate health care issue and enables providers to assist both victims and their children. When victims or children exposed to IPV are identified early, providers may be able to break the isolation and coordinate with DV advocates to help patients understand their options, live more safely within the relationship, or safely leave the relationship. Expert opinion suggests that such interventions in adult health settings may lead to reduced morbidity and mortality. Talking with patients about IPV provides a valuable opportunity for providers to learn about their experiences with abuse. Battered women report that one of the most important aspects of their interactions with a physician was being listened to about the abuse. Even if a patient chooses not to disclose being abused, the provider’s inquiry can often communicate support and increase the likelihood of future discussion of the issue.

Assessment for exposure to lifetime abuse has major implications for primary prevention and early intervention to end the cycle of violence. Victims are often unaware of the concurrence of incest in homes with IPV. Assessing for IPV provides an opportunity to educate victims about the increased risk of child abuse and the health effects of childhood exposure to violence.

Adolescents who grow up in violent households are more likely to engage in fighting, carry a weapon, attempt suicide, and become part of an escalating epidemic of dating violence. Adolescent males who witnessed IPV are more likely to become teen fathers. Adolescent girls who witness IPV are more likely to have unintended and rapid, repeat pregnancies, have sex with a partner who has multiple partners, and use alcohol or drugs before having sex. Routine assessment for lifetime abuse is part of a larger trend to meet the psychosocial needs of patients while moving towards prevention.

Asking about IPV and having resource and referral materials in health settings also sends a prevention message that IPV is unacceptable, has serious health consequences, and provides the patient with important community referral information and resources. In most counties, programs serving victims of IPV include hot lines, walk-in services and shelters. These programs typically provide safety planning, confidential emergency housing, short-time focused counseling, legal advocacy, housing support and help identifying financial support.

Most states have enacted mandatory reporting laws, which require the reporting of specified injuries and wounds, suspected abuse or IPV for individuals being treated by a health care professional. Mandatory reporting laws are distinct from elder abuse or vulnerable adult abuse reporting laws, in that the individuals to be protected are not limited to a specific class, but pertain to all individuals to whom the health care professional provides treatment or medical care, or who come before the health care facility.

The laws vary from state to state, but generally fall into four categories:

1. **States that require reporting of injuries caused by weapons.**
2. **States that mandate reporting for injuries caused in violation of criminal laws, as a result of violence, or through nonaccidental means;**
3. **States that specifically address reporting in IPV cases.**
4. **States that have no general mandatory reporting laws. Professionals should know their state laws and the requirements. (See Florida laws located in this chapter).**

Some professionals find it uncomfortable to begin the conversation and to ask the necessary questions regarding domestic violence. These guidelines are identified by the federal government’s National Guideline Clearinghouse for intervention in IPV/DV. They list the Family Violence Prevention Fund’s 2004 Publication of National Consensus Guidelines on Identifying and Responding to Domestic Violence Victimization in Health Care Settings.
When should inquiry for past and present IPV victimization occur?
- Conducted routinely, regardless of the presence or absence of indicators of abuse.
- Conducted orally as part of a face-to-face health care encounter.
- Included in written or computer-based health questionnaires.
- Conducted in private: no friends, relatives (except children under 3) or caregivers should be present.
- Confidential: prior to inquiry, patients should be informed of any reporting requirements or other limits to provider/patient confidentiality.
- Assisted, if needed, by interpreters who have been trained to ask about abuse and who do not know the patient or the patient’s partner, caregiver, friends or family socially.

When should assessment occur?
- Initial assessment should occur immediately after disclosure.
- Repeat and/or expanded assessments should occur during follow-up appointments.
- At least one follow-up appointment (or referral) should be offered after disclosure of current or past abuse with health care provider, social worker or DV advocate.

What should assessment include?
- For the patient who discloses current abuse, assessment should include at a minimum:
  - Assessment of immediate safety
    - “Are you in immediate danger?”
    - “Do you want to (or have to) go home with your partner?”
    - “Do you have somewhere safe to go?”
    - “Have there been threats or direct abuse of the children (if she/he has children)”?
    - “Are you afraid your life may be in danger?”
    - “Has the violence gotten worse or is it getting scarier? Is it happening more often?”
    - “Has your partner used weapons, alcohol or drugs?”
    - “Has your partner ever held you or your children against your will?”
    - “Does your partner ever watch you closely, follow you or stalk you?”
    - “Has your partner ever threatened to kill you, him/herself or your children?”

If the patient states that there has been an escalation in the frequency or severity of violence, that weapons have been used, or that there has been hostage-taking, stalking, homicide or suicide threats, providers should conduct a homicide/suicide assessment.

Health and safety assessment
Assess the impact of the IPV (past or present) on the patient’s health. There are common health problems associated with current or past IPV victimization. Disclosure should prompt providers to consider these healthcare risks and assess:

Health care assessment
- How the (current or past) IPV victimization affects the presenting health issue.
  - “Does your partner control your access to health care or how you care for yourself?”
- How the (current or past) IPV victimization relates to other associated health issues.

Assessment of the pattern and history of current abuse:

Pattern and history of current abuse
- “How long has the violence been going on?”
- “Have you ever been hospitalized because of the abuse?”

For the patient who discloses past history of IPV victimization and for the patient who discloses past, but not current, IPV victimization:

Patients with past history
Past
- “When did the abuse occur?”
- “Do you feel you are still at risk?”
- “Are you in contact with your ex-partner?”
- “Do you share children or custody?”
- “How do you think the abuse has affected you emotionally and physically?”

Past but not current
- “Domestic violence is common and happens in all kinds of relationships.”
- “Abuse can impact your health in many ways.”
- “What happened to you may be related to health problems now.”
- “How do you feel about this now? Is there anything I can do for you now?”

If the patient feels the issue is still affecting her physically or emotionally, offer to set up an appointment to discuss it further with a primary care provider, mental health provider, social worker or DV advocate, depending on the patient’s needs.

What to do if a patient says “no”
- Respect her/his response.
- Let the patient know that you are available should the situation ever change.
- Assess again at previously recommended intervals.
- If patient says “no” but you believe she/ he may be at risk, discuss the specific risk factors and offer information and resources in exam, waiting rooms, or bathrooms.

Interventions with victims of IPV
Interventions will vary based on the severity of the abuse, the patient’s decisions about what she/ he wants for assistance at that time and if the abuse is happening currently. It is important to let the patient know that you will help regardless of whether she/he decides to stay in or leave the abusive relationship. For all patients who disclose current abuse, providers should:

Provide validation:
- Listen nonjudgmentally.
- “I am concerned for your safety (and the safety of your children.)”
- “You are not alone and help is available.”
- “You don’t deserve the abuse and it is not your fault.”
- “Stopping the abuse is the responsibility of your partner, not you.”

Provide information:
Domestic violence is common and happens in all kinds of relationships.

Violence tends to continue and often becomes more frequent and severe.

Abuse can impact your health in many ways.

You are not to blame, but exposure to violence in the home can emotionally and physically hurt your children or other dependent loved ones.

Respond to safety issues:
- Offer the patient a brochure about safety planning and go over it with her/him.
- Review ideas about keeping information private and safe from the abuser.
- Offer the patient immediate and private access to an advocate in person or via phone.
- If the patient wants immediate police assistance, offer to place the call.
- Reinforce the patient’s autonomy in making decisions regarding her/his safety.
- If there is significant risk of suicide, the patient should be kept safe in the health setting until emergency psychiatric evaluation can be obtained.
- Make referrals to local resources.
- Describe any advocacy and support systems within the health care setting.
  - Refer patient to advocacy and support services within the community.
  - Refer patients to organizations that address their unique needs such as organizations with multiple language capacities, or those that specialize in working with specific populations (i.e. teen, elderly, disabled, deaf or hard of hearing, particular ethnic or cultural communities or lesbian, gay, transgender or bisexual clients).
  - Offer a choice of available referrals including on-site advocates, social workers, local DV resources or the National DV Hotline (800) 799-SAFE, TTY (800) 787-3224.

Reporting IPV to law enforcement or social service agencies

Some states have requirements to report current victimization to law enforcement or social services. Providers should:
- Learn applicable statutes in your state.
- If you practice in a state with a mandated reporting law, inform patients about any limits of confidentiality prior to conducting assessment.

Confidentiality procedures

Inappropriate disclosure of health information may violate patient/provider confidentiality and threaten patient safety. Perpetrators who discover that a victim has sought care may retaliate with further violence. Employers, insurers, law enforcement agencies and community members who discover abuse may discriminate against a victim or alert the perpetrator. It is imperative that policy, protocol and practice surrounding the use and disclosure of health information regarding victims of IPV should respect patient confidentiality and autonomy and serve to improve the safety and health status of victims of IPV. The federal medical records privacy regulations issued in August 2002 (in effect April 14, 2003) have specific implications for victims of violence.

Prior to implementing a domestic violence program:
- Review relevant state privacy laws (See Florida State Laws located later in this chapter).
- Follow the federal regulations and privacy principles for victims of IPV.

Documentation

Documentation should be conducted by a health care provider who is authorized to record in the patient’s medical record. Providers should document the patient’s statements and avoid pejorative or judgmental documentation (e.g., write “patient declines services” rather than “patient refuses services,” “patient states” rather than “patient alleges”).

Document relevant history:
- Chief complaint or history of present illness.
- Record details of the abuse and its relationship to the presenting problem.
- Document any concurrent medical problems that may be related to the abuse.
- For current IPV victims, document a summary of past and current abuse including:
  - Social history, including relationship to abuser and abuser’s name, if possible.
  - Patient’s statement about what happened, not what led up to the abuse (e.g., “boyfriend John Smith hit me in the face,” not “patient arguing over money”).
- Include the date, time and location of incidents where possible.
- Patient’s appearance and demeanor (e.g., “teary, shirt ripped,” not “distraught”).
- Any objects or weapons used in an assault (e.g., knife, iron, closed or open fist).
- Patient’s accounts of any threats made or other psychological abuse.
- Names or descriptions of any witnesses to the abuse.

Document results of physical examination:
- Findings related to IPV, neurological, gynecological, mental status exam if indicated.
- If there are injuries, (present or past) describe type, color, texture, size and location.
- Use a body map and/or photographs to supplement written description.
- Obtain a consent form prior to photographing patient. Include a label and date.

Document laboratory and other diagnostic procedures:
- Record the results of any lab tests, x-rays, or other diagnostic procedures and their relationship to the current or past abuse.

Document results of assessment, intervention and referral:
- Record information pertaining to the patient’s health and safety assessment including your assessment of potential for serious harm, suicide and health impact of IPV.
- Document referrals made and options discussed.
- Document follow-up arrangements.

If patient does not disclose IPV victimization:
- Document that assessment was conducted and that the patient did not disclose abuse.
- If you suspect abuse, document your reasons for concern: i.e., “physical findings are not congruent with history or description”;
- “patient presents with indications of abuse.”

Follow-up and continuity of care for victims

At least one follow-up appointment (or referral) with a health care provider, social worker or DV counselor.
- “If you like, we can set up a follow-up appointment (or referral) to discuss this further.”
- “Is there a number or address that is safe to use to contact you?”
- “Are there days/hours when we can reach you alone?”
- “Is it safe for us to make an appointment reminder call?”

At every follow-up visit with patients currently in abusive relationships:

Follow-up visits
- Review the medical record and ask about current and past episodes of IPV.
- Communicate concern and assess both safety and coping or survival strategies:
  - “I am still concerned for your health and safety.”
  - “Have you sought counseling, a support group or other assistance?”
  - “Has there been any escalation in the severity or frequency of the abuse?”
  - “Have you developed or used a safety plan?”
  - “Told any family or friends about the abuse?”
  - “Have you talked with your children about the abuse and what to do to stay safe?”
- Reiterate options to the patient (individual safety planning, talking with friends or family, advocacy services and support groups, transitional/temporary housing, etc.)

For current and previous victims of IPV:
- Ensure that the patient has a connection to a primary-care provider.
- Coordinate and monitor an integrated care plan with community based experts as needed, or other health care specialists, trained social workers or mental health care providers as needed.

If patient does not disclose current or past IPV victimization:
- Document that assessment was conducted and that the patient did not disclose abuse.
- If you suspect abuse, document your reasons for concern: i.e., “physical findings are not
congruent w/ history or description,” “patient presents with indicators of violence.”

**Guideline for medical provider summary**

**Intimate partner violence (IPV)**

- **Mandatory reporting laws**
  - Before inquiring, learn your state’s mandatory reporting law and your local law enforcement’s response to mandatory reports.
  - If you suspect children are being neglected or harmed, file a CPS report. (Advocate on behalf of adult victim/ survivor’s safety with CPS)
  - If patient is over 65 or a dependent adult, file an APS report.

**Inquiry**

- Discuss any reporting requirements for both DV and child abuse before inquiring.
- Establish the setting: ask in private, ensure confidentiality, and use a trained interpreter (not family members).
- Simple direct questions work best:
  - Because violence is so common in many patients’ lives, I’ve begun to ask all my patients:
    - Has your partner ever hit you, hurt you, or threatened you?
    - Does your partner make you feel afraid?
    - Has your partner ever forced you to have sex when you didn’t want to?
    - How does your partner treat you?
- Also ask about past history of IPV:
  - Have you ever had a partner who hit you, hurt you or threatened you?
  - Have you ever had a partner who treated you badly?
  - Have you ever had a partner who forced you to have sex when you didn’t want to?
- Respect patient’s decision whether or not to disclose.

**Assessment of current IPV – if you get a positive answer**

- Give messages of support.
- You are not alone.
- You do not deserve to be treated this way.
- You are not to blame.

**Current abuse**

- Assess immediate danger:
  - “Are you afraid to go home today?”
- Assess for safety in clinic:
  - “Is the perpetrator with the patient?”
- Assess for current safety: (“red flags for lethality risk”)
  - Threats of homicide.
  - Weapons involved.
  - History of strangulation or stalking.
- Assess for suicidality and homicidality of either patient or perpetrator.
- Assess for safety of children.

**Past abuse**

If patient discloses past abuse and the abuse is not current, give supportive messages and explain that the effects of abuse can continue for years after the abuse has ended.

**Assess long-term danger**

- Assess for pattern of abuse.
- Assess for history of effects of abuse.
  - Specifically, any injuries or hospitalization?
  - Economic coercion, social isolation or other effects?
- Assess support system (family, friends, etc.) and coping strategies.
- Assess readiness for change.

**Intervention**

- Repeat messages of support:
  - I’m glad you talked to me about this today.
  - You deserve to be respected by your partner.
  - I’m concerned for your safety (and any children).
- Offer crisis support numbers:
  - Domestic Violence National HOTLINE: 800 799 SAFE (TTY 800 787 3224) – 24 hours a day, in all languages, toll-free, confidential and can provide crisis counseling and connect victims with local DV advocates who can help with safety planning, getting restraining orders and finding shelter.
  - Help prepare a safety plan with the patient or connect with someone who can.
  - Offer police and legal assistance, and recognize that this may not be a viable option for many patients (those who do not feel that police or legal help would enhance their safety and for many undocumented immigrants).
  - Arrange for a follow-up visit and a safe way to contact patient.
  - Expand the patient’s support to multiple members of a multidisciplinary team if patient is willing.

**Documentation**

Why it’s so important: If done properly, your documentation can communicate the situation to other providers. Also, the medical record can serve as powerful legal evidence which can be used to back up a victim’s claim of abuse.

- History.
- Write legibly.
- Use patient’s own words in quotes.
- Document as much information as patient will provide regarding specific events (who, what, where, when).
- Physical findings.
- Describe injuries in detail.
- Draw diagrams of injuries, using the body map if possible.
- If patient consents, take photographs of injuries.
- Take serial photographs of injuries over time.

**Physical evidence**

- If patient consents, preserve physical evidence in paper bag.
- Describe physical evidence in detail.

**Follow-up**

- Establish and maintain a primary care provider.
- Offer patient and any DV exposed children access to child care, DV support groups and services, legal services and advocacy, and the local police station.
- Offer patient and any DV exposed children a referral to a mental health provider to help process the trauma they experienced and emphasize that mental health symptoms are a common response to trauma.
- Consider the implications of past or current abuse on current health problems that patient and any DV exposed children are experiencing.

**What can you do**

In a dental health care setting, dentists have the opportunity to see many injuries they may deem suspicious; in this event they must take great caution in handling the patient and the situation. Many of the patients in this situation not only have physical injuries, but also have mental disorders, as well as a bad situation to which they feel they must return. There are several steps that are recommended in order to help assist the professional in developing a process to compile the necessary information for the authorities.

- Put up posters in the facility treatment rooms regarding domestic violence. This could prompt the patient to talk if they feel like the dentist/dental hygienist is someone who really cares.
- Put safety cards in your reception areas and restrooms for patients and guests to see.
- Educate all professionals in the office on the importance of detecting, assessing and responding to abuse patients.
- Educate all professionals in the office on the importance of detecting, assessing and responding to abuse patients.
- Post a list of local domestic violence service agencies in your reception and exam rooms.
- Also post the Florida Domestic Violence Hot line (800) 500-1119.
- Follow the guidelines listed above.
- Know your state and federal laws regarding domestic violence/IPV.

To learn more about making your health care facility a more open and supportive space in which to discuss and address intimate partner violence, and to receive free patient and clinical tools, contact the Family Violence Prevention Fund toll-free 888-Rx-ABUSE (TTY 800-595-4889) or online [www.endabuse.org/health](http://www.endabuse.org/health).
Background

The Goal: To provide support, information, and open the possibilities of change, and not necessarily “fix” the problem.

Definition: Intimate partner violence (IPV) is a pattern of assaultive and coercive behaviors including physical, sexual and psychological abuse that adults or adolescents use against their intimate partners. Remember that intimate partner violence can be seen at all socioeconomic levels, in all races and in both same sex as well as heterosexual relationships.

Why we need to ask: Violence can impact a victim’s overall health, and can escalate in both frequency and severity resulting in repeat visits to the health care system.

It’s common, even in pregnancy: One-third of U.S. women report being physically or sexually abused by a husband or boyfriend at some point in their lives (one in 12 pregnant women). It’s often why women visit the ED: 37 percent of all medical personnel routinely screen for IPV.

They want us to ask: 70-81 percent of patients reported that they would like their health care providers to ask them about IPV.

Because children are affected: Children who witness domestic violence or are abused themselves are at increased risk for a number of adverse health effects including behavioral problems, drug and alcohol abuse, STIs, and eating disorders.

What are the health effects?
In addition to injuries sustained during violent episodes, physical and psychological abuse are linked to a number of adverse physical health effects, including arthritis, chronic neck or back pain, migraine and other frequent headaches, stammering, problems seeing, sexually transmitted infections, chronic pelvic pain and stomach ulcers.

Domestic violence is associated with eight out of 10 of the Healthy People 2010 Leading Health indicators.

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Connection to domestic violence</th>
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<tbody>
<tr>
<td>Tobacco use</td>
<td>Increased risk of smoking</td>
</tr>
<tr>
<td>Substance abuse</td>
<td>Increased risk of high-risk alcohol use</td>
</tr>
<tr>
<td>Injury and violence</td>
<td>Leading cause of injuries and homicide</td>
</tr>
<tr>
<td>Mental health</td>
<td>Increased risk of mental health problems</td>
</tr>
<tr>
<td>Responsible sexual behavior</td>
<td>Increased sexual risk-taking and STIs, less likely to use condoms consistently</td>
</tr>
<tr>
<td>Access to health care</td>
<td>Increased risk of late entry into prenatal care</td>
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<tr>
<td>Immunizations</td>
<td>Children of battered women are less likely to get immunizations</td>
</tr>
<tr>
<td>Overweight and obesity</td>
<td>Increased poor nutritional behaviors</td>
</tr>
</tbody>
</table>

Florida: Domestic violence facts
- There were 115,170 reported cases of domestic violence in 2006.
- Of the reported cases, 55 percent of the offenses were committed by a spouse or cohabitant.
- 54 percent of the domestic violence-related cases in 2006 ended in an arrest.
- There were 1,089 forcible rapes, 369 cases of forcible sodomy and 947 cases of forcible fondling reported in Florida in 2006.
- 35 percent of forcible sex offense cases ended in an arrest.
- There were 164 domestic violence-related homicides in Florida in 2006.

Florida Domestic Violence Hotline 1-800-500-1119
National Domestic Violence Hotline 1-800-799-SAFE
National Sexual Assault Hotline 1-800-656-HOPE

General domestic violence facts:
- One in four women will experience domestic violence in her lifetime.
- One in 33 men has experienced an attempted or completed rape.
- An estimated 1.3 million women are victims of physical assault by an intimate partner each year.
- The majority (73 percent) of family violence victims are female. Females were 84 percent of spousal abuse victims and 86 percent of abuse victims at the hands of a boyfriend.
- The cost of intimate partner violence exceeds $5.8 billion each year, $4.1 billion of which is for direct medical and mental health services.
- Boys who witness domestic violence are twice as likely to abuse their own partners and children when they become adults.

Florida Statutes 39.415, 790, 794 and 45.164. 512(c)(1): Require mandatory reporting of child abuse, vulnerable adults, gunshot wounds or other life-threatening injuries indicating violence, sexual battery and domestic violence.

These situations are all required by Florida law to be reported to authorities, and disclosures are permitted by HIPAA. Also, all deaths are required to be reported to the law enforcement and to coroners or medical examiners.

Many people believe that the term “vulnerable adults” not only means elder abuse, but also includes any victims of abuse and that this law requires medical health care professionals to report any incident that they believe to be caused by violence, as well as abuse to elder patients.

The National Coalition Against Domestic Violence and the Florida Coalition Against Domestic Violence (established in 1977) work to end domestic violence through education, training and policy advocacy.

Florida Statute 39.201(1) – Any person, including a health care provider, who knows or has reasonable cause to suspect child abuse, abandonment or neglect by a parent, legal custodian, caregiver, or other person responsible for the child’s welfare, must report such knowledge or suspicion to the Department of Children and Families (DCF) Central Abuse Hotline.

Florida Statute 415.1034(2) Suspected vulnerable adult abuse – Any person who knows or has reasonable cause to suspect the abuse, neglect or exploitation of vulnerable adults must immediately report such knowledge to the DCF Central Abuse Hotline.

Florida Statute 790. 24 Gunshot wounds or other life-threatening injuries indicating violence – Any physician, nurse or employee of a hospital, sanitarium, clinic or nursing home treating or receiving a request for treatment must report immediately to local law enforcement any gunshot wound or life-threatening injury indicating an act of violence.

Florida Statute 794.027 Sexual battery – Any person who observed the commission of a crime of sexual battery must immediately report such offense to a law enforcement official.
Florida Statute 45 CFR 164. 512 (c)(1) – Domestic violence is not required by law to be reported, but the HIPAA Law allows disclosures of the information to the appropriate authorities. A health care provider may report domestic violence to a government authority, including a social service or protective services agency authorized by law to receive reports of such domestic violence. (Except for gunshot wounds or other life-threatening injuries indicating violence. P. S. 790. 24, for which it is mandatory.)

Conclusion
Domestic violence is a serious problem worldwide and it must be stopped. Nearly 5.3 million intimate partner victimizations occur among U.S. women ages 18 and older each year. This violence results in nearly 2.0 million injuries and nearly 1,300 deaths. Of the IPV injuries, more than 555,000 require medical attention, and more than 145,000 are serious enough to warrant hospitalization for one or more nights. IPV also results in more than 18.5 million mental health care visits each year. Add to that the 13.6 million days of lost productivity from paid work and household chores among IPV survivors and the value of IPV murder victims’ expected lifetime earnings, and it is clear to see that intimate partner violence against women places a significant burden on society, on lives and on the quality of life. This is a problem that can be stopped through education, public awareness and concern. By routinely assessing all patients for IPV victimization, medical professionals can provide a way to get support services such as counseling, social services, mental health care, and to provide safety for their patients.

References:
* www.cdc.gov
* http:endabuse.org
* http://wikipedia.domesticviolence.com
* Florida Statutes

DOMESTIC VIOLENCE IN THE
HEALTH CARE SETTING
Final Examination Questions
Choose True or False for questions 1 through 5 and mark your answers online at www.onlinedentalCE.com.

1. Domestic violence (also known as domestic abuse, spousal abuse, or intimate partner violence) occurs when a family member, partner or ex-partner attempts to physically or psychologically dominate another.
   True  False

2. Common couple violence (CCV) is connected to general control behavior, and arises in a single argument where only one partner physically lashes out at the other.
   True  False

3. The Hope Card Project makes an attempt to remedy several problems through the issuance of an ID card to victims of abuse. The card is used to identify both parties in a domestic violence protection order.
   True  False

4. Research has shown that a major factor in helping a victim to establish lasting independence from the abusive partner is her or his ability to get medical assistance.
   True  False

5. Florida Statutes require mandatory reporting of child abuse, vulnerable adults, gunshot wounds or other life-threatening injuries indicating violence, sexual battery and domestic violence. These situations are all required by Florida law to be reported to authorities, and disclosures are permitted by HIPAA.
   True  False
CHAPTER 3
CHAPTER 466
DENTISTRY, DENTAL HYGIENE AND DENTAL LABORATORIES
(8 CE HOURS)

List the governing agency of the dental profession and define its function.

List the new provisions of 466.005 dealing with expert witness certificates.

Know the scope and area of practice for a dental hygienist and recent changes in the law.

List the delegation of duties under 466.024.

List the restrictions for use of the term specialties under 466.0282.

Know the continuing education requirements for each licensee.

Define dental laboratory under 466.031.

Introduction
In this course, we have set out to highlight some of the laws regarding licensing, continuing education, prescribing drugs and other important matters regarding your profession to help you stay current on the laws relating to the practice of dentistry. Please pay particular attention to the underlined portions of this law course, which are recent law changes that may affect your practice. You should understand that these laws do change often; this course is based on the August 2011 revised version of state statutes. This course does not include the rules under the Department of Health - Board of Dentistry. You may go to http://www.doh.state.fl.us/mqa/dentistry and read the very latest chapter of 466 Florida Statutes, and Rule 64B5 Florida Administrative Code.

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466.002 Persons exempt from operation of chapter.
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466.00671 Renewal of the health access dental license.
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466.014 Continuing education; dental hygienists.
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466.023 Dental hygienists; scope and area of practice.
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466.026 Prohibitions; penalties.
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466.02751 Establishment of practitioner profile for designation as a controlled substance prescribing practitioner.
466.028 Grounds for disciplinary action; action by the board.
466.0282 Specialties.
466.0285 Proprietorship by nondentists.
466.031 “Dental laboratory” defined.
466.032 Registration.
466.033 Registration certificates.
466.034 Change of ownership or address.
466.035 Advertising.
466.036 Information; periodic inspections; equipment and supplies.
466.037 Suspension and revocation; administrative fine.
466.038 Rules.
466.039 Violations.
466.041 Hepatitis B carriers.

466.001 Legislative purpose and intent. –
The legislative purpose for enacting this chapter is to ensure that every dentist or dental hygienist practicing in this state meets minimum requirements for safe practice without undue clinical interference by persons not licensed under this chapter. It is the legislative intent that dental services be provided only in accordance with the provisions of this chapter and not be delegated to unauthorized individuals. It is the further legislative intent that dentists and dental hygienists who fall below minimum competency or who otherwise present a danger to the public shall be prohibited from practicing in this state. All provisions of this chapter relating to the practice of dentistry and dental hygiene shall be liberally construed to carry out such purpose and intent.

466.003 Definitions. – As used in this chapter:
(1) “Board” means the Board of Dentistry.
(2) “Dentist” means a person licensed to practice dentistry pursuant to this chapter.

History.–ss. 1, 3, ch. 79-330; ss. 2, 3, ch. 81-318; ss. 2, 23, 24, ch. 86-291; s. 60, ch. 91-137; s. 7, ch. 91-156; s. 4, ch. 91-429; s. 22, ch. 93-268; s. 2, ch. 94-104; s. 250, ch. 97-103; s. 1, ch. 2005-189.

466.002 Persons exempt from operation of chapter. – Nothing in this chapter shall apply to the following practices, acts, and operations:
(1) The practice of her or his profession including surgical procedures involving the oral cavity by a physician or surgeon licensed as such under the laws of this state.
(2) A qualified anesthetist giving an anesthetic for a dental operation under the direct supervision of a licensed dentist.

(3) The practice of dentistry in the discharge of their official duties by graduate dentists or dental surgeons in the United States Army, Air Force, Marines, Navy, Public Health Service, Coast Guard, or United States Department of Veterans Affairs.

For the practice of dentistry by licensed dentists of other states or countries at meetings of dental organizations approved by the board, while appearing as clinicians.

(5) Students in Florida schools of dentistry and dental hygiene or dental assistant educational programs, while performing regularly assigned work under the curriculum of such schools.

(6) Instructors in Florida schools of dentistry, instructors in dental programs that prepare persons holding D.D.S. or D.M.D. degrees for certification by a specialty board and that are accredited in the United States by January 1, 2005, in the same manner as the board recognizes accreditation for Florida schools of dentistry that are not otherwise affiliated with a Florida school of dentistry, or instructors in Florida schools of dental hygiene or dental assistant educational programs, while performing regularly assigned instructional duties under the curriculum of such schools. A full-time dental instructor at a dental school or dental program approved by the board may be allowed to practice dentistry at the teaching facilities of such school or program, upon receiving a teaching permit issued by the board, in strict compliance with such rules as are adopted by the board pertaining to the teaching permit and with the established rules and procedures of the dental school or program as recognized in this section.

History.–ss. 1, 3, ch. 79-330; ss. 2, 3, ch. 81-318; ss. 2, 23, 24, ch. 86-291; s. 60, ch. 91-137; s. 7, ch. 91-156; s. 4, ch. 91-429; s. 22, ch. 93-268; s. 2, ch. 94-104; s. 250, ch. 97-103; s. 1, ch. 2005-189.
(b) Supplying artificial substitutes for the natural teeth or furnishing, supplying, constructing, reproducing, or repairing any prosthetic denture, bridge, appliance, or any other structure designed to be worn in the human mouth except on the written work order of a duly licensed dentist.

c) The placing of an appliance or structure in the human mouth or the adjusting or attempting to adjust the same.

d) Delivering the same to any person other than the dentist upon whose work order the work was performed.

(e) Professing to the public by any method to furnish, supply, construct, reproduce, or repair any prosthetic denture, bridge, appliance, or other structure designed to be worn in the human mouth.

(f) Diagnosing, prescribing, or treating or professing to diagnose, prescribe, or treat disease, pain, deformity, deficiency, injury, or physical condition of the human teeth or jaws or oral-maxillofacial region.

(g) Extracting or attempting to extract human teeth.

(h) Correcting or attempting to correct malformations of teeth or of jaws.

(i) Repairing or attempting to repair cavities in the human teeth.

(4) “Dental hygiene” means the rendering of educational, preventive, and therapeutic dental services pursuant to ss. 466.023 and 466.024 and any related extra-oral procedures required in the performance of such services.

(5) “Dental hygienist” means a person licensed to practice dental hygiene pursuant to this chapter.

(6) “Dental assistant” means a person, other than a dental hygienist, who, under the supervision and authorization of a dentist, provides dental care services directly to a patient. This term shall not include a certified registered nurse anesthetist licensed under part I of chapter 464.

(7) “Department” means the Department of Health.

(8) “Direct supervision” means supervision whereby a dentist diagnoses the condition to be treated, a dentist authorizes the procedure to be performed, a dentist remains on the premises while the procedures are performed, and a dentist approves the work performed before dismissal of the patient.

(9) “Indirect supervision” means supervision whereby a dentist authorizes the procedure and a dentist is on the premises while the procedures are performed.

(10) “General supervision” means supervision whereby a dentist authorizes the procedures which are being carried out but need not be present when the authorized procedures are being performed. The authorized procedures may also be performed at a place other than the dentist’s usual place of practice. The issuance of a written work authorization to a commercial dental laboratory by a dentist does not constitute general supervision.

(11) “Irremediable tasks” are those intraoral treatment tasks which, when performed, are irreversible and create unalterable changes within the oral cavity or the contiguous structures or which cause an increased risk to the patient. The administration of anesthetics other than topical anesthesia is considered to be an “irremediable task” for purposes of this chapter.

(12) “Remediable tasks” are those intraoral treatment tasks which are reversible and do not create unalterable changes within the oral cavity or the contiguous structures and which do not cause an increased risk to the patient.

(13) “Oral and maxillofacial surgery” means the specialty of dentistry involving diagnosis, surgery, and adjunctive treatment of diseases, injuries, and defects involving the functional and esthetic aspects of the hard and soft tissues of the oral and maxillofacial regions. This term may not be construed to apply to any individual exempt under s. 466.002(1).

(14) “Health access setting” means a program or an institution of the Department of Children and Family Services, the Department of Health, the Department of Juvenile Justice, a nonprofit community health center, a Head Start center, a federally qualified health center or look-alike as defined by federal law, a school-based prevention program, a clinic operated by an accredited college of dentistry, or an accredited dental hygiene program in this state if such community service program or institution immediately report to the Board of Dentistry all violations of s. 466.027, s. 466.028, or other practice act or standard of care violations related to the actions or inactions of a dentist, dental hygienist, or dental assistant engaged in the delivery of dental care in such setting.

(15) “School-based prevention program” means preventive oral health services offered at a school by one of the entities defined in subsection (14) or by a nonprofit organization that is exempt from federal income taxation under s. 501(a) of the Internal Revenue Code, and described in s. 501(c)(3) of the Internal Revenue Code.

History.–s. 1, ch. 79-330; ss. 2, 3, ch. 81-318; ss. 3, 23, 24, ch. 86-291; s. 60, ch. 91-137; s. 7, ch. 91-156; s. 4, ch. 91-429; s. 1, ch. 94-104; s. 126, ch. 94-218; s. 2, ch. 97-67; s. 107, ch. 97-264; s. 130, ch. 2000-318; s. 1, ch. 2008-64; s. 4, ch. 2011-95.

Note.–Section 21, ch. 2011-95, provides that “[e]xcept as otherwise specifically provided in this act, this act shall take effect upon becoming a law, and shall not apply retroactively.”

466.004 Board of Dentistry.

(1) To carry out the provisions of this chapter, there is created within the department the Board of Dentistry consisting of 11 members who shall be appointed by the governor and subject to confirmation by the Senate. Seven members of the board must be licensed dentists actively engaged in the clinical practice of dentistry in this state; two members must be licensed dental hygienists actively engaged in the practice of dental hygiene in this state; and the remaining two members must be laypersons who are not, and have never been, dentists, dental hygienists, or members of any closely related profession or occupation. Each member of the board who is a licensed dentist must have been actively engaged in the practice of dentistry primarily as a clinical practitioner for at least 5 years immediately preceding the date of her or his appointment to the board and must remain primarily in clinical practice during all subsequent periods of appointment to the board. Each member of the board who is connected in any way with any dental college or community college must be in compliance with s. 456.007. At least one member of the board must be 60 years of age or older. Members shall be appointed for 4-year terms, but may serve no more than a total of 10 years.

(2) To advise the board, it is the intent of the Legislature that councils be appointed as specified in paragraphs (a), (b), and (c). The department shall provide administrative support to the councils and shall provide public notice of meetings and agenda of the councils. Councils shall include at least one board member who shall chair the council and shall include nonboard members. All council members shall be appointed by the board chair. Council members shall be appointed for 4-year terms, and all members shall be eligible for reimbursement of expenses in the manner of board members.

(a) A Council on Dental Hygiene shall be appointed by the board chair and shall include one dental hygienist member of the board, who shall chair the council, one dental member of the board, and three dental hygiene members who are actively engaged in the practice of dental hygiene in this state. In making the appointments, the chair shall consider recommendations from the Florida Dental Hygiene Association. The council shall meet at the request of the board chair, a majority of the members of the board, or the council chair; however, the council must meet at least three times a year. The council is charged with the responsibility of and shall meet for the purpose of developing rules and policies for recommendation to the board, which the board shall consider, on matters pertaining to that part of dentistry consisting of educational, preventive, or therapeutic dental hygiene services; dental hygiene licensure, discipline, or regulation; and dental hygiene education. Rule and policy recommendations of the council shall be considered by the board at its next regularly scheduled meeting in the same manner in which it considers rule and policy recommendations from designated subcommittees of the board. Any rule or policy proposed by the board pertaining
to the specified part of dentistry defined by this subsection shall be referred to the council for a recommendation before final action by the board. The board may take final action on rules pertaining to the specified part of dentistry defined by this subsection without a council recommendation if the council fails to submit a recommendation in a timely fashion as prescribed by the board.

(b) A Council on Dental Assisting shall be appointed by the board chair and shall include one board member who shall chair the council and three dental assistants who are actively engaged in dental assisting. The council shall meet at the request of the board chair or a majority of the members of the board. The council shall meet for the purpose of developing recommendations to the board on matters pertaining to that part of dentistry related to dental assisting.

(c) With the concurrence of the State Surgeon General, the board chair may create and abolish other advisory councils relating to dental subjects, including, but not limited to: examinations, access to dental care, indigent care, nursing home and institutional care, public health, disciplinary guidelines, and other subjects as appropriate. Such councils shall be appointed by the board chair and shall include at least one board member who shall serve as chair.

(3) The board shall maintain its headquarters in Tallahassee.

(4) The board is authorized to adopt rules pursuant to ss. 120.536(1) and 120.54 to implement the provisions of this chapter and chapter 456, including the establishment of a fee to defray the cost of duplicating any license certification or permit, not to exceed $10 per duplication.

(5) The board is authorized to publish and distribute such pamphlets, newsletters, and other publications as are reasonably necessary.

(6) All provisions of chapter 456 relating to the board shall apply.

History.—ss. 1, 3, ch. 79-330; ss. 2, 3, ch. 81-318; ss. 4, 23, 24, ch. 86-291; s. 17, ch. 87-172; s. 47, ch. 90-228; s. 1, ch. 90-341; s. 60, ch. 91-137; s. 7, ch. 91-156; s. 4, ch. 91-429; s. 97, ch. 92-149; s. 127, ch. 94-218; s. 1, ch. 96-281; s. 1107, ch. 97-103; s. 69, ch. 98-166; s. 128, ch. 98-200; s. 55, ch. 99-95; s. 1, ch. 99-183; s. 1, ch. 2000-115; s. 128, ch. 2000-160; s. 2, ch. 2005-189; s. 55, ch. 2006-1; s. 85, ch. 2008-6.

1466.005 Expert witness certificate.—

(1) (a) The department shall issue a certificate authorizing a dentist who holds an active and valid license to practice dentistry in another state or a province of Canada to provide expert testimony in this state, if the dentist submits to the department:

1. A complete registration application, containing the dentist’s legal name, mailing address, telephone number, business locations, the names of the jurisdictions where the dentist holds an active and valid license to practice dentistry, and the license number or other identifying number issued to the dentist by the jurisdiction’s licensing entity; and

2. An application fee of $50.

(b) The department shall approve an application for an expert witness certificate within 10 business days after receipt of the completed application and payment of the application fee if the applicant holds an active and valid license to practice dentistry in another state or a province of Canada and has not had a previous expert witness certificate revoked by the board. An application is approved by default if the department does not act upon the application within the required period. A dentist must notify the department in writing of his or her intent to rely on a certificate approved by default.

(c) An expert witness certificate is valid for 2 years after the date of issuance.

(2) An expert witness certificate authorizes the dentist to whom the certificate is issued to do, only the following:

(a) Provide a verified written medical expert opinion as provided in s. 766.203.

(b) Provide expert testimony about the prevailing professional standard of care in connection with medical negligence litigation pending in this state against a dentist licensed under this chapter.

(c) An expert witness certificate does not authorize a dentist to engage in the practice of dentistry as defined in s. 466.003. A dentist issued a certificate under this section who does not otherwise practice dentistry in this state is not required to obtain a license under this chapter or pay any license fees. An expert witness certificate shall be treated as a license in any disciplinary action, and the holder of an expert witness certificate shall be subject to discipline by the board.

History.—s. 6, ch. 2011-233.

1Note. — Section 16, ch. 2011-233, provides that “[t]his act shall take effect October 1, 2011, and applies to causes of action accruing on or after that date.”

1466.006 Examination of dentists.—

(1) (a) It is the intent of the Legislature to reduce the costs associated with an independent state-developed practical or clinical examination to measure an applicant’s ability to practice the profession of dentistry and to use the American Dental Licensing Examination developed by the American Board of Dental Examiners, Inc., in lieu of an independent state-developed practical or clinical examination. The Legislature finds that the American Dental Licensing Examination, in both its structure and function, consistently meets generally accepted testing standards and has been found, as it is currently organized and operating, to adequately and reliably measure an applicant’s ability to practice the profession of dentistry.

(b) Any person desiring to be licensed as a dentist shall apply to the department to take the licensure examinations and shall verify the information required on the application by oath. The application shall include two recent photographs. There shall be an application fee set by the board not to exceed $100 which shall be nonrefundable. There shall also be an examination fee set by the board, which shall not exceed $425 plus the actual per applicant cost to the department for purchase of some or all of the examination from the American Board of Dental Examiners or its successor entity, if any. provided the board finds the successor entity’s clinical examination complies with the provisions of this section. The examination fee may be refundable if the applicant is found ineligible to take the examinations.

(2) An applicant shall be entitled to take the examinations required in this section to practice dentistry in this state if the applicant:

(a) Is 18 years of age or older.

(b) 1. Is a graduate of a dental school accredited by the American Dental Association Commission on Dental Accreditation or its successor entity, if any, or any other dental accrediting entity recognized by the United States Department of Education; or

2. Is a dental student in the final year of a program at a school that an accredited dental school who has completed all the coursework necessary to prepare the student to perform the clinical and diagnostic procedures required to pass the examinations. With respect to a dental student in the final year of a program at a dental school, a passing score on the examinations is valid for 365 days after the date the examinations were completed. A dental school student who takes the licensure examinations during the student’s final year of an approved dental school must have graduated before being certified for licensure pursuant to s. 466.011.

(c) 1. Has successfully completed the National Board of Dental Examiners dental examination; or

2. Has an active health access dental license in this state; and

a. The applicant has at least 5,000 hours within 4 consecutive years of clinical practice experience providing direct patient care in a health access setting as defined in s. 466.003; the applicant is a retired veteran dentist of any branch of the United States Armed Services who has practiced dentistry while on
active duty and has at least 3,000 hours within 3 consecutive years of clinical practice experience providing direct patient care in a health access setting as defined in s. 466.003; or the applicant has provided a portion of his or her salaried time teaching health profession students in any public education setting, including, but not limited to, a community college, college, or university, and has at least 3,000 hours within 3 consecutive years of clinical practice experience providing direct patient care in a health access setting as defined in s. 466.003;

b. The applicant has not been disciplined by the board, except for citation offenses or minor violations;

c. The applicant has not filed a report pursuant to s. 456.049; and

d. The applicant has not been convicted of or pled nolo contendere to, regardless of adjudication, any felony or misdemeanor related to the practice of a health care profession.

(3) If an applicant is a graduate of a dental college or school not accredited in accordance with paragraph (2)(b) or of a dental college or school not approved by the board, the applicant shall not be entitled to take the examinations required in this section to practice dentistry until she or he satisfies one of the following:

(a) Completes a program of study, as defined by the board by rule, at an accredited American dental school and demonstrates receipt of a D.D.S. or D.M.D. from said school; or

(b) Completes a 2-year supplemental dental education program at an accredited dental school and receives a dental diploma, degree, or certificate as evidence of program completion.

(4) Notwithstanding any other provision of law in chapter 456 pertaining to the clinical dental licensure examination or national examinations, to be licensed as a dentist in this state, an applicant must successfully complete the following:

(a) A written examination on the laws and rules of the state regulating the practice of dentistry;

(b) 1. A practical or clinical examination, which shall be the American Dental Licensing Examination produced by the American Board of Dental Examiners, Inc., or its successor entity, if any, that is administered in this state and graded by dentists licensed in this state and employed by the department for just such purpose, provided that the board has attained, and continues to maintain thereafter, representation on the board of directors of the American Board of Dental Examiners, the examination development committee of the American Board of Dental Examiners, and such other committees of the American Board of Dental Examiners as the board deems appropriate by rule to assure that the standards established herein are maintained organizationally. A passing score on the American Dental Licensing Examination administered in this state and graded by dentists, who are licensed in this state is valid for 365 days after the date the official examination results are published.

2. a. As an alternative to the requirements of subparagraph 1., an applicant may submit scores from an American Dental Licensing Examination previously administered in a jurisdiction other than this state after October 1, 2011, and such examination results shall be recognized as valid for the purpose of licensure in this state. A passing score on the American Dental Licensing Examination administered out-of-state shall be the same as the passing score for the American Dental Licensing Examination administered in this state and graded by dentists, who are licensed in this state. The examination results are valid for 365 days after the date the official examination results are published. The applicant must have completed the examination after October 1, 2011.

b. This subparagraph may not be given retroactive application.

3. If the date of an applicant’s passing American Dental Licensing Examination scores from an examination previously administered in a jurisdiction other than this state under subparagraph 2. is older than 365 days, then such scores shall nevertheless be recognized as valid for the purpose of licensure in this state, but only if the applicant demonstrates that all of the following additional standards have been met:

a. (I) The applicant completed the American Dental Licensing Examination after October 1, 2011.

(II) This sub-subparagraph may not be given retroactive application:

b. The applicant graduated from a dental school accredited by the American Dental Association Commission on Dental Accreditation or its successor entity, if any, or any other dental accrediting organization recognized by the United States Department of Education. Provided, however, if the applicant did not graduate from such a dental school, the applicant may submit proof of having successfully completed a full-time supplemental general dentistry program accredited by the American Dental Association Commission on Dental Accreditation of at least 2 consecutive academic years at such accredited sponsoring institution. Such program must provide didactic and clinical education at the level of a D.D.S. or D.M.D. program accredited by the American Dental Association Commission on Dental Accreditation;

c. The applicant currently possesses a valid and active dental license in good standing, with no restriction, which has never been revoked, suspended, restricted, or otherwise disciplined, from another state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico;

d. The applicant submits proof that he or she has never been reported to the National Practitioner Data Bank, the Healthcare Integrity and Protection Data Bank, or the American Association of Dental Boards Clearinghouse. This sub-subparagraph does not apply if the applicant successfully appealed to have his or her name removed from the data banks of these agencies;

e. (I) In the 5 years immediately preceding the date of application for licensure in this state, the applicant must submit proof of having been consecutively engaged in the full-time practice of dentistry in another state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico, or, if the applicant has been licensed in another state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico for less than 5 years, the applicant must submit proof of having been engaged in the full-time practice of dentistry since the date of his
(II) As used in this section, “full-time practice” is defined as a minimum of 1,200 hours per year for each and every year in the consecutive 5-year period or, where applicable, the period since initial licensure, and must include any combination of the following:

(A) Active clinical practice of dentistry providing direct patient care.

(B) Full-time practice as a faculty member employed by a dental or dental hygiene school approved by the board or accredited by the American Dental Association Commission on Dental Accreditation.

(C) Full-time practice as a student at a postgraduate dental education program approved by the board or accredited by the American Dental Association Commission on Dental Accreditation.

(III) The board shall develop rules to determine what type of proof of full-time practice is required and to recoup the cost to the board of verifying full-time practice under this section. Such proof must, at a minimum, be:

(A) Admissible as evidence in an administrative proceeding;

(B) Submitted in writing;

(C) Submitted by the applicant under oath with penalties of perjury attached;

(D) Further documented by an affidavit of someone unrelated to the applicant who is familiar with the applicant’s practice and testifies with particularity that the applicant has been engaged in full-time practice; and

(E) Specifically found by the board to be both credible and admissible.

(IV) An affidavit of only the applicant is not acceptable proof of full-time practice unless it is further attested to by someone unrelated to the applicant who has personal knowledge of the applicant’s practice. If the board deems it necessary to assess credibility or accuracy, the board may require the applicant or the applicant’s witnesses to appear before the board and give oral testimony under oath:

(f) The applicant must submit documentation that he or she has completed, or will complete, prior to licensure in this state, continuing education equivalent to this state’s requirements for the last full reporting biennium;

(g) The applicant must prove that he or she has never been convicted of, or pled nolo contendere to, regardless of adjudication, any felony or misdemeanor related to the practice of a health care profession in any jurisdiction;

(h) The applicant must successfully pass a written examination on the laws and rules of this state regulating the practice of dentistry and must successfully pass the computer-based diagnostic skills examination; and

(i) The applicant must submit documentation that he or she has successfully completed the National Board of Dental Examiners dental examination.

(5) (a) The practical examination required under subsection (4) shall be the American Dental Licensing Examination developed by the American Board of Dental Examiners, Inc. or its successor entity, if any, provided the board finds that the successor entity’s clinical examination complies with the provisions of this section, and shall include, at a minimum:

1. A comprehensive diagnostic skills examination covering the full scope of dentistry and an examination on applied clinical diagnosis and treatment planning in dentistry for dental candidates;

2. Two restorations on a live patient or patients. The board by rule shall determine the class of such restorations;

3. A demonstration of periodontal skills on a live patient;

4. A demonstration of prosthetic and restorative skills in complete and partial dentures and crowns and bridges and the utilization of practical methods of evaluation, specifically including the evaluation by the candidate of completed laboratory products such as, but not limited to, crowns and inlays filled to prepared model teeth;

5. A demonstration of restorative skills on a mannequin which requires the candidate to complete procedures performed in preparation for a cast restoration;

6. A demonstration of endodontic skills; and

7. A diagnostic skills examination demonstrating ability to diagnose conditions within the human oral cavity and its adjacent tissues and structures from photographs, slides, radiographs, or models pursuant to rules of the board. If an applicant fails to pass the diagnostic skills examination in three attempts, the applicant shall not be eligible for reexamination unless she or he completes additional educational requirements established by the board.

(b) The department shall consult with the board in planning the times, places, physical facilities, training of personnel, and other arrangements concerning the administration of the examination. The board or a duly designated committee thereof shall approve the final plans for the administration of the examination;

(c) If the applicant fails to pass the clinical examination in three attempts, the applicant shall not be eligible for reexamination unless she or he completes additional educational requirements established by the board; and

(d) The board may by rule provide for additional procedures which are to be tested, provided such procedures shall be common to the practice of general dentistry. The board by rule shall determine the passing grade for each procedure and the acceptable variation for examiners. No such rule shall apply retroactively.

The department shall require a mandatory standardization exercise for all examiners prior to each practical or clinical examination and shall retain for employment only those dentists who have substantially adhered to the standard of grading established at such exercise.

(6) (a) It is the finding of the Legislature that absent a threat to the health, safety, and welfare of the public, the relocation of applicants to practice dentistry within the geographic boundaries of this state, who are lawfully and currently practicing dentistry in another state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico, based on their scores from the American Dental Licensing Examination administered in a state other than this state, is substantially related to achieving the important state interest of improving access to dental care for underserved citizens of this state and furthering the economic development goals of the state. Therefore, in order to maintain valid active licensure in this state.
1. As used in this section, “full-time practice” means that the applicant has been engaged in full-time practice of dentistry within the geographic boundaries of this state within the last 365 days; and
e. Include such additional proof as specifically found by the board to be both credible and admissible.
3. An affidavit of only the applicant is not acceptable proof of full-time practice of dentistry within the geographic boundaries of this state within 1 year, unless it is further attested to by someone unrelated to the applicant who has personal knowledge of the applicant’s practice within the last 365 days. If the board deems it necessary to assess credibility or accuracy, the board may require the applicant or the applicant’s witnesses to appear before the board and give oral testimony under oath.
(c) It is the further intent of the Legislature that a license issued pursuant to paragraph (a) shall expire in the event the board finds that it did not receive acceptable proof of full-time practice within the geographic boundaries of this state within 1 year after the initial issuance of the license. The board shall make reasonable attempts within 30 days prior to the expiration of such a license to notify the licensee in writing at his or her last known address of the need for proof of full-time practice in order to continue licensure. If the board has not received a satisfactory response from the licensee within the 30-day period, the licensee must be served with actual or constructive notice of the pending expiration of licensure and be given 20 days in which to submit proof required in order to continue licensure. If the 20-day period expires and the board finds it has not received acceptable proof of full-time practice within the geographic boundaries of this state within 1 year after the initial issuance of the license, then the board must issue an administrative order finding that the license has expired. Such an order may be appealed by the former licensee in accordance with the provisions of chapter 120. In the event of expiration, the licensee shall immediately cease and desist from practicing dentistry and shall immediately surrender to the board the wallet-size identification card and wall card. A person who uses or attempts to use a license issued pursuant to this section which has expired commits unlicensed practice of dentistry, a felony of the third degree pursuant to s. 466.026(1)(b), punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

Note.—Section 21, ch. 2011-95, provides that “[e]xcept as otherwise specifically provided in this act. this act shall take effect upon becoming a law, and shall not apply retroactively.”

466.0065 Regional licensure examinations.—
(1) It is the intent of the Legislature that schools of dentistry be allowed to offer regional licensure examinations to dental students who are in the final year of a program at an approved dental school for the sole purpose of facilitating the student’s licensing in other jurisdictions. This section does not allow a person to be licensed as a dentist in this state without taking the examinations as set forth in s. 466.006, nor does this section mean that regional examinations administered under this section may be substituted for complying with testing requirements under s. 466.006.
(2) Each school of dentistry in this state which is accredited by the Commission on Accreditation of the American Dental Association or its successor agency may, upon written approval by the Board of Dentistry, offer regional licensure examinations only to dental students in the final year of a program at an approved dental school, if the board has approved the hosting school’s written plan to comply with the following conditions:
(a) A member of the regional examination body’s board of directors or equivalent thereof must be a member of the American Association of Dental Examiners.
(b) The student must have successfully passed parts I and II of the National Board of Dental Examiners examination within 2 years before taking the regional examination.
(c) The student must possess medical malpractice insurance in amounts not less than the amounts required to take the Florida licensure examinations.
(d) At least one of the examination monitors must be a dentist licensed in this state who has completed all necessary standardization exercises required by the regional examination body. Recruitment of examination monitors is the responsibility of the regional examination body.
(e) Adequate arrangements, as defined by the regional examination body and as otherwise required by law, must be made, when necessary, for patients who require followup care as a result of procedures performed during the clinical portion of the regional examination. The regional examination body must inform patients in writing of their right to followup care in advance of any procedures performed by a student.
(f) The board chair or the chair’s designee must be allowed to observe testing while it is in progress.

(g) Each student, upon being deemed eligible by the dental school to apply to the regional examination body to take the regional examination, must receive written disclosure in at least 12-point boldface type that states: “This examination does not meet the licensure requirements of chapter 466, Florida Statutes, for licensure in the State of Florida. Persons wishing to practice dentistry in Florida must pass the Florida licensure examinations.”

(h) The student must be enrolled as a dental student in the student’s final year of a program at an approved dental school that is accredited by the Commission on Accreditation of the American Dental Association or its successor agency.

(i) The student must have completed all coursework deemed necessary by the dental school to prepare the student to perform all clinical and diagnostic procedures required to pass the regional examination.

(j) The student’s academic record must not include any evidence suggesting that the student poses an unreasonable risk to any live patients who are required for the clinical portion of the regional examination. In order to protect the health and safety of the public, the dental school may request additional information and documents pertaining to the candidate’s mental and physical health in order to fully assess the candidate’s fitness to engage in exercises involving a live patient.

(3) A student who takes the examination pursuant to this section, a dental school that submits a plan pursuant to this section, or a regional examination body that a dental school proposes to host under this section does not have standing to assert that a state agency has taken action for which a hearing may be sought under ss. 120.569 and 120.57.

History.--s. 2, ch. 2004-300; s. 11, ch. 2011-95.

1Note.--Section 21, ch. 2011-95, provides that “[e]xcept as otherwise specifically provided in this act, this act shall take effect upon becoming a law, and shall not apply retroactively.”

466.0067 Application for health access dental license. -- The Legislature finds that there is an important state interest in attracting dentists to practice in underserved health access settings in this state and further, that allowing out-of-state dentists who meet certain criteria to practice in health access settings without the supervision of a dentist licensed in this state is substantially related to achieving this important state interest. Therefore, notwithstanding the requirements of s. 466.006, the board shall grant a health access dental license to practice dentistry in this state in health access settings as defined in s. 466.003 to an applicant that:

(1) Files an appropriate application approved by the board;
(2) Pays an application license fee for a health access dental license, laws-and-rule exam fee, and an initial licensure fee. The fees specified in this subsection may not differ from an applicant seeking licensure pursuant to s. 466.006;
(3) Has not been convicted of or pled nolo contendere to, regardless of adjudication, any felony or misdemeanor related to the practice of a health care profession;
(4) Submits proof of graduation from a dental school accredited by the Commission on Dental Accreditation of the American Dental Association or its successor agency;
(5) Submits documentation that she or he has completed, or will obtain prior to licensure, continuing education equivalent to this state’s requirement for dentists licensed under s. 466.006 for the last full reporting biennium before applying for a health access dental license;
(6) Submits proof of her or his successful completion of parts I and II of the dental examination by the National Board of Dental Examiners and a state or regional clinical dental licensing examination that the board has determined effectively measures the applicant’s ability to practice safely;
(7) Currently holds a valid, active, dental license in good standing which has not been revoked, suspended, restricted, or otherwise disciplined from another of the United States, the District of Columbia, or a United States territory;
(8) Has never had a license revoked from another of the United States, the District of Columbia, or a United States territory;
(9) Has never failed the examination specified in s. 466.006, unless the applicant was reexaminated pursuant to s. 466.006 and received a license to practice dentistry in this state;
(10) Has not been reported to the National Practitioner Data Bank, unless the applicant successfully appealed to have his or her name removed from the data bank;
(11) Submits proof that he or she has been engaged in the active, clinical practice of dentistry providing direct patient care for 5 years immediately preceding the date of application, or in instances when the applicant has graduated from an accredited dental school within the preceding 5 years, submits proof of continuous clinical practice providing direct patient care since graduation; and
(12) Has passed an examination covering the laws and rules of the practice of dentistry in this state as described in s. 466.006(4)(a).

History.--ss. 3, 6, ch. 2008-64; s. 104, ch. 2010-5; s. 10, ch. 2011-95.

1Note.--Repealed January 1, 2015, by s. 6, ch. 2008-64, unless reenacted by the Legislature.

1Note.--Section 21, ch. 2011-95, provides that “[e]xcept as otherwise specifically provided in this act, this act shall take effect upon becoming a law, and shall not apply retroactively.”

466.00672 Revocation of health access dental license. --

(1) The board shall revoke a health access dental license upon:
(a) The licensee’s termination from employment from a qualifying health access setting;
(b) Final agency action determining that the licensee has violated any provision of s. 466.027 or s. 466.028, other than infractions constituting citation offenses or minor violations; or
(c) Failure of the Florida dental licensure examination.
(2) Failure of an individual licensed pursuant to s. 466.0067 to limit the practice of dentistry to health access settings as defined
in s. 466.003 constitutes the unlicensed practice of dentistry.

History.—ss. 5, 6, ch. 2008-64; s. 8, ch. 2011-95.

1Note.—Repealed January 1, 2015, by s. 6, ch. 2008-64, unless reenacted by the Legislature.

2Note.—Section 21, ch. 2011-95, provides that “[e]xcept as otherwise specifically provided in this act, this act shall take effect upon becoming a law, and shall not apply retroactively.”

466.00673 Repeal of a health access dental license. — Effective January 1, 2015, ss. 466.0067-466.00673 are repealed unless reenacted by the Legislature. Any health access dental license issued before January 1, 2015, shall remain valid according to ss. 466.0067-466.00673, without effect from repeal.

History.—s. 6, ch. 2008-64.

466.007 Examination of dental hygienists. —

(1) Any person desiring to be licensed as a dental hygienist shall apply to the department to take the licensure examinations and shall verify the information required on the application by oath. The application shall include two recent photographs of the applicant. There shall be a nonrefundable application fee set by the board not to exceed $100 and an examination fee set by the board which shall not be more than $225. The examination fee may be refunded if the applicant is found ineligible to take the examinations.

(2) An applicant shall be entitled to take the examinations required in this section to practice dental hygiene in this state if the applicant:

(a) Is 18 years of age or older.

(b) 1. Is a graduate of a dental hygiene college or school approved by the board or accredited by the Commission on Accreditation of the American Dental Association or its successor agency; or

2. Is a graduate of a dental college or school accredited in accordance with s. 466.006(2)(b), or a graduate of an unaccredited dental college or school, and has met the requirements of subsection (3).

(c) 1. In the case of a graduate of a dental hygiene college or school under subparagraph (2)(b)1., has successfully completed either the National Board of Dental Hygiene examination or the National Board of Dental Examiners dental examination, within 10 years of the date of application.

2. In the case of a graduate of a dental college or school under subparagraph (2)(b)2., has successfully completed either the National Board of Dental Hygiene examination or the National Board of Dental Examiners dental examination, within 10 years of the date of application.

(3) A graduate of a dental college or school shall be entitled to take the examinations required in this section to practice dental hygiene in this state if, in addition to the requirements specified in subsection (2), the graduate meets the following requirements:

(a) Submits the following credentials for review by the board:

1. Transcripts totaling 4 academic years of postsecondary dental education; and

2. A dental school diploma which is comparable to a D.D.S. or D.M.D. Such credentials shall be submitted in a manner provided by rule of the board.

The board shall approve those credentials which comply with this paragraph and with rules of the board adopted pursuant to this paragraph. The provisions of this paragraph notwithstanding, an applicant of a foreign dental college or school not accredited in accordance with s. 466.006(2)(b) who cannot produce the credentials required by this paragraph, as a result of political or other conditions in the country in which the applicant received his or her education, may seek the board’s approval of his or her educational background by submitting, in lieu of the credentials required in this paragraph, such other reasonable and reliable evidence as may be set forth by board rule. The board shall not accept such other evidence until it has made a reasonable attempt to obtain the credentials required by this paragraph from the educational institutions the applicant is alleged to have attended, unless the board is otherwise satisfied that such credentials cannot be obtained.

(b) Successfully completes one or more courses, of a scope and duration approved and defined by board rule, that meet the requirements of law for instructing health care providers on the human immunodeficiency virus and acquired immune deficiency syndrome. In addition, the board may require an applicant who graduated from a nonaccredited dental college or school to successfully complete additional coursework, only after failing the initial examination, as defined by board rule, at an educational institution approved by the board or accredited as provided in subparagraph (2)(b)1.

A graduate of a foreign dental college or school not accredited in accordance with s. 466.006(2)(b) may not take the coursework set forth in this paragraph until the board has approved the credentials required by paragraph (a).

(4) To be licensed as a dental hygienist in this state, an applicant must successfully complete the following:

(a) A written examination on the laws and rules of this state regulating the practice of dental hygiene.

(b) A practical or clinical examination. The practical or clinical examination shall test competency in areas to be established by rule of the board, which shall include testing the ability to adequately perform a prophylaxis. On or after October 1, 1986, every applicant who is otherwise qualified shall be eligible to take the examination a total of three times, notwithstanding the number of times the applicant has previously failed. If an applicant fails the examination three times, the applicant shall no longer be eligible to take the examination unless he or she obtains additional educational requirements established by the board.

The department shall require a mandatory standardization exercise pursuant to s. 466.017(1)(b) for all examiners prior to each practical or clinical examination and shall retain for employment only those dentists and dental hygienists who have substantially adhered to the standard of grading established at such exercise. It is the intent of the Legislature that the examinations relate to those procedures which are actually performed by a dental hygienist in general practice.

History.—ss. 1, 3, ch. 79-330; ss. 2, 3, ch. 81-318; ss. 6, 23, 24, ch. 86-291; s. 16, ch. 88-205; s. 60, ch. 91-137; s. 7, ch. 91-156; s. 4, ch. 91-429; s. 98, ch. 92-149; s. 1, ch. 94-105; s. 2, ch. 96-281; s. 1108, ch. 97-103; s. 70, ch. 98-166; s. 129, ch. 2000-160; s. 4, ch. 2005-189; s. 11, ch. 2008-64; s. 13, ch. 2011-95.

1Note.—Section 21, ch. 2011-95, provides that “[e]xcept as otherwise specifically provided in this act, this act shall take effect upon becoming a law, and shall not apply retroactively.”

466.0075 Applicants for examination; medical malpractice insurance. — The board may require any person applying to take the examination to practice dentistry in this state or the examination to practice dental hygiene in this state to maintain medical malpractice insurance in amounts sufficient to cover any incident of harm to a patient during the clinical examination.

History.—s. 4, ch. 96-281.

466.00775 Rulemaking. — The board shall adopt rules pursuant to ss. 120.53(1) and 120.54 to administer ss. 466.003(14), 466.0067, 466.00671, 466.00672, 466.00673, 466.021, and 466.032.

History.—s. 7, ch. 2008-64.

466.008 Certification of foreign educational institutions. —

(1) The Legislature recognizes the need to ensure that graduates of foreign dental schools who have received an education which is reasonably comparable to that of similar accredited institutions in the United States and which adequately prepare their
students for the practice of dentistry shall be subject to the same licensure requirements as graduates of accredited dental schools or colleges. It is the purpose of this section to provide for the evaluation of foreign dental schools and the certification of those foreign dental schools which provide an education which is reasonably comparable to that of similar accredited institutions in the United States and which adequately prepare their students for the practice of dentistry.

(2) The department shall be responsible for the certification of foreign dental schools based on standards established pursuant to subsection (4). The department may contract with outside consultants or a national professional organization to survey and evaluate foreign dental schools. Such consultant or organization shall report to the department regarding its findings in the survey and evaluation.

(3) The department shall establish a technical advisory group to review and comment upon the survey and evaluation of a foreign dental school contracted for pursuant to subsection (2) prior to any final action by the department regarding certification of the foreign dental school. The technical advisory group shall be selected by the department and shall consist of four dentists, two of whom shall be selected from a list of five recognized United States dental educators recommended by the foreign school seeking certification. None of the members of the technical advisory group shall be affiliated with the school seeking certification.

(4) Any foreign dental school which wishes to be certified pursuant to this section shall make application to the department for such certification, which shall be based upon a finding that the educational program of the foreign dental school is reasonably comparable to that of similar accredited institutions in the United States and adequately prepares its students for the practice of dentistry. Curriculum, faculty qualifications, student attendance, plant and facilities, and other relevant factors shall be reviewed and evaluated. The board, with the cooperation of the department, shall identify by rule the standards and review procedures and methodology to be used in the certification process consistent with this subsection. The department shall not grant certification if deficiencies found are of such magnitude as to prevent the students in the school from receiving an educational base suitable for the practice of dentistry.

(5) Periodic surveys and evaluations of all certified schools shall be made to ensure continued compliance with this section. Certification shall include provisional and full certification. The provisional form of certification shall be for a period determined by the department, not to exceed 3 years, and shall be granted to an institution, in accordance with rule, to provide reasonable time for the school seeking permanent certification to overcome deficiencies found by the department. Prior to the expiration of a provisional certification and before the full certification is granted, the school shall be required to submit evidence that deficiencies noted at the time of initial application have been remedied. A school granted full certification shall provide evidence of continued compliance with this section. In the event that the department denies certification or recertification, the department shall give the school a specific listing of the deficiencies which caused the denial and the requirements for remedying the deficiencies, and shall permit the school, upon request, to demonstrate by satisfactory evidence, within 90 days, that it has remedied the deficiencies listed by the department.

(6) A school shall pay a registration fee established by rule of the department, not to exceed $1,000, at the time of application for certification and shall pay all reasonable costs and expenses the department expects to incur, in an amount not to exceed $40,000, for the conduct of the certification survey.

(7) The department shall renew a certification upon receipt of a renewal application, accompanied by a fee not to exceed $500. Each fully certified institution shall submit a renewal application every 7 years. Any renewal which is not renewed shall automatically expire.

History.--s. 99, ch. 92-149.

466.009 Reexamination.--

(1) The department shall permit any person who fails an examination which is required under s. 466.006 or s. 466.007 to retake the examination. If the examination to be retaken is a practical or clinical examination, the applicant shall pay a reexamination fee set by rule of the board in an amount not to exceed the original examination fee.

(2) If an applicant for a license to practice dentistry fails the practical or clinical examination because of a failing grade on just one part or procedure tested, she or he shall be required to retake only that part or procedure. However, if any such applicant fails more than one part or procedure of any such examination, she or he shall be required to retake the entire examination.

(3) If an applicant for a license to practice dentistry fails the practical or clinical examination, such applicant shall be required to retake only that portion if she or he reappears within 12 months. If, however, the applicant fails the prophylaxis, she or he shall be required to retake the entire examination.

History.--ss. 1, 3, ch. 79-330; ss. 2, 3, ch. 81-318; ss. 23, 24, ch. 86-291; s. 60, ch. 91-137; s. 7, ch. 91-156; s. 4, ch. 91-429; s. 252, ch. 97-103; s. 14, ch. 2011-95.

Note.--Section 21, ch. 2011-95, provides that "[e]xcept as otherwise specifically provided in this act, this act shall take effect upon becoming a law, and shall not apply retroactively."

466.011 Licensure.-- The board shall certify for licensure by the department any applicant who satisfies the requirements of s. 466.006, s. 466.0067, or s. 466.007. The board may refuse to certify an applicant who has violated any of the provisions of s. 466.026 or s. 466.028.

History.--ss. 1, 3, ch. 79-330; ss. 2, 3, ch. 81-318; ss. 23, 24, ch. 86-291; s. 50, ch. 90-228; s. 4, ch. 90-341; s. 60, ch. 91-137; s. 7, ch. 91-156; s. 4, ch. 91-429; s. 3, ch. 94-105; s. 3, ch. 96-281; s. 8, ch. 2008-64; s. 15, ch. 2011-95.

466.013 Renewal of license.--

(1) The department shall renew a license upon receipt of the renewal application and the fee set by the board not to exceed $300.

(2) The department shall adopt rules establishing a procedure for the biennial renewal of licenses.

History.--ss. 1, 3, ch. 79-330; ss. 2, 3, ch. 81-318; ss. 23, 24, ch. 86-291; s. 36, ch. 89-162; s. 60, ch. 91-137; s. 7, ch. 91-156; s. 4, ch. 91-429; s. 180, ch. 94-119.

466.0135 Continuing education; dentists.--

(1) In addition to the other requirements for renewal set out in this chapter, each licensed dentist shall be required to complete biennially not less than 30 hours of continuing professional education in dental subjects. Programs of continuing education shall be programs of learning that contribute directly to the dental education of the dentist and may include, but shall not be limited to, attendance at lectures, study clubs, college postgraduate courses, or scientific sessions of conventions; and research, graduate study, teaching, or service as a clinician. Programs of continuing education shall be acceptable when adhering to the following general guidelines:

(a) The aim of continuing education for dentists is to improve all phases of dental health care delivery to the public.

(b) Continuing education courses shall address one or more of the following areas of professional development, including, but not limited to:

1. Basic medical and scientific subjects, including, but not limited to, biology, physiology, pathology, biochemistry, and pharmacology;

2. Clinical and technological subjects, including, but not limited to, clinical techniques and procedures, materials, and equipment; and

3. Subjects pertinent to oral health and safety.

(c) The board may also authorize up to three hours of credit biennially for a practice management course that includes principles of ethical practice management, provides substance abuse, effective communication with patients, time management, and burnout prevention instruction.
(d) Continuing education credits shall be earned at the rate of one-half credit hour per 25-30 contact minutes of instruction and one credit hour per 50-60 contact minutes of instruction.

(2) Programs meeting the general requirements of subsection (1) may be developed and offered to dentists by any of the following agencies or organizations:

(a) The American Dental Association, the National Dental Association, and state, district, or local dental associations and societies affiliated with the American Dental Association or the National Dental Association.

(b) National, state, district, or local dental specialty organizations affiliated with the American Dental Association.

(c) Dental colleges or schools accredited as provided in this chapter.

(d) Other organizations, schools, or agencies approved by the board.

(3) In applying for license renewal, the dentist shall submit a sworn affidavit, on a form acceptable to the department, attesting that she or he has completed the continuing education required in this section in accordance with the guidelines and provisions of this section and listing the date, location, sponsor, subject matter, and hours of completed continuing education courses.

The applicant shall retain in her or his records such receipts, vouchers, or certificates as may be necessary to document completion of the continuing education courses listed in accordance with this subsection. With cause, the board may request such documentation by the applicant, and the board may request such documentation from applicants selected at random without cause.

(4) Compliance with the continuing education requirements of this section shall be mandatory for the issuance of a renewal certificate by the department; however, the board shall have the authority to excuse licensees, as a group or as individuals, from the continuing educational requirements, or any part thereof, in the event an unusual circumstance, emergency, or hardship has prevented compliance with this section.

History.–s. 1, 3, ch. 79-330; ss. 2, 3, ch. 81-318; ss. 8, 23, 24, ch. 86-291; s. 60, ch. 91-137; s. 7, ch. 91-156; s. 4, ch. 91-429; s. 254, ch. 97-103; s. 122, ch. 2000-153.

466.015 Inactive status. –

(1) The board shall adopt rules relating to application procedures for inactive status, to the renewal of inactive licenses, and to the reactivation of licenses. The board shall prescribe by rule an application fee for inactive status, a biennial renewal fee for inactive status, a delinquency fee, and a fee for the reactivation of a license. None of these fees may exceed the biennial renewal fee established by the board for an active license.

(2) The department shall not reactivate a license unless the inactive or delinquent licensee has paid any applicable biennial renewal or delinquency fee, or both, and a reactivation fee.

History.–s. 1, 3, ch. 79-330; s. 327, ch. 81-259; ss. 2, 3, ch. 81-318; s. 101, ch. 83-329; ss. 9, 23, 24, ch. 86-291; s. 60, ch. 91-137; s. 7, ch. 91-156; s. 4, ch. 91-429; s. 181, ch. 94-119.

466.016 License to be displayed. – Every practitioner of dentistry or dental hygiene within the meaning of this chapter shall post and keep conspicuously displayed her or his license in the office wherein she or he practices, in plain sight of the practitioner’s patients.

Any dentist or dental hygienist who practices at more than one location shall be required to display a copy of her or his license in each office where she or he practices.

History.–s. 1, 3, ch. 79-330; ss. 2, 3, ch. 81-318; ss. 23, 24, ch. 86-291; s. 60, ch. 91-137; s. 7, ch. 91-156; s. 4, ch. 91-429; s. 255, ch. 97-103.

466.017 Prescription of drugs; anesthesia. –

(1) A dentist shall have the right to prescribe drugs or medicine, subject to limitations imposed by law; perform surgical operations within the scope of her or his practice and training; administer general or local anesthesia or sedation, subject to limitations imposed by law; and use such appliances as may be necessary to the proper practice of dentistry.

(2) Pharmacists licensed pursuant to chapter 465 may fill prescriptions of legally licensed dentists in this state for any drugs necessary for the practice of dentistry.

(3) The board shall adopt rules which:

(a) Define general anesthesia.

(b) Specify which methods of general or local anesthesia or sedation, if any, are limited or prohibited for use by dentists.

(c) Establish minimal training, education, experience, or certification for a dentist to use general anesthesia or sedation, which rules may exclude, in the board’s discretion, those dentists using general anesthesia or sedation in a competent and effective manner as of the effective date of the rules.

(d) Establish further requirements relating to the use of general anesthesia or sedation, including, but not limited to, office equipment and the training of dental assistants or dental hygienists who work with dentists using general anesthesia or sedation.

(e) Establish an administrative mechanism enabling the board to verify compliance with training, education, experience, equipment, or certification requirements of dentists, dental hygienists, and dental assistants adopted pursuant to this subsection. The board may charge a fee to defray the cost of verifying compliance with requirements adopted pursuant to this paragraph.

(4) A dentist who administers or employs the use of any form of anesthesia must possess a certification in either basic cardiopulmonary resuscitation for health professionals or advanced cardiac life support approved by the American Heart Association or the American Red Cross or an equivalent agency-sponsored course with recertification every 2 years.

Each dental office which uses any form of anesthesia must have immediately available and in good working order such resuscitative equipment, oxygen, and other resuscitative drugs as are specified by rule of the board in order to manage possible adverse reactions.

(5) A licensed dentist may utilize an X-ray machine, expose dental X-ray films, and interpret or read such films. The provisions of part IV of chapter 468 to the contrary notwithstanding, a licensed dentist may authorize or direct a dental assistant to operate such equipment and expose such films under her or his direction and supervision, pursuant to rules adopted by the board in accordance with s. 466.024 which ensure that said assistant is competent by reason of training and experience to operate said equipment in a safe and efficient manner. The board may charge a fee not to exceed $35 to defray the cost of verifying compliance with requirements adopted pursuant to this section.
(6) The provisions of s. 465.0276 notwithstanding, a dentist need not register with the board or comply with the continuing education requirements of that section if the dentist confines her or his dispensing activity to the dispensing of fluorides and chlorohexidine rinse solutions; provided that the dentist complies with and is subject to all laws and rules applicable to pharmacists and pharmacies, including, but not limited to, chapters 465, 499, and 893, and all applicable federal laws and regulations, when dispensing such products.

History.—ss. 1, 3, ch. 79-330; ss. 13, 15, 25, 27, 30, 34, 62, ch. 80-406; s. 328, ch. 81-259; ss. 2, 3, ch. 81-318; s. 1, ch. 85-156; ss. 10, 23, 24, ch. 86-291; s. 1, ch. 87-208; s. 37, ch. 89-162; s. 60, ch. 91-137; s. 7, ch. 91-156; s. 4, ch. 91-429; s. 34, ch. 95-144; s. 256, ch. 97-103; s. 109, ch. 97-264.

466.018 Dentist of record; patient records.—
(1) Each patient shall have a dentist of record. The dentist of record shall remain primarily responsible for all dental treatment on such patient regardless of whether the treatment is rendered by the dentist or by another dentist, dental hygienist, or dental assistant rendering such treatment in conjunction with, at the direction or request of, or under the supervision of such dentist of record. The dentist of record shall be identified in the record of the patient. If treatment is rendered by a dentist other than the dentist of record or by a dental hygienist or assistant, the name or initials of such person shall be placed in the record of the patient. In any disciplinary proceeding brought pursuant to this chapter or chapter 456, it shall be presumed as a matter of law that treatment was rendered by the dentist of record unless otherwise noted on the patient record pursuant to this section. The dentist of record and any other treating dentist are subject to discipline pursuant to this chapter or chapter 456 for treatment rendered the patient and performed in violation of such chapter. One of the purposes of this section is to ensure that the responsibility for each patient is assigned to one dentist in a multidentist practice of any nature and to assign primary responsibility to the dentist for treatment rendered by a dental hygienist or assistant under her or his supervision. This section shall not be construed to assign any responsibility to a dentist of record for treatment rendered pursuant to a proper referral to another dentist not in practice with the dentist of record or to prohibit a patient from voluntarily selecting a new dentist without permission of the dentist of record.

(2) If the dentist of record is not identified in the patient record as required by subsection (1), it shall be presumed as a matter of law that the dentist of record is the owner of the dental practice in which the patient was treated. Further, the dentist of record in a multidentist practice shall not change unless the subsequent treating dentist acknowledges in writing in the record that she or he is now the dentist of record for the patient. It shall be presumed as a matter of law that a new dentist of record has taken or reviewed the patient’s medical history and dental records, that she or he has examined the patient, and that she or he has either developed a new treatment plan or has agreed to continue the preexisting treatment plan. However, the dentist of record shall be changed when the dentist of record leaves the practice where the treatment was being rendered and the patient elects to continue treatment in the office where treatment began.

(3) Every dentist shall maintain written dental records and medical history records which justify the course of treatment of the patient. The records shall include, but not be limited to, patient history, examination results, test results, and, if taken, X rays.

(4) In a multidentist practice of any nature, the owner dentist shall maintain either the original or a duplicate of all patient records, including dental charts, patient histories, examination and test results, study models, and X rays, of any patient treated by a dentist at the owner dentist’s practice facility. The purpose of this requirement is to impose a duty upon the owner of a multidentist practice to maintain patient records for all patients treated at the owner’s practice facility whether or not the owner was involved in the patient’s treatment. This subsection does not relieve the dentist of record in a multidentist practice of the responsibility to maintain patient records. An owner dentist of a multidentist practice may be relieved of the responsibility to maintain the original or duplicate patient records for patients treated at the owner dentist’s practice facility if, upon request of the owner of the practice, he or she transfers custody of the records to another dentist, the patient, or the patient’s legal representative and retains, in lieu of the records, a written statement, signed by the owner dentist, the person who received the records, and two witnesses, that lists the date, the records that were transferred, and the persons to whom the records were transferred. Further, the dentist of record may be relieved of the responsibility to maintain the original or duplicate patient records if she or he leaves the practice where the treatment was rendered, transfers custody of the records to the owner of the practice, and retains, in lieu of the records, a written statement, signed by the dentist of record, the owner of the practice, and two witnesses, that lists the date and the records that were transferred. The owner dentist shall provide reasonable access to duplicate records at cost.

(5) All patient records kept in accordance with this section shall be maintained for a period of 4 years from the date of the patient’s last appointment.

History.—ss. 1, 3, ch. 79-330; ss. 2, 3, ch. 81-318; ss. 3, 41, ch. 82-179; ss. 11, 23, 24, ch. 86-291; s. 60, ch. 91-137; s. 7, ch. 91-156; s. 4, ch. 91-429; s. 257, ch. 97-103; s. 71, ch. 98-166; s. 130, ch. 2000-160.

466.019 Advertising by dentists.—
(1) The purpose of this section is to ensure that the public has access to information which provides a sufficient basis upon which to make an informed selection of dentists while also ensuring that the public is protected from false or misleading advertisements which would detract from a fair and rational selection process. The board shall adopt rules to carry out the intent of this section, the purpose of which shall be to regulate the manner of such advertising in keeping with the provisions hereof.

(2) No advertisement by a licensed dentist shall contain any false, fraudulent, misleading, or deceptive statement or claim or any statement or claim which:
(a) Contains misrepresentations of fact;
(b) Is likely to mislead or deceive because in context it makes only a partial disclosure of relevant facts;
(c) Contains laudatory statements about the dentist or group of dentists;
(d) Is intended or is likely to create false, unjustified expectations of favorable results;
(e) Relates to the quality of dental services provided as compared to other available dental services;
(f) Is intended or is likely to appeal primarily to a layperson’s fears;
(g) Contains fee information without a disclaimer that such is a minimum fee only; or
(h) Contains other representations or implications that in reasonable probability will cause an ordinary, prudent person to misunderstand or to be deceived.

(3) For purposes of this section, D.D.S. or D.M.D. are synonymous and may be used interchangeably by licensed dentists who have graduated from an accredited American dental school with a D.D.S. or D.M.D. degree, when advertising dental services.

History.—ss. 1, 3, ch. 79-330; ss. 2, 3, ch. 81-318; ss. 12, 23, 24, ch. 86-291; ss. 14, 60, ch. 91-137; s. 7, ch. 91-156; s. 4, ch. 91-429.

466.021 Retention of dental laboratories by dentist; penalty.—Each licensed dentist who uses the services of any dental laboratory for the purpose of constructing, altering, repairing, or duplicating any denture, implant, veneer, partial denture, bridge splint, orthodontic or other prosthetic appliance, or other suitable form of artificial oral restorative device shall be required to furnish the dental laboratory with a written prescription in a form prescribed by rule of the board. This prescription shall be dated and signed by the dentist and shall include the license number of the dentist, the patient’s name or number with sufficient descriptive information to clearly identify each separate and individual piece of work to be performed by the dental laboratory, and a specification of materials to be contained in each work product. A copy of the prescription shall be retained in a file in...
the prescribing dentist’s office for a period of 4 years following the date the prescription was issued, and the original prescription shall be retained in a file by the dental laboratory for a period of 4 years. A registered dental laboratory shall disclose in writing at the time of delivery of the final restoration to the prescribing dentist the materials and all certificates of authenticity that constitute each product manufactured and the point of origin of manufacture of each restoration, including the address and contact information of the dental laboratory. The file of prescriptions to be kept by the dentist and the dental laboratory shall be open to inspection at any reasonable time by the department or its constituted agent. Failure of the dentist to keep records of each prescription shall subject the dentist to suspension or revocation of her or his license to practice dentistry in this state. Failure of a dental laboratory that has accepted a prescription to have the original or electronic copy of each prescription and to ensure the accuracy of each product’s material disclosure at the time it is delivered to the prescribing dentist as required by this section is admissible evidence of a violation of this chapter and constitutes a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083. This section does not preclude a registered dental laboratory from working for another registered dental laboratory if that work is performed pursuant to written authorization, in a form to be prescribed by rule of the board, which evidences that the originating laboratory has obtained a valid prescription and which sets forth the work to be performed and the resulting material certifications to be provided. A dental laboratory accepting prescriptions from dentists is liable for damages caused by inaccuracies in the material disclosure, certificates of authenticity, or point of origin provided by the dental laboratory to the prescribing dentist. This section does not preclude a registered laboratory from providing its services to dentists licensed and practicing in another state if that work is requested or otherwise authorized in written form that clearly identifies the name and address of the requesting dentist and sets forth the work to be performed and otherwise complies with all applicable laws and treaties.

History.–ss. 1, 3, ch. 79-330; ss. 2, 3, ch. 81-318; ss. 23, 24, ch. 86-291; s. 60, ch. 91-137; s. 7, ch. 91-156; s. 93, ch. 91-224; s. 4, ch. 91-429; s. 258, ch. 97-103; s. 2, ch. 99-183; s. 126, ch. 99-397; s. 6, ch. 2005-189; s. 9, ch. 2008-64.

466.022 Peer review; records; immunity; confidentiality. –

(1) The Legislature finds that effective peer review of consumer complaints by professional associations of dentists is a valuable service to the public. In performing such service, any member of a peer review organization or committee shall, pursuant to s. 466.028(1)(f), report to the department the name of any licensee who he or she believes has violated this chapter. Any such peer review committee member shall be afforded the privileges and immunities of any other complainant or witness which are provided by s. 456.073(11). Furthermore, a professional organization or association of dentists which sponsors, sanctions, or otherwise operates or participates in peer review activities is hereby afforded the same privileges and immunities afforded to any member of a duly constituted medical review committee by s. 766.101(3).

(2) Information obtained from the official records of peer review organizations or committees shall not be subject to discovery or introduction into evidence in any disciplinary proceeding against a licensee. Further, no person who voluntarily serves on a peer review committee or who investigates a complaint for the committee shall be permitted or required to testify in any such disciplinary proceeding as to any evidence or other matters produced or presented during the proceedings of such organization or committee or as to any findings, recommendations, evaluations, opinions, or other actions of such organization or committee or any members thereof. However, nothing in this section shall be construed to mean that information, documents, or records otherwise available and obtained from original sources are immune from discovery or use in any such disciplinary proceeding merely because they were presented during proceedings of a peer review organization or committee. Members of peer review organizations shall assist the department in identification of such original sources when possible.

(3) Peer review information obtained by the department as background information shall remain confidential and exempt from ss. 119.07(1) and 286.011 regardless of whether probable cause is found. The provisions of s. 766.101 continue to apply in full notwithstanding the fact that peer review information becomes available to the department pursuant to this chapter. For the purpose of this section, official records of peer review organizations or committees include correspondence between the dentist who is the subject of the complaint and the organization; correspondence between the complainant and the organization; diagnostic data, treatment plans, and radiographs used by investigators or otherwise relied upon by the organization or committee; results of patient examinations; interviews; evaluation worksheets; recommendation worksheets; and peer review report forms.

(4) The provisions of this section shall apply to ethics review committees of a professional association of dentists.

History.–ss. 13, 24, ch. 86-291; s. 2, ch. 87-208; s. 8, ch. 89-162; s. 60, ch. 91-137; s. 22, ch. 91-140; s. 7, ch. 91-156; s. 4, ch. 91-429; s. 35, ch. 95-144; s. 318, ch. 96-406; s. 1109, ch. 97-103; s. 72, ch. 98-166; s. 131, ch. 2000-160.

466.023 Dental hygienists; scope and area of practice. –

(1) Except as otherwise provided in s. 466.024, only dental hygienists may be delegated the task of removing calculus deposits, accretions, and stains from exposed surfaces of the teeth and from the gingival sulcus and the task of performing root planing and curettage. In addition, dental hygienists may expose dental X-ray films, apply topical preventive or prophylactic agents, and perform all tasks delegable by the dentist in accordance with s. 466.024. The board by rule shall determine whether such functions shall be performed under the direct, indirect, or general supervision of the dentist.

(2) Dental hygienists may perform their duties:

(a) In the office of a licensed dentist;
(b) In public health programs and institutions of the Department of Children and Family Services, Department of Health, and Department of Juvenile Justice under the general supervision of a licensed dentist;
(c) In a health access setting as defined in s. 466.003; or
(d) Upon a patient of record of a dentist who has issued a prescription for the services of a dental hygienist, which prescription shall be valid for 2 years unless a shorter length of time is designated by the dentist, in:

1. Licensed public and private health facilities;
2. Other public institutions of the state and federal government;
3. Public and private educational institutions;
4. The home of a nonambulatory patient; and
5. Other places in accordance with the rules of the board.

However, the dentist issuing such prescription shall remain responsible for the care of such patient. As used in this subsection, “patient of record” means a patient upon whom a dentist has taken a complete medical history, completed a clinical examination, recorded any pathological conditions, and prepared a treatment plan.

(3) Dental hygienists may, without supervision, provide educational programs, faculty or staff training programs, and authorized fluoride rinse programs; apply fluorides; instruct a patient in oral hygiene care; supervise the oral hygiene care of a patient; and perform other services that do not involve diagnosis or treatment of dental conditions and that are approved by rule of the board.

(4) The board by rule may limit the number of dental hygienists or dental assistants to be supervised by a dentist if they perform expanded duties requiring direct or indirect supervision pursuant to the provisions of this chapter. The purpose of the limitation shall be to protect the health and safety of patients and to ensure that procedures which require more than general supervision be adequately supervised. However, the Department of Children and Family Services, Department
of Health, Department of Juvenile Justice, and public institutions approved by the board shall not be so limited as to the number of dental hygienists or dental assistants working under the supervision of a licensed dentist.

(5) Dental hygienists may, without supervision, perform dental charting as provided in s. 466.0235.

(6) Dental hygienists are exempt from the provisions of part IV of chapter 468.

**History.**—ss. 1, 3, ch. 79-330; ss. 2, 3, ch. 81-318; ss. 14, 23, 24, ch. 86-291; s. 60, ch. 91-137; s. 7, ch. 91-156; s. 4, ch. 91-429; s. 36, ch. 95-144; s. 5, ch. 96-281; s. 225, ch. 99-8; s. 1, ch. 2006-149; s. 5, ch. 2011-95.

Note.—Section 21, ch. 2011-95, provides that “except as otherwise specifically provided in this act, this act shall take effect upon becoming a law, and shall not apply retroactively.”

466.0235 Dental charting. —

(1) For purposes of this section, the term “dental charting” means a recording of visual observations of clinical conditions of the oral cavity without the use of X rays, laboratory tests, or other diagnostic methods or equipment, except the instruments necessary to record visual restorations, missing teeth, suspicious areas, and periodontal pockets.

(2) A dental hygienist may, without supervision and within the lawful scope of his or her duties as authorized by law, perform dental charting of hard and soft tissues in public and private educational institutions of the state and Federal Government, nursing homes, assisted living and long-term care facilities, community health centers, county health departments, mobile dental or health units, health access settings as defined in s. 466.003, and epidemiological surveys for public health. A dental hygienist may also perform dental charting on a volunteer basis at health fairs.

(3) Each person who receives a dental charting pursuant to this section, or the parent or legal guardian of the person, shall receive and acknowledge a written disclosure form before receiving the dental charting procedure that states that the purpose of the dental charting is to collect data for use by a dentist at a prompt subsequent examination. The disclosure form shall also emphasize that diagnosis of caries, soft tissue disease, oral cancer, temporomandibular joint disease (TMJ), and dento-facial malocclusions can only be completed by a dentist in the context of delivering a comprehensive dental examination.

(4) The board shall approve the content of charting and disclosure forms to be used under this section. Both forms shall emphasize the inherent limitations of dental charting and encourage complete examination by a dentist in rendering a professional diagnosis of the patient’s overall oral health needs.

(5) Dental charting performed under this section is not a substitute for a comprehensive dental examination.

(6) Medical clearance by a physician or dentist is required before a periodontal probe may be used on a person who receives a dental charting.

(7) Nothing in this section shall be construed to permit direct reimbursement for dental charting performed under this section by Medicaid, health insurers, health maintenance organizations, prepaid dental plans, or other third-party payors beyond what is otherwise allowable by law.

(8) All referrals made in conjunction with the provision of dental charting services under this section shall be in strict conformance with federal and state patient referral, anti-kickback, and patient brokering laws.

(9) A dental hygienist performing dental charting without supervision shall not be deemed to have created either a patient of record or a medical record.

Note.—Section 21, ch. 2011-95, provides that “except as otherwise specifically provided in this act, this act shall take effect upon becoming a law, and shall not apply retroactively.”

466.024 Delegation of duties; expanded functions. —

(1) A dentist may not delegate irremediable tasks to a dental hygienist or dental assistant, except as provided by law. A dentist may delegate remediable tasks to a dental hygienist or dental assistant when such tasks pose no risk to the patient. A dentist may only delegate remediable tasks so defined by law or rule of the board. The board by rule shall designate which tasks are remediable and delegable, except that the following are by law found to be remediable and delegable:

(a) Taking impressions for study casts but not for the purpose of fabricating any intraoral restorations or orthodontic appliance.

(b) Placing periodontal dressings.

(c) Removing periodontal or surgical dressings.

(d) Removing sutures.

(e) Placing or removing rubber dams.

(f) Placing or removing matrices.

(g) Placing or removing temporary restorations.

(h) Applying cavity liners, varnishes, or bases.

(i) Polishing amalgam restorations.

(j) Polishing clinical crowns of the teeth for the purpose of removing stains but not changing the existing contour of the tooth.

(k) Obtaining bacteriological cytological specimens not involving cutting of the tissue.

This subsection does not limit delegable tasks to those specified herein.

(2) A dental hygienist licensed in this state may perform the following remediable tasks in a health access setting as defined in s. 466.003 without the physical presence, prior examination, or authorization of a dentist:

(a) Perform dental charting as defined in s. 466.0235 as and provided by rule.

(b) Measure and record a patient's blood pressure rate, pulse rate, respiration rate, and oral temperature.

(c) Record a patient’s case history.

(d) Apply topical fluorides, including fluoride varnishes, which are approved by the American Dental Association or the Food and Drug Administration.

(e) Apply dental sealants.

(f) Remove calculus deposits, accretions, and stains from exposed surfaces of the teeth and from tooth surfaces within the gingival sulcus.

1. A dentist licensed under this chapter or a physician licensed under chapter 458 or chapter 459 must give medical clearance before a dental hygienist removes calculus deposits, accretions, and stains from exposed surfaces of the teeth or from tooth surfaces within the gingival sulcus.

2. A dentist shall conduct a dental examination on a patient within 13 months after a dental hygienist removes the patient’s calculus deposits, accretions, and stains from exposed surfaces of the teeth or from tooth surfaces within the gingival sulcus. Additional oral hygiene services may not be performed under this paragraph without a clinical examination by a dentist who is licensed under this chapter.

This subsection does not authorize a dental hygienist to perform root planing or gingival curettage without supervision by a dentist.

(3) For all remediable tasks listed in subsection (2), the following disclaimer must be provided to the patient in writing before any procedure is performed:

(a) The services being offered are not a substitute for a comprehensive dental exam by a dentist.

(b) The diagnosis of caries, soft tissue disease, oral cancer, temporomandibular joint disease (TMJ), and dento-facial malocclusions will be completed only by a dentist in the context of delivering a comprehensive dental exam.

(4) This section does not prevent a program operated by one of the health access settings as defined in s. 466.003 or a nonprofit organization that is exempt from federal income taxation under s. 501(a) of the Internal Revenue Code and described in s. 501(c)(3) of the Internal Revenue Code from billing and obtaining reimbursement for the services described in this section which are provided by a dental hygienist or from making or maintaining any records pursuant to s. 456.057 necessary to obtain reimbursement.

(5) A dental hygienist who performs, without supervision, the remediable tasks listed in subsection (2) shall:

(a) Provide a dental referral in strict
compliance with federal and state patient referral, anti-kickback, and patient brokering laws.

(b) Encourage the establishment of a dental home.

(c) Maintain professional malpractice insurance coverage that has minimum limits of $100,000 per occurrence and $300,000 in the aggregate through the employing health access setting or individual policy.

(6) Notwithstanding subsection (1) or subsection (2), a dentist may delegate the tasks of gingival curettage and root planing to a dental hygienist but not to a dental assistant.

(7) All other remediable tasks shall be performed under the direct, indirect, or general supervision of a dentist, as determined by rule of the board, and after such formal or on-the-job training by the dental hygienist or dental assistant as the board by rule may require. The board by rule may establish a certification process for expanded-duty dental assistants, establishing such training or experience criteria or examinations as it deems necessary and specifying which tasks may be delegable only to such assistants. If the board does establish such a certification process, the department shall implement the application process for such certification and administer any examinations required.

(8) Notwithstanding subsection (1) or subsection (2), a dentist may not delegate to anyone other than another licensed dentist:

(a) Any prescription of drugs or medications requiring the written order or prescription of a licensed dentist or physician.

(b) Any diagnosis for treatment or treatment planning.

(9) Notwithstanding any other provision of law, a dentist is primarily responsible for all procedures delegated by her or him.

(10) A dental assistant may not perform an intraoral procedure except after such formal or on-the-job training as the board by rule shall prescribe.

466.025 Permitting of dental interns serving at state institutions; certification of dentists practicing at government facilities; permitting of nonprofit corporations.

(1) The department shall, upon presentation of satisfactory credentials meeting such requirements as the board may by rule prescribe, issue a permit to a graduate of an approved dental school or college who has not been licensed to practice dentistry in this state to serve as a dental intern in state-maintained and state-operated hospitals or institutes of Florida that may offer such a post or in such hospitals or institutions as shall be approved by the board; provided such hospitals or institutions maintain a recognized staff of one or more licensed dentists. Such intern shall function under the general supervision of the dental staff of such hospital. Her or his work shall be limited to the patients confined to the hospital in which she or he serves, and she or he shall serve without fee or compensation other than that received in salary or other remuneration from such hospital. The board shall have the power to revoke the permit of any such intern at any time upon the recommendation by the executive officer of the dental staff of the hospital or institution in which the intern serves or for any other just cause.

(2) The department shall have the authority to issue temporary certificates to graduates of accredited dental schools to practice in state and county government facilities, working under the general supervision of licensed dentists of this state in the state or county facility, provided such certificates shall be issued only to graduates of schools approved by the board and further subject to cancellation for just cause. A certificate issued under this section is valid only for such time as the dentist remains employed by a state or county government facility.

(3) The department shall have the authority, upon presentation of satisfactory credentials and under such rules as the board may prescribe, to issue a permit to a nonprofit corporation chartered for one or more of the following purposes:

(a) Training and teaching dental assistants in the public schools of the state.

(b) Promoting research and training among duly licensed dentists in the state.

(c) Providing dental care for indigent persons.

Such nonprofit corporations shall function pursuant to rule of the board. The board shall have the power to revoke the permit issued to any such corporations for any violation of the rules. Such permits shall be granted and issued for a period of 1 year and shall be renewed only upon application and approval of the board and upon a showing by the nonprofit corporation that it is complying and will comply with the rules and regulations and all provisions prescribed by the board.

466.026 Prohibitions; penalties.

(1) Each of the following acts constitutes a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084:

(a) Practicing dentistry or dental hygiene unless the person has an appropriate, active license issued by the department pursuant to this chapter.

(b) Using or attempting to use a license issued pursuant to this chapter which license has been suspended or revoked.

(c) Knowingly employing any person to perform duties outside the scope allowed such person under this chapter or the rules of the board.

(d) Giving false or forged evidence to the department or board for the purpose of obtaining a license.

(e) Selling or offering to sell a diploma conferring a degree from a dental college or dental hygiene school or college, or a license issued pursuant to this chapter, or procuring such diploma or license with intent that it shall be used as evidence of that which the document stands for, by a person other than the one upon whom it was conferred or to whom it was granted.

(2) Each of the following acts constitutes a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083:

(a) Using the name or title “dentist,” the letters “D.D.S.” or “D.M.D.”; or any other words, letters, title, or descriptive matter which in any way represents a person as being able to diagnose, treat, prescribe, or operate for any disease, pain, deformity, disability, injury, or physical condition of the teeth or jaws or oral-maxillofacial region unless the person has an active dentist’s license issued by the department pursuant to this chapter.

(b) Using the name “dental hygienist” or the initials “R.D.H.” or otherwise holding herself or himself out as an actively licensed dental hygienist or implying to any patient or consumer that she or he is an actively licensed dental hygienist unless that person has an active dental hygienist’s license issued by the department pursuant to this chapter.

(c) Presenting her as his own license of another.

(d) Knowingly concealing information relative to violations of this chapter.

(e) Performing any services as a dental assistant as defined herein, except in the office of a licensed dentist, unless authorized by this chapter or by rule of the board.

466.027 Sexual misconduct.

The dentist-patient relationship is founded on mutual trust. Sexual misconduct in the practice of dentistry means violation of the dentist-patient relationship through which the dentist uses said relationship to induce or attempt to induce the patient to engage, or to engage or attempt to engage the patient, in sexual activity outside the scope of the practice or the scope of generally accepted examination or treatment of the patient. Sexual misconduct in the practice of dentistry is prohibited.
History.—ss. 1, 3, ch. 79-330; s. 329, ch. 81-259; ss. 2, 3, ch. 81-318; ss. 23, 24, ch. 86-291; s. 60, ch. 91-137; s. 7, ch. 91-156; s. 4, ch. 91-429.

466.0275 Lawful investigations; consent handwriting samples; mental or physical examination. — Every dentist who accepts a license to practice dentistry in this state shall, by so accepting the license or by making and filing a renewal of licensure to practice in this state, be deemed to have given consent, during a lawful investigation of a complaint to the following:

1. To render a handwriting sample to an agent of the department and, further, to have waived any objections to its use as evidence against her or him.

2. Only in those circumstances where there is probable cause to believe that the dentist is guilty of violations of laws governing controlled substances, or any violation of criminal law, the dentist shall be deemed to waive the confidentiality and to execute a release of medical reports pertaining to the mental or physical condition of the dentist herself or himself. The department shall issue an order, based on the need for additional information, to produce such medical reports for the time period relevant to the investigation. As used in this section, “medical reports” means a compilation of medical treatment of the dentist herself or himself which includes symptoms, diagnosis, treatment prescribed, relevant history, and progress. The dentist shall also be deemed to waive any objection to the admissibility of the reports as constituting privileged communications. Such material maintained by the department shall remain confidential and exempt from s. 119.07(1) until probable cause is found and an administrative complaint issued.

History.—s. 20, ch. 88-392; s. 1, ch. 89-296; ss. 60, 64, ch. 91-137; s. 23, ch. 91-140; ss. 7, 8, ch. 91-156; s. 4, ch. 91-429; s. 319, ch. 96-406; s. 1110, ch. 97-103.

466.02751 Establishment of practitioner profile for designation as a controlled substance prescribing practitioner. — The Department of Health shall establish a practitioner profile for dentists licensed under this chapter for a practitioner’s designation as a controlled substance prescribing practitioner as provided in s. 456.44.

History.—s. 29, ch. 2011-141.

466.028 Grounds for disciplinary action; action by the board.—

1. The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2):

   (a) Attempting to obtain, obtaining, or renewing a license under this chapter by bribery, fraudulent misrepresentations, or through an error of the department or the board.

   (b) Having a license to practice dentistry or dental hygiene revoked, suspended, or otherwise acted against, including the denial of licensure, by the licensing authority of another state, territory, or country.

   (c) Being convicted or found guilty of or entering a plea of nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to the practice of dentistry or dental hygiene. A plea of nolo contendere shall create a rebuttable presumption of guilt to the underlying criminal charges.

   (d) Advertising goods or services in a manner which is fraudulent, false, deceptive, or misleading in form or content contrary to s. 466.019 or rules of the board adopted pursuant thereto.

   (e) Advertising, practicing, or attempting to practice under a name other than one’s own.

   (f) Failing to report to the department any person who the licensee knows, or has reason to believe, is clearly in violation of this chapter or of the rules of the department or the board.

   (g) Aiding, assisting, procuring, or advising any unlicensed person to practice dentistry or dental hygiene contrary to this chapter or to a rule of the department or the board.

   (h) Being employed by any corporation, organization, group, or person other than a dentist or a professional corporation or limited liability company composed of dentists to practice dentistry.

   (i) Failing to perform any statutory or legal obligation placed upon a licensee.

   (j) Making or filing a report which the licensee knows to be false, failing to file a report or record required by state or federal law, knowingly impedes or obstructing such filing or inducing another person to do so. Such reports or records shall include only those which are signed in the capacity as a licensee.

   (k) Committing any act which would constitute sexual battery, as defined in chapter 794, upon a patient or intentionally touching the sexual organ of a patient.

   (l) Making deceptive, untrue, or fraudulent representations in or related to the practice of dentistry.

   (m) Failing to keep written dental records and medical history records justifying the course of treatment of the patient including, but not limited to, patient histories, examination results, test results, and X rays, if taken.

   (n) Failing to make available to a patient or client, or to her or his legal representative or to the department if authorized in writing by the patient, copies of documents in the possession or under control of the licensee which relate to the patient or client.

   (o) Performing professional services which have not been duly authorized by the patient or client, or her or his legal representative, except as provided in ss. 766.103 and 768.13.

   (p) Prescribing, procuring, dispensing, administering, mixing, or otherwise preparing a legend drug, including any controlled substance, other than in the course of the professional practice of the dentist. For the purposes of this paragraph, it shall be legally presumed that prescribing, procuring, dispensing, administering, mixing, or otherwise preparing legend drugs, including all controlled substances, in excessive or inappropriate quantities is not in the best interest of the patient and is not in the course of the professional practice of the dentist, without regard to her or his intent.

   (q) Prescribing, procuring, dispensing, or administering any medicinal drug appearing on any schedule set forth in chapter 893, by a dentist to herself or himself, except those prescribed, dispensed, or administered to the dentist by another practitioner authorized to prescribe them.

   (r) Prescribing, procuring, ordering, dispensing, administering, supplying, selling, or giving any drug which is a Schedule II amphetamine or a Schedule II sympathomimetic amine drug or a compound thereof, pursuant to chapter 893, to or for any person except for the clinical investigation of the effects of such drugs or compounds when an investigative protocol therefor is submitted to, and reviewed and approved by, the board before such investigation is begun.

   (s) Being unable to practice her or his profession with reasonable skill and safety to patients by reason of illness or use of alcohol, drugs, narcotics, chemicals, or any other type of material or as a result of any mental or physical condition. In enforcing this paragraph, the department shall have, upon a finding of the State Surgeon General or her or his designee that probable cause exists to believe that the licensee is unable to practice dentistry or dental hygiene because of the reasons stated in this paragraph, the authority to issue an order to compel a licensee to submit to a mental or physical examination by physicians designated by the department. If the licensee refuses to comply with such order, the department’s order directing such examination may be enforced by filing a petition for enforcement in the circuit court where the licensee resides or does business. The licensee against whom the petition is filed shall not be named or identified by initials in any public court records or documents, and the proceedings shall be closed to the public. The department shall be entitled to the summary procedure provided in s. 51.011. A licensee affected under this paragraph shall at reasonable intervals be afforded an opportunity to demonstrate
that she or he can resume the competent practice of her or his profession with reasonable skill and safety to patients.

(t) Fraud, deceit, or misconduct in the practice of dentistry or dental hygiene.

(u) Failure to provide and maintain reasonable sanitary facilities and conditions.

(v) Failure to provide adequate radiation safeguards.

(w) Performing any procedure or prescribing any therapy which, by the prevailing standards of dental practice in the community, would constitute experimentation on human subjects, without first obtaining full, informed, and written consent.

(x) Being guilty of incompetence or negligence by failing to meet the minimum standards of performance in diagnosis and treatment when measured against generally prevailing peer performance, including, but not limited to, the undertaking of diagnosis and treatment for which the dentist is not qualified by training or experience or being guilty of dental malpractice. For purposes of this paragraph, it shall be legally presumed that a dentist is not guilty of incompetence or negligence by declining to treat an individual if, in the dentist’s professional judgment, the dentist or a member of her or his clinical staff is not qualified by training and experience, or the dentist’s treatment facility is not clinically satisfactory or properly equipped to treat the unique characteristics and health status of the dental patient, provided the dentist refers the patient to a qualified dentist or facility for appropriate treatment. As used in this paragraph, “dental malpractice” includes, but is not limited to, three or more claims within the previous 5-year period which resulted in indemnity being paid, or any single indemnity paid in excess of $25,000 in a judgment or settlement, as a result of negligent conduct on the part of the dentist.

(y) Practicing or offering to practice beyond the scope permitted by law or accepting and performing professional responsibilities which the licensee knows or has reason to know that she or he is not competent to perform.

(z) Delegating professional responsibilities to a person who is not qualified by training, experience, or licensure to perform them.

(aa) The violation of a lawful order of the board or department previously entered in a disciplinary hearing; or failure to comply with a lawfully issued subpoena of the board or department.

(bb) Conspiring with another licensee or with any person to commit an act, or committing an act, which would tend to coerce, intimidate, or preclude another licensee from lawfully advertising her or his services.

(cc) Being adjudged mentally incompetent in this or any other state, the discipline for which shall last only so long as the adjudication.

(dd) Prescribing blank prescription or laboratory work order forms.

(ee) Prescribing, ordering, dispensing, administering, supplying, selling, or giving growth hormones, testosterone or its analogs, human chorionic gonadotropin (HCG), or other hormones for the purpose of muscle building or to enhance athletic performance. For the purposes of this subsection, the term “muscle building” does not include the treatment of injured muscle. A prescription written for the drug products listed above may be dispensed by the pharmacist with the presumption that the prescription is for legitimate medical use.

(ff) Operating or causing to be operated a dental office in such a manner as to result in dental treatment that is below minimum acceptable standards of performance for the community. This includes, but is not limited to, the use of substandard materials or equipment, the imposition of time limitations within which dental procedures are to be performed, or the failure to maintain patient records as required by this chapter.

(gg) Administering anesthesia in a manner which violates rules of the board adopted pursuant to s. 466.017.

(hh) Failing to report to the department any licensee under chapter 458 or chapter 459 who the dentist knows has violated the grounds for disciplinary action set out in the law under which that person is licensed and who provides health care services in a facility licensed under chapter 395, or a health maintenance organization certificated under part I of chapter 641, in which the dentist also provides services.

(ii) Failing to report to the board, in writing, within 30 days if action has been taken against one’s license to practice dentistry in another state, territory, or country.

(jj) Advertising specialty services in violation of this chapter.

(kk) Allowing any person other than another dentist or a professional corporation or limited liability company composed of dentists to direct, control, or interfere with a dentist’s clinical judgment; however, this paragraph may not be construed to limit a patient’s right of informed consent. To direct, control, or interfere with a dentist’s clinical judgment may not be interpreted to mean dental services contractually excluded, the application of alternative benefits that may be appropriate given the dentist’s prescribed course of treatment, or the application of contractual provisions and scope of coverage determinations in comparison with a dentist’s prescribed treatment on behalf of a covered person by an insurer, health maintenance organization, or a prepaid limited health service organization.

(ll) Providing deceptive or fraudulent expert witness testimony related to the practice of dentistry.

(mm) Violating any provision of this chapter or chapter 456, or any rules adopted pursuant thereto.

(2) The board may enter an order denying licensure or imposing any of the penalties in s. 456.072(2) against any applicant for licensure or licensee who is found guilty of violating any provision of subsection (1) of this section or who is found guilty of violating any provision of s. 456.072(1).

(3) There shall be a minimum 6-month suspension of the license of a dentist who is convicted of a violation of paragraph (1)(2).

(4) The department shall reissue the license of a disciplined licensee upon certification by the board that the disciplined licensee has complied with all of the terms and conditions set forth in the final order.

(5) In addition, if the department finds that an applicant has a complaint filed against her or him in another jurisdiction, the board may deny the application pending final disposition of the complaint.

(6) Upon the department’s receipt from an insurer or self-insurer of a report of a closed claim against a dentist pursuant to s. 627.912 or upon the receipt from a claimant of a presuit notice against a dentist pursuant to s. 766.106 the department shall review each report and determine whether it potentially involved conduct by a licensee that is subject to disciplinary action, in which case the provisions of s. 456.073 shall apply. However, if it is reported that a dentist has had any indemnity paid in excess of $25,000 in a judgment or settlement or has had three or more claims for dental malpractice within the previous 5-year period which resulted in indemnity being paid, the department shall investigate the occurrence upon which the claims were based and determine if action by the department against the dentist is warranted.

(7) Subject to the authority and conditions established in s. 456.073, the probable cause panel of the board may recommend that the department seek a specified penalty in cases in which probable cause has been found and the panel has directed that an administrative complaint be filed. If the department seeks a penalty other than that recommended by the probable cause panel, the department shall provide the board with a written statement which sets forth the reasons therefor. Nothing in this subsection shall preclude a probable cause panel of any other board under the jurisdiction of the department from making similar recommendations as penalties.
1(8) The purpose of this section is to facilitate uniform discipline for those acts made punishable under this section and, to this end, a reference to this section constitutes a general reference under the doctrine of incorporation by reference.

History. -- ss. 1, 3, ch. 79-330; s. 5, ch. 80-354; s. 330, ch. 81-259; ss. 2, 3, ch. 81-318; s. 2, ch. 83-172; s. 5, ch. 85-6; ss. 18, 23, 24, ch. 86-291; s. 42, ch. 88-1; s. 21, ch. 88-277; s. 21, ch. 88-392; s. 11, ch. 89-66; ss. 29, 49, ch. 90-228; s. 3, ch. 90-341; s. 60, ch. 91-137; s. 7, ch. 91-156; s. 66, ch. 91-220; s. 4, ch. 91-429; s. 46, ch. 92-149; s. 6, ch. 92-178; s. 2, ch. 94-105; s. 61, ch. 95-144; s. 3, ch. 97-67; s. 262, ch. 97-103; s. 110, ch. 97-264; s. 73, ch. 98-166; s. 132, ch. 2000-160; s. 34, ch. 2001-277; s. 31, ch. 2003-416; s. 11, ch. 2005-240; s. 86, ch. 2006-8; s. 7, ch. 2011-233.

1Note. -- Section 16, ch. 2011-233, provides that “[t]his act shall take effect October 1, 2011, and applies to causes of action accruing on or after that date.”

466.0285 Proprietorship by nondentists. – (1) No person other than a dentist licensed pursuant to this chapter, nor any entity other than a professional corporation or limited liability company composed of dentists, may:
(a) Employ a dentist or dental hygienist in the operation of a dental office.
(b) Control the use of any dental equipment or material while such equipment or material is being used for the provision of dental services, whether those services are provided by a dentist, a dental hygienist, or a dental assistant.
(c) Direct, control, or interfere with a dentist’s clinical judgment. To direct, control, or interfere with a dentist's clinical judgment may not be interpreted to mean dental services contractually excluded, the application of alternative benefits that may be appropriate given the dentist’s prescribed course of treatment, or the application of contractual provisions and scope of coverage determinations in comparison with a dentist’s prescribed treatment on behalf of a covered person by an insurer, health maintenance organization, or a prepaid limited health service organization.

Any lease agreement, rental agreement, or other arrangement between a nondentist and a dentist whereby the nondentist provides the dentist with dental equipment or dental materials shall contain a provision whereby the dentist expressly maintains complete care, custody, and control of the equipment or practice.

(2) The purpose of this section is to prevent a nondentist from influencing or otherwise interfering with the exercise of a dentist’s independent professional judgment. In addition to the acts specified in subsection (1), no person who is not a dentist licensed pursuant to this chapter nor any entity that is not a professional corporation or limited liability company composed of dentists shall enter into a relationship with a licensee pursuant to which such unlicensed person or such entity exercises control over the following:
(a) The selection of a course of treatment for a patient, the procedures or materials to be used as part of such course of treatment, and the manner in which such course of treatment is carried out by the licensee;
(b) The patient records of a dentist;
(c) Policies and decisions relating to pricing, credit, refunds, warranties, and advertising; and
(d) Decisions relating to office personnel and hours of practice.

(3) Any person who violates this section commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(4) Any contract or arrangement entered into or undertaken in violation of this section shall be void as contrary to public policy. This section applies to contracts entered into or renewed on or after October 1, 1997.
466.031 “Dental laboratory” defined. — The term “dental laboratory” as used in this chapter:

1. Includes any person, firm, or corporation who constructs or repairs dental prosthetic devices, or who in any way supplies or manufactures artificial substitutes for the natural teeth, or who furnishes, supplies, constructs, or reproduces or repairs any prosthetic denture, bridge, or appliance to be worn in the human mouth or who in any way holds itself out as a dental laboratory.

2. Excludes any dental laboratory technician.

366.032 Registration. — Every person, firm, or corporation operating a dental laboratory in this state shall register biennially with the department on forms to be provided by the department and, at the same time, pay to the department a registration fee not to exceed $300 for which the department shall issue a registration certificate entitled the holder to operate a dental laboratory for a period of 2 years.

1. If the dental laboratory operator to comply with subsection (1), the department shall notify her or him by registered mail, within 1 month after the registration renewal date, return receipt requested, at her or his last known address of such failure and inform her or him of the provisions of subsections (3) and (4).

2. Any dental laboratory operator who has not complied with subsection (1) within 3 months after the registration renewal date shall be required to pay the delinquency fee of $40 in addition to the regular registration fee.

3. The department is authorized to commence and maintain proceedings to enjoin the operator of any dental laboratory that has not complied with this section from operating a dental laboratory in this state until she or he has obtained a registration certificate and paid the required fees.

4. The department shall not require an examination, but shall issue a registration certificate upon completion of the registration form and compliance with any rules promulgated by the department under s. 466.038.

466.033 Registration certificates. — The department shall not require an examination, but shall issue a registration certificate upon completion of the registration form and compliance with any rules promulgated by the department under s. 466.038.

466.034 Change of ownership or address. — When the ownership or address of any dental laboratory operating in this state is changed, the owner thereof shall notify the department within 30 days of such change of ownership or address.

466.035 Advertising. — Dental laboratories shall not solicit or advertise, directly or indirectly, by mail, card, newspaper, pamphlet, radio, television, or otherwise to the general public to construct, reproduce, or repair prosthetic dentures, bridges, plates, or other appliances to be used or worn as substitutes for natural teeth or for the regulation of natural teeth.

466.036 Information; periodic inspections; equipment and supplies. — The department may require from the applicant for a registration certificate to operate a dental laboratory any information necessary to carry out the purpose of this chapter, including proof that the applicant has the equipment and supplies necessary to operate as determined by rule of the department, and shall require periodic inspection of all dental laboratories operating in this state. Such inspections shall include, but not be limited to, inspection of sanitary conditions, equipment, supplies, and facilities on the premises. The department shall specify dental equipment and supplies that are not permitted in a registered dental laboratory.

466.037 Suspension and revocation; administrative fine. — The department may suspend or revoke the certificate of any dental laboratory registered under s. 466.032, for failing to comply with the provisions of this chapter or rules adopted by the department under this chapter. The department may impose an administrative fine.

466.038 Rules. — The department, upon consultation with the Board of Dentistry and industry representatives of the dental laboratory profession, has authority to adopt rules pursuant to ss. 120.53(1) and 120.54 to enforce the provisions of this chapter pertaining to and regulating dental laboratories.

History.—ss. 2, 3, ch. 79-330; ss. 2, 3, ch. 81-318; ss. 23, 24, ch. 86-291; s. 60, ch. 91-137; s. 7, ch. 91-156; s. 4, ch. 91-429.
466.039 Violations. – It shall be unlawful for any person, firm, or corporation to operate as a dental laboratory as defined in this chapter, except those registered as provided in s. 466.032. Violation shall constitute a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083. History.–ss. 2, 3, ch. 79-330; ss. 2, 3, ch. 81-318; ss. 23, 24, ch. 86-291; s. 60, ch. 91-137; s. 7, ch. 91-156; s. 95, ch. 91-224; s. 4, ch. 91-429.

466.041 Hepatitis B carriers. –
(1) Any licensee or applicant for licensure who is a carrier of the hepatitis B virus is required to so notify the board.
(2) The board shall by rule establish procedures for reporting carrier status and shall establish practice requirements which will protect the public from transmission of the hepatitis B virus in a dental practice setting or during dental procedures.
(3) Any report of hepatitis B carrier status filed by a licensee or applicant in compliance with the requirements established by the board shall be confidential and exempt from the provisions of s. 119.07(1), except for the purpose of the investigation or prosecution of alleged violations of this chapter by the department.
History.–ss. 18, 19, ch. 89-374; ss. 60, 65, ch. 91-137; s. 25, ch. 91-140; ss. 7, 9, ch. 91-156; s. 4, ch. 91-429; s. 320, ch. 96-406.

Final Examination Questions
Choose True or False for questions 1 through 10 and mark your answers online at www.onlinedentalCE.com.

1. An expert witness certificate does not authorize a dentist to engage in the practice of dentistry as defined in s. 466.033.
   True  False

2. Failure of an individual licensed pursuant to s. 466.0067 to limit the practice of dentistry to health access settings as defined in s. 466.003 constitutes the unlicensed practice of dentistry.
   True  False

3. Dental hygienists must complete 40 hours of continuing education.
   True  False

4. Every dentist and dental hygienist must display his or her license in plain site, even if he or she practice, in more than one location.
   True  False

5. Advertising that relates to the quality of dental services provided as compared to other available dental services is allowed.
   True  False

6. Dental hygienists are prohibited from applying fluorides under 466.023.
   True  False

7. Dental hygienists may, without supervision, perform dental charting as provided in 466.0235.
   True  False

8. A dental assistant may not perform an intraoral procedure except after such formal or on-the-job training as the board shall prescribe.
   True  False

9. When the ownership or address of any dental laboratory operating in this state is changed, the owner thereof shall notify the department within 60 days of such address of ownership or address.
   True  False

10. Any licensee or applicant for licensure who is a carrier of the hepatitis B virus is required to so notify the board.
    True  False
CHAPTER 4
DENTISTS’ ROLE CARING FOR THE PATIENT WITH CARDIOVASCULAR DISEASE
(6 CE HOURS)

Learning objectives
- Discuss heart disease and dental treatment.
- Define cardiovascular disease.
- Identify the prevalence of cardiovascular disease in the United States and globally.
- Discuss the most common types of cardiovascular disease.
- Identify the non-modifiable and modifiable risk factors for developing cardiovascular disease.
- Identify the common signs and symptoms of cardiovascular disease.
- Discuss how to screen for cardiovascular disease.
- Discuss the ways to prevent cardiovascular disease.
- Discuss the treatment modalities of the various cardiovascular diseases.

Introduction
Since 1989, a number of cross-sectional, case-control, and longitudinal studies have reported that the clinical signs of periodontitis may be associated with cardiovascular events; other studies have reported no significant association. Several basic science and animal studies also have reported systemic effects of periodontal infection. Cardiovascular disease is the top cause of death in the United States for men and women and carries with it considerable morbidity. In addition, total costs for cardiovascular disease in 2003 were estimated to reach almost $352 billion. Because periodontal and cardiovascular diseases are highly prevalent in the United States population, periodontal disease also becomes a public health problem worthy of attention, even though the strength of the association may be only moderate.

As a result of this link with cardiovascular disease, interest in periodontal disease prevention and treatment is likely to intensify in the private and public health sectors and in the general public. One consequence of this link is that dentists and physicians may need to focus more on primary prevention of infection by periodontal pathogens, and in patients with disease, they may need to focus more on secondary prevention. End-points for secondary prevention will involve eliminating periodontal pathogens and reducing inflammation, while pocket reduction, tooth retention and regenerative procedures may become less important. Controlling inflammation and infection may create an increased need for anti-inflammatory pharmacological strategies for high-risk patients.

Other actions that may be needed are:
- Educating health professionals and the public about the relationship between periodontal and cardiovascular diseases.
- Restructuring benefits for public programs to provide infection control services to Medicaid and Medicare recipients.
- Advocating for medical insurance coverage of periodontal services.
- Establishing a surveillance program to monitor periodontal disease trends in the population and identify high-risk groups to target with intervention programs.

In addition, coordinating efforts with groups that are active in reducing other cardiovascular disease risk factors, such as smoking, diabetes and obesity, may be a useful strategy.

Heart disease and dental treatment
Patients with certain heart conditions have a higher risk of endocarditis, an infection of the heart that can be life threatening. It occurs when bacteria in the bloodstream attach to damaged heart valves or other damaged heart tissue.

People with certain heart conditions may need antibiotics before they have dental treatment that is likely to cause bleeding. Although the American Heart Association in 2007 updated its guidelines on the use of antibiotics before dental treatments, advising antibiotics for fewer people than previously, pre-treatment with antibiotics is still recommended for people who have had endocarditis in the past. It is also recommended for people with artificial heart valves and people who have heart transplants and later developed heart valve problems.

Pre-treatment with antibiotics also is recommended for people with certain heart conditions that were present at birth:
- Cyanotic heart disease that has not been repaired or was repaired incompletely. This includes people with shunts and conduits.
- A heart defect that was completely repaired with a prosthetic material or device. In this case, antibiotics are advised only for the first six months after the procedure.
- Any repaired heart defect that still has some defect at or next to the site of a prosthetic patch or device.

Antibiotics before dental work no longer are advised for people with:
- Acquired heart valve dysfunction (for example, rheumatic heart disease).
- Mitral valve prolapse.
- Bicuspid valve disease.
- Calcified aortic stenosis.
- Congenital heart conditions, such as ventricular septal defect, atrial septal defect and hypertrophic cardiomyopathy.

The American Heart Association guidelines recommend pre-treatment antibiotics for dental procedures that involve an incision or manipulation of the gums or the tissues around a tooth root.

Antibiotics are not required for the following:
- Routine anesthetic injections through noninfected tissue.
- X-rays.
- Placement of dentures.
- Placement or adjustment of removable orthodontic appliances.
- Placement of the bracket part of braces (not bands).
- The natural loss of baby teeth in children.
- Bleeding from trauma to the lips or mouth.

Myocardial infarction (heart attack)

Oral effects
A heart attack can sometimes feel like pain that starts in the chest and spreads to the lower jaw.

Dental considerations
Most patients should wait at least six months to have dental treatments. The dentist and physician should discuss a patient’s medical condition before dental treatment. And before dental work begins, a dentist must question the patient to determine which drugs and their dosages a patient is taking. Particularly important are anticoagulants, which are frequently ordered for heart patients.

High blood pressure (hypertension)

Oral effects
Some anti-hypertensive medications cause dry mouth or an altered sense of taste (dysgeusia). Others may make a person more likely to faint when they are raised from the relatively flat position in the dentist’s chair to a sitting or standing position.

Placement or adjustment of removable orthodontic appliances.
Coronary artery bypass graft (CABG)

Oral effects
There are no oral effects from this procedure.

Dental considerations
Unless they need dental treatment within a few weeks after the surgery, people who have had coronary artery bypass grafts generally do not require antibiotics before a dental procedure. However, for the first couple of weeks after surgery, they may feel severe pain when reclining in the dental chair. Help such patients find a comfortable position in the chair.

Angina
Oral effects
Angina pain that starts in the chest can spread to the lower jaw.

As with other conditions, calcium channel blockers can cause gingival hyperplasia.

Dental considerations
People with stable angina can be treated like any other patient, with a few differences. There must be oxygen and nitroglycerin available in the office, and the dentist should talk to a patient’s physician before an appointment.

People with unstable angina should not receive non-emergency dental care; for emergency dental care, the patient’s heart should be continuously monitored.

Stress can trigger angina attacks. Talk to patients about ways to reduce stress during an appointment, and instruct them to bring their medicines with them and let you know immediately if they feel chest pain.

High cholesterol (hyperlipidemia)
Oral effects
There are no oral effects from high cholesterol.

Dental considerations
Some drugs used to treat high cholesterol can make patients feel faint when they get up from the dental chair. This condition puts people at risk of a heart attack or stroke. Make sure patients know they should tell their dental professional about conditions like this. Some drugs taken for high cholesterol can cause problems when taken with certain drugs that a dentist may prescribe.

Stroke
Oral effects
Stroke can cause many long-term effects. These include:

- Paralysis
- Difficulty speaking and swallowing
- Increased or decreased sensitivity to pain
- Blurred vision
- Poor memory
- Personality changes (anxiety, depression)

In some people, a stroke paralyzes one side of the body. If this happens, a family member or caregiver may need to help a patient with daily dental care or use specialized toothbrushes and floss holders. Dentures may need to be remade or adjusted.

If a patient’s face or tongue is paralyzed, he or she may not be able to rinse the mouth or realize there is food left in the mouth. The dentist might suggest use of a fluoride gel or saliva substitute.

Dental considerations
Some stroke survivors take blood thinners. A dentist should ascertain whether that is the case before undertaking any major dental work. Usually, routine dental treatment is safe. Ask patients to bring a copy of their most recent blood tests to your office at every visit.

Congestive heart failure
Oral effects
Many medicines used to treat congestive heart failure (CHF) cause xerostomia.

Dental considerations
For patients being treated for CHF with no complications, side effects or physical limitations, there are usually no special changes needed for dental treatment. However, depending on the medications taken and the overall health of the patient, a dentist may wish to make some changes in treatment.

People with more severe heart failure should not lie down in the dental chair too far because the fluid build-up in their lungs may affect their breathing. They should also take it slow when changing position (standing to sitting, or lying down to sitting). These changes can make them dizzy and light-headed.

A dentist should confirm how serious a patient’s CHF is by talking with the patient’s physician or cardiologist. Some people with CHF should have dental treatment in a hospital setting. This includes people whose disease is considered class III or IV under the New York Heart Association functional classification system.

Pacemaker implantation
Oral effects
There are no specific oral effects caused by having a pacemaker.

Dental considerations
Certain electromagnetic devices that a dentist or dental hygienist may use could potentially interact and cause a problem with a patient’s pacemaker. Although the chances of that happening are small, examples include machines used for ultrasound or electrosurgery. A dentist should be able to find out about interactions from the patient’s physician or from the pacemaker manufacturer. Ask patients to talk with their physician about possible interactions before visiting the dental office.

Patients should avoid elective dental care within the first few weeks after receiving a pacemaker. If they must receive dental care then, the dentist and physician should decide whether pre-treatment antibiotics are needed.

The relationship between periodontal disease and cardiovascular disease
Periodontal disease has been demonstrated to have a relationship to cardiovascular disease, with an increased prevalence of coronary artery disease in patients with serious gum disease.

Several studies have indicated a very strong link between the presence of these two diseases in a patient.

It should be pointed out that although various studies suggest that there is a strong correlation among people with a history of periodontal disease toward a higher risk for cardiovascular disease, there is not any clear evidence of a causative role between these two disease conditions. However, because of the high correlation and relationship between the two, known cardiovascular patients should optimize their periodontal care.

Inflammation is believed to be a major factor related to both periodontitis, the bacterially induced chronic inflammatory disease, and atherosclerotic cardiovascular disease. Moderate to severe forms of periodontitis are associated with increased systemic inflammation, which can be present from the very early stages of atherosclerosis and can continue to play a role in subsequent cardiovascular complications. Consequently, the incidence of cardiovascular events, such as myocardial infarction, is increased in the presence of chronic inflammatory conditions, including periodontal disease.

Bacterial infection also may be another direct link between periodontal and cardiovascular diseases, because the same species of gram-negative anaerobic bacteria that are found in periodontally diseased pockets around the teeth are the same as those found in atherosclerotic plaques in arteries.

Right now, scientists suspect that the bacteria that cause periodontal disease may be able to release toxins into or travel through the bloodstream and help to form fatty plaques in the arteries. These plaque deposits can block blood flow and lead to serious complications, such as blood clots.

The progression of periodontal disease depends on a variety things, including environmental and genetic factors. Additional factors that have an influence on these two diseases include smoking, diabetes, obesity, dyslipidemia, hypertension, major depression, physical inactivity, older age, male gender and a family history of the disease.

Introduction to cardiovascular disease
Cardiovascular disease is a broad term that is used interchangeably to describe “heart disease.” Cardiovascular diseases encompass a vast array of heart conditions that may overlap, such as coronary artery disease (CAD), hypertension (HTN), acute myocardial infarction (AMI or MI), congestive heart failure (CHF) and cerebrovascular accident (CVA). According to the World Health Organization (WHO), Centers for Disease Control and Prevention (CDC) and the American Heart Association (AHA) (2009), cardiovascular disease is the leading cause of death worldwide and a major cause of disability. It has actually been the leading cause of death since 1900 in the United States.

In 2003, the WHO reported that cardiovascular disease made up 16.7 million, or 29.2 percent
of all global deaths. Of these deaths, 7.6 million were due to heart attacks and 5.7 million were due to CVA. If current trends are allowed to continue, by 2015, an estimated 20 million people will die from cardiovascular disease (mainly from heart attacks and strokes). Cardiovascular disease kills more people than the next-most common causes of death combined, including cancer, chronic lower respiratory disease, accidents, diabetes, influenza and pneumonia. According to the heart association, in 2006, more than 80,000,000 people in the U.S. had one or more forms of cardiovascular disease. The most common forms of cardiovascular disease include hypertension, 73,600,000; coronary heart disease,16,800,000; acute myocardial infarction, 7,900,000; angina pectoris (chest pain or discomfort caused by reduced blood supply to the heart muscle), 9,800,000; cerebrovascular accident, 6,500,000; and congestive heart failure, 5,700,000.

In 2009, the CDC estimated that 785,000 Americans would have a new coronary heart attack, and about 470,000 would have a recurrent attack in 2010 alone. To put it into perspective, approximately every 25 seconds, an individual would have a coronary event; one person would die every minute.

Although cardiovascular disease is the leading cause of death, most times it is preventable by avoiding unhealthy habits, such as a high-fat diet, physical inactivity and smoking. Every day, dentists are responsible for patients and their families who are living with some form of cardiovascular disease. However, dentists are not immune either, and the daily stressful grind of working as dentists, hygienists or dental assistants could pose the risk of developing cardiovascular disease – and many also are at risk from bad habits such as smoking and a high-fat diet. This continuing education course is designed to help professionals reduce the overall risk of cardiovascular disease for themselves as well as for their patients.

Pathophysiology of cardiovascular diseases
The heart is a hollow, muscular organ that is responsible for pumping an adequate supply of blood throughout the body continuously to vital organs for survival. To reduce the risk of developing cardiovascular disease, it is important that people nurture their bodies with healthy, nutritious foods and exercise and avoid harmful substances.

Cardiovascular diseases are mainly caused by a buildup of plaque (atherosclerosis) inside the coronary arteries. Over time, the plaque diminishes blood flow and oxygen to the heart, brain and other vital organs secondary to the inflammatory process. The extensive inflammation further exacerbates the ability of oxygenated blood to flow freely in the bloodstream, leading to a further buildup of plaque and an accumulation of blood clots. Blood clots accumulate when a blood vessel is stenosed secondary to the limited blood flow; therefore, it backs up into the previous chamber behind the valve. The pressure in the previous chamber will increase due to the resistance in the stenosed blood vessel. Consequently, the heart is forced to work harder, resulting in hypertrophy (enlargement), especially left ventricular hypertrophy, and an increase in the workload, which in turn raises the heart’s oxygen demands.

Once the blood vessels are blocked by plaque or clots, they cannot supply blood to the heart and brain, which then become damaged and weakened, potentially leading to a myocardial infarction, congestive heart failure or arrhythmias. Although there are several types of plaque that may result in serious coronary events, retrospective analyses have demonstrated that 70 percent of all fatal acute myocardial infarctions and sudden coronary deaths are attributable to plaque rupture or erosion.

Although atherosclerosis is the predominant predictor of cardiovascular disease, there are other potential pathological rationales for each of the major specific cardiac diagnosis and significant overlapping in each of the most common heart conditions.

Acute myocardial infarction (AMI) is caused by reduced blood flow through one or more of the coronary arteries, secondary to coronary heart disease or cardiomyopathy (disease of the heart muscle fibers). Myocardial infarction includes ST-segment elevation MI (STEMI), non-ST-segment elevation MI (NSTEMI), and unstable angina as a group of clinical diseases called acute coronary syndrome (ACS). Rupture or erosion of the plaque initiates all ACS. Three stages occur when there is occlusion of a vessel: ischemia, injury and infarct.

- **Ischemia** is the first stage, and it indicates that blood flow and oxygen demands are out of balance. The electrocardiogram (ECG) will reveal ST-segment depression or T wave changes.
- **Injury** is the second stage, and it indicates the ischemia is prolonged enough to damage that area of the heart. The ECG will reveal ST-segment elevation in at least two different leads.
- **Infarct** is the third stage, and it indicates actual death of the myocardial cells and is irreversible. In the early stages of an MI, the ECG will reveal hyperacute (very tall) or narrow T-waves. Within hours, the T-waves become inverted and ST-segment elevation occurs in the leads facing the area of the damage. The last stage is the development of a pathologic Q wave. Q waves are permanent evidence of myocardial necrosis.

Coronary artery disease is the primary cause of acute myocardial infarction secondary to atherosclerosis.

Congestive heart failure, also known as “heart or pump failure,” is a syndrome that occurs when the heart is unable to adequately pump to meet the body’s metabolic needs. The most common cause of CHF is coronary artery disease, but it also can be caused by hypertension, valvular heart disease and congenital heart defects. Heart failure is classified as right- or left-sided ventricular failure. Left-sided heart failure is broken down into two subcategories, systolic and diastolic heart failure.

Systolic heart failure results from the heart’s inability to contract forcefully during systole to eject an adequate amount of blood into circulation. In systolic heart failure, the following things occur [30]:

- Preload increases (degree of myocardial stretch at the end of diastole and just before contraction).
- Decreased contractility of the heart muscle that affects the stroke volume (SV) and cardiac output (CO). Stroke volume is the amount of blood ejected by the left ventricle during each systole. Cardiac output is the volume of blood in liters ejected by the heart each minute. The normal cardiac output in adults varies from four to seven liters/minute.
- All of these inadequate functions lead to an increased peripheral resistance (hypertension). The ejection fraction (EF) is the percentage of blood ejected from the heart during systole; normal is 50 to 70 percent.

Diastolic heart failure results when the left ventricle is unable to relax adequately during diastole (rest). Over time, the ventricle will stiffen because of its inability to relax completely, leading to insufficient blood filling, resulting in a decreased cardiac output. The ejection fraction may be within the normal range. Diastolic heart failure occurs in 20 to 40 percent of all heart failure cases, especially in older adults and women after an MI.

- Right-sided heart failure occurs over time caused by left ventricular failure, with myocardial infarction in the right ventricle or pulmonary hypertension occurring. In right-sided heart failure, the right ventricle is unable to empty completely, leading to increased volume and pressure in the systemic veins.

Hypertension: Over time, uncontrolled or prolonged elevation of the blood pressure can lead to a variety of changes in the myocardium (middle layer composed of striated muscle fibers), coronary vasculature and conduction system of the heart. The most significant changes can lead to the development of left ventricular hypertrophy (LVH); coronary artery disease; various conduction system diseases and systolic and diastolic dysfunction of the myocardium, which manifest clinically as angina or myocardial infarction; cardiac arrhythmias (especially atrial fibrillation, premature ventricular contractions and ventricular tachycardia); and congestive heart failure.
Hypertension is an established risk factor for the development of coronary artery disease, almost doubling the risk. It also increases the risk of sudden cardiac death.

- Fifteen to 20 percent of people will develop left ventricular hypertrophy, especially if the individual is obese.
- Left ventricular hypertrophy plays a significant role in cardiovascular disease. It occurs secondary to increased pressure demands on the left ventricle to become enlarged and thickened. As the left ventricle enlarges and becomes thick, it is unable to effectively pump out an adequate amount of oxygenated blood into the body. Therefore, blood backs up into the left atrium and then into the lungs, causing pulmonary congestion, dyspnea and activity intolerance.

**Assessing risk factors for the cardiac patient**

It is imperative that dentists obtain a thorough history of their patients to assess risk factors and symptoms suggesting cardiovascular disease. Because the majority of cardiovascular disease is due to atherosclerosis, by the time it is discovered, it may be too late. Therefore, dentists need to understand the potential risk factors when assessing their patient for cardiovascular disease. Non-modifiable risks are risks that an individual does not control or have the ability to change:

- **Age.** As we age, our risks of developing cardiovascular disease, especially coronary artery disease and vascular disease, increases. More than 83 percent of people who die of coronary heart disease are 65 or older. In 2005, nearly 151,000 Americans under the age of 65 died due to cardiovascular disease. However, all individuals over the age of 40 are at a higher risk of developing coronary artery disease.
- **Gender.** Although heart disease is sometimes thought of as a “man’s disease,” it is the leading cause of death for both women and men in the U.S., and women account for 51 percent of the total heart disease deaths. Heart disease is often perceived as an “older woman’s disease,” linked to the loss of estrogen after menopause and because it is the leading cause of death among women aged 65 and older. However, heart disease is the third leading cause of death among women aged 25–44 years and the second leading cause of death among women aged 45–64. Unfortunately, women who suffer an acute myocardial infarction (MI), typically tend to die more frequently than men.
- **Ethnicity.** According to the CDC in 2009, cardiovascular disease death rates per 100,000 population for the five largest U.S. racial/ethnic groups are as follows: blacks, 300; whites, 228; Hispanics, 173; American Indian/Alaskan natives, 160; and Asian and Pacific Islanders, 128.
  - Blacks suffer from hypertension more than Caucasians and have a higher risk of developing cardiovascular disease, especially coronary artery disease.
  - In 2002, age-adjusted death rates for heart disease were higher among black women (169.7 per 100,000) than among white women (151.2 per 100,000).
  - White women with abdominal obesity (greater waist circumference than hip circumference) are more likely to develop cardiovascular disease than white women with distributed fat in the buttocks, hips and thighs (greater hip circumference than waist circumference).
  - Heart disease risk is also higher among Mexican Americans, American Indians, native Hawaiians and some Asian Americans, all linked to higher rates of coinciding obesity and diabetes.
  - According to the CDC (2008), heart disease is the leading cause of death and stroke is the sixth among American Indians and Alaska natives. The heart disease death rate was 20 percent greater and the stroke death rate 14 percent greater among American Indians and Alaska natives (1996–1998) than among all U.S. races (1997) after adjusting for misreporting of American Indian and Alaska native races on state death certificates. American Indians and Alaska natives die from heart diseases at younger ages than other racial and ethnic groups in the U.S. Thirty-six percent of those who die of heart disease die before age 65. Diabetes is an extremely important risk factor for cardiovascular disease among American Indians.
  - **Genetics.** Any family history for coronary artery disease in a first-degree relative (parent, sibling or child) is the major risk factor for developing cardiovascular disease. It is a higher risk than hypertension, obesity, diabetes or sudden cardiac death. In addition, the younger the age of onset in a first-degree relative, the greater the risk for developing coronary artery disease.

**Modifiable risks** are personal habits and choices that an individual has the ability to modify or change:

- **Cigarette smoking** is a major risk factor for cardiovascular disease, especially coronary artery disease and peripheral vascular disease (PVD). Individuals who choose to smoke increase their risk of developing cardiovascular disease two to four times higher than that of a nonsmoker. Cigarette smoking is also a powerful independent risk factor for sudden cardiac death in patients with coronary heart disease; smokers have about twice the risk of nonsmokers. Cigarette smoking also acts with other risk factors to greatly increase the risk for coronary heart disease.
  - Other forms of smoking, such as cigars, pipes and secondhand smoke, also add to the risk of developing coronary artery disease and cerebrovascular accidents, although the risk is not as high as with cigarette smoking.
  - Dentists should inquire about patients’ smoking history in terms of the pack per years, which is the number of packs per day multiplied by the number of years smoked.
- **Physical inactivity.** A sedentary, inactive lifestyle is a significant risk factor for the development of cardiovascular disease. Regular, moderate-to-vigorous physical activity helps prevent heart and blood vessel disease by controlling the blood pressure, blood lipids and clotting factors.
- **Being obese or overweight.** Obesity leads to diabetes, hypertension and high cholesterol (hypercholesteremia/hyperlipidemia). According to the WHO, in 2009, there were more than 1 billion overweight adults; at least 300 million of them were considered obese. In addition, the WHO estimated there were 155 million overweight or obese children worldwide, and 22 million under the age of 5 were overweight. In 2000, 22 percent of American preschool-age children were overweight, and 10 percent were considered obese. In essence, one in four preschool age children was overweight or obese. Obesity and overweight conditions are assessed by using body mass index (BMI), defined as the weight in kilograms divided by the square of the height in meters (kg/m²).
  - A BMI over 25 kg/m² is defined as overweight, and a BMI of over 30 kg/m² as obese. These markers provide common benchmarks for assessment, but the risks of disease in all populations can increase progressively from lower BMI levels.
  - Overweight and obesity conditions lead to adverse metabolic effects in numerous ways, but especially on a person’s cardiovascular system, resulting in hypertension, hyperlipidemia and insulin resistance.
- **Psychological factors,** such as stress, may contribute to the risk of developing cardiovascular disease. Research has demonstrated that people who are highly competitive, concerned about meeting deadlines and often angry are at a higher risk of developing cardiovascular disease. In addition, researchers have noted a significant correlation between coronary heart disease risk and stress in a person’s life, their health behaviors and socioeconomic status. These factors may affect established risk factors. For example, people under stress may overeat, start smoking or smoke more than they otherwise would.
  - Dentists can assess this risk by asking the patient, “Have you ever experienced road rage?” or “How do you respond when you have to wait for an appointment?”
- **Alcohol use** can raise the blood pressure, leading to heart failure and stroke. It may also affect the cardiovascular system by contributing to high triglycerides, obesity and irregular heartbeats.
  - The risk of heart disease in people who drink moderate amounts of alcohol (an
average of one drink for women or two drinks for men per day) is lower than in nondrinkers. One drink is defined as 1½ ounces of 80-proof spirits (such as bourbon, Scotch, vodka and gin), 1 ounce of 100-proof spirits, 4 ounces of wine or 12 ounces of beer.

**Other potential risk factors.** It is important to assess the patient for other chronic health problems that may exacerbate the cardiac symptoms and increase the risk of cardiovascular disease. Dentists should inquire about other co-morbidities by obtaining information regarding the onset, duration, frequency, location and associating symptoms.

- **Cerebrovascular accident (CVA)** is a rapid onset of neurological deficits due to a decreased flow of oxygenated blood to the brain. CVA coincides with cardiovascular disease because most of the modifiable risk factors for CVA include hypertension, cardiac disease, hyperlipidemia and smoking. Therefore, the prevention strategies discussed in this course are applicable for the prevention of CVA because of the significant overlapping modifiable risk factors.

- **Diabetes mellitus** seriously increases an individual’s risk of developing cardiovascular disease. Even if the overall glucose (blood sugar) levels are under control, diabetes increases the risk of heart disease and stroke, but the risks are even greater if blood sugar is not well controlled. According to the American Diabetes Association (ADA), most of the cardiovascular complications related to diabetes have to do with the way the heart pumps blood through the body. Diabetes can change the chemical makeup of some of the substances found in the blood, and this can cause blood vessels to narrow or to clog up completely, which is known as atherosclerosis. Because of the compounding effects of diabetes and cardiovascular disease, it is estimated that about 65 percent of people living with diabetes will die from some form of heart or blood vessel disease.

- **Hyperlipidemia/dyslipidemia** is an elevation of lipids (fats) in the bloodstream measured by assessing the cholesterol, triglycerides, LDL, HDL cholesterol esters (compounds), phospholipids and triglycerides. A high lipid profile is typically known as a modifiable risk factor because it can be the result of choosing a lifestyle that consists of a high fatty diet and possibly drinking alcohol. However, hyperlipidemia may be due to genetic factors beyond an individual’s choice.

  - Over the past few decades, numerous research studies have demonstrated that elevated plasma cholesterol levels, especially low-density lipoprotein cholesterol (LDL-C), has an enormous impact on developing cardiovascular disease.

- **Hypertension (HTN)** increases the heart’s workload, causing the heart to thicken and become stiffer. It increases the risk of coronary artery disease, cerebrovascular accident, heart attack/myocardial infarction, kidney failure and congestive heart failure. The risk of cardiovascular disease is exacerbated if hypertension coincides with obesity, smoking, high blood cholesterol levels or diabetes.

- **Metabolic syndrome (also known as insulin resistance)** is a syndrome that occurs prior to the development of diabetes. The majority of individuals living with metabolic syndrome are unaware of it because they are usually asymptomatic. However, people with a severe form of insulin resistance (metabolic X) may have a condition called acanthosis nigricans, in which they will notice dark patches of skin, usually on the back of the neck, elbows, knees, knuckles and the armpits, an early sign of pre-diabetes. According to the American Heart Association and the National Heart, Lung and Blood Institute, metabolic syndrome is diagnosed when a minimum of three of the following criteria are met:
  - **Elevated waist circumference (abdominal obesity).** Increased abdominal adiposity (waist greater than 40 inches in men and greater than 35 inches for women). The excess fat in the intra-abdominal area is a huge component of the metabolic syndrome. The majority of experts concur that the combination of obesity, obesity-related cytokines called adipokines, excess nutrients and inflammatory cytokines are the main contributors to beta cell death and insulin resistance in type 2 diabetes. Regardless of which event occurred, the mechanisms that are responsible for insulin receptor binding or post receptor can be reversed by weight loss.
  - **Elevated triglycerides (TG) greater than 150 mg/dl.**
  - **Reduced HDL cholesterol** (less than 40 mg/dl in men and less than 50 mg/dl for women).
  - **Fasting blood glucose** (hyperglycemia) greater than 100 mg/dl.
  - **Increased blood pressures** (130/85 mm Hg or greater).

**Signs and symptoms of cardiovascular disease**

Over time, many experienced health care professionals can hypothesize a potential diagnosis based upon their gut feeling and the symptoms of the patient. However, the best way to truly assess and diagnose the nature of the symptoms is by collecting a thorough history and performing an explicit assessment, because the severity of these symptoms varies. The symptoms may get more severe as the buildup of plaque continues to narrow the coronary arteries. In other instances, some people do not demonstrate any signs and symptoms of an inevitable myocardial infarction, congestive heart failure or an arrhythmia, which is called silent coronary artery disease.

- **Chest pain** is one of the most common complaints in adults and may indicate potential cardiovascular disease [43]. Although cardiovascular disease is not always the primary cause of the chest pain, health care professionals, including dentists, need to be able to assess the symptomology and nature of the chest pain. Chest pain may be associated with cardiovascular problems, pulmonary, gastrointestinal (GI), musculoskeletal, neurologic, psychogenic or idiopathic causes [24]. Therefore, each of the most common cardiovascular natures of chest pain will be explored and elaborated upon in detail to help differentiate the nature of the pain [43]:
  - **Angina pectoris** chest pain or discomfort occurs when the heart muscle is not getting enough blood [4]. The most common symptom of coronary artery disease is angina, although in some individuals, the first sign of CAD is a myocardial infarction. The angina pain is paroxysmal pain in the substernal area that may radiate to the precordium, upper extremities, neck or jaw. Angina pain typically lasts 30 seconds to a few minutes, and patients describe it as dull, pressing, squeezing or aching pain. Angina pain may be precipitated by exertion, emotional stress, sexual activity, exposure to cold and occasionally by eating. However, unstable angina may occur while at rest. Angina pain is alleviated by rest within 10 minutes and/or administration of a nitroglycerin (NTG) sublingual (S/L) tablet within two to four minutes. Typically, angina symptoms last less than 20 minutes (versus greater than 20 minutes with an MI) [13].
  - **Myocardial infarction** chest pain may be sudden and intense, similar to the “movie heart attack,” where no one doubts what is happening. However, the majority of myocardial infarctions start slowly, with mild pain or discomfort. Often people affected are not significantly sure what is going on. Although they may be aware of the symptoms of an MI, they typically will assume other irrational things are causing their symptoms. Other common symptoms associated with MI chest pain include any of the following:
  - **Chest discomfort.** Most heart attacks involve discomfort in the center of the chest that lasts more than a few minutes, or that goes away and comes back. It can feel like uncomfortable pressure, squeezing, fullness or pain.
  - **Discomfort in other areas of the upper body.** Symptoms can include pain or
discomfort in one or both arms, the back, neck, jaw or stomach.

- Shortness of breath with or without chest discomfort.
- Other signs may include breaking out in a cold sweat, nausea or light-headedness.
  
  - It is important to understand that women enduring an MI may present with subtle or other symptoms. As with men, women’s most common heart attack symptom is chest pain or discomfort. However, women are somewhat more likely than men to experience some of the other common symptoms, particularly shortness of breath, nausea/vomiting and back or jaw pain.

- Mitral valve prolapse (MVP) chest pain typically occurs during rest and may last for a few minutes to several hours. Patients typically describe MVP as “sticking,” and it may be associated with tachyarrhythmias and light-headedness.

- Dyspnea (shortness of breath) is another common symptom of coronary artery disease and congestive heart failure. Shortness of breath occurs when coronary heart failure is caused by the heart’s inability to pump enough blood throughout the body. Because the heart has two ventricles, right and left, it is possible for one side (typically the left) to fail by itself for a short period. Initially, the left ventricle will fail because of its inability to pump an adequate amount of blood to the rest of the body, causing fluid to back up into the lungs. The most common symptoms of left-sided congestive heart failure include, but are not limited to:
  
  - Shortness of breath and fatigue. As the left ventricle enlarges because of its inability to pump efficiently and blood backs up into the left atrium, other symptoms will be noted caused by right-sided heart failure, including exacerbated fatigue, swelling in the ankles, feet, legs, abdomen and neck.

- Palpitations are typically reported by patients who are at risk of developing cardiovascular disease. Palpitations are defined by the patient as the heart beating or skipping beats at times. It is important to distinguish the timing of the palpitations. For instance, if it occurs after exercise, it is probably a normal physiological response caused by the increased release of catecholamines. However, more serious pathological causes may be contemplated if the patient reports:
  
  - The heart “stopped momentarily,” which may imply an atrial or ventricular ectopic beat.
  - The heartbeat skips significantly, which may imply a potential arrhythmia, such as atrial fibrillation.

The dentist or medical professional should also inquire about other potential symptoms that coincide with the palpitations, such as anxiety, weakness, dizziness and light-headedness; fainting or nearly fainting; sweating; dyspnea; or chest pain.

A dentist should never assume the heart of a patient without symptoms is functioning at the optimal level because some may be asymptomatic initially. The majority of patients with coronary artery disease may be unaware of the existence for years because of the lack of symptoms, especially the elderly because the body compensates for the atherosclerosis by developing collateral circulation. Research has demonstrated that some patients with coronary artery disease may not develop any symptoms until 75 percent of the coronary artery is narrowed (stenosed).

Once the coronary artery has developed enough stenosis, the primary initial symptom is angina, which should lead the health care professional to immediately suspect coronary artery disease and/or myocardial infarction. Always inquire about other symptoms, such as radiation of chest pain, especially the left arm and jaw; nausea; dyspnea; and light-headedness. Early screening and prevention measures are imperative for early detection.

### Screening for and diagnosing cardiovascular disease

Ideally, all health care professionals, including dentists, should screen patients at risk for cardiovascular disease to try to prevent the development and damage to the patient’s heart muscle and left ventricle. Because of the prevalence of cardiovascular disease globally in all cultures, ages, races and socioeconomic statuses, there are stringent guidelines set aside by professional organizations to screen for cardiovascular disease:

- **Blood pressure** recommendations are guided by the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure. The JNC VII recommends accurately assessing the baseline blood pressure (BP) by making sure that the patient is sitting for a minimum of five minutes in a chair (rather than on an exam table), with feet on the floor and arms supported at heart level, and to be sure to use an appropriate-sized cuff. At least two measurements should be made on two different occasions before confirming a hypertensive diagnosis.

  - Normal blood pressure is less than 120/80.
  - Prehypertension is 120-139 (systolic) or 80-89 (diastolic).
  - Stage 1 hypertension is 140-159 (systolic) or 90-99 (diastolic).
  - Stage 2 hypertension is greater than 160 (systolic) or 100 (diastolic).

- **For persons older than 50, systolic blood pressure greater than 140 mmHg is a much more important cardiovascular disease risk factor than diastolic blood pressure.**

- The risk of cardiovascular disease beginning at 115/75 mmHg doubles with each increment of 20/10 mmHg; individuals who are normotensive at age 55 have a 90 percent lifetime risk for developing hypertension.

- **Individuals with a systolic blood pressure of 120–139 mmHg or a diastolic blood pressure of 80–89 mmHg should be considered as prehypertensive and require health-promoting lifestyle modifications to prevent cardiovascular disease.**

### Cholesterol and lipid profile: The United States Preventive Services Task Force (USPSTF) (2001) and the American Academy of Family Physicians (AAFP) (2006) recommends routine screening of a fasting lipoprotein panel for men aged 20 to 35 and females age 20 to 45 if the patient is at risk for coronary artery disease (hypertension, smoking, DM, family history of coronary artery disease before age 50 in male relatives and age 60 in female relatives or a family history suggestive of familial hyperlipidemia). The USPSTF and AAFP strongly recommend routine screening for all men at age 35 and women at 45. The National Cholesterol Education Program (NCEP III) (2004) recommends that all men and women aged 20 and over should have a fasting lipoprotein panel completed, then repeat every five years if the results are normal. Desirable or optimal levels for persons with or without existing heart disease are as follows:

  - **Total cholesterol:** Less than 200 milligrams (mg) per deciliter (dl).
  - **Low density lipoprotein (LDL) cholesterol (“bad” cholesterol):** Less than 100 mg/dL.
  - **High density lipoprotein (HDL) cholesterol (“good” cholesterol):** 40 mg/dL or higher. However, the AHA has recommended that men maintain a level above 50 mg/dL and women 60 mg/dL to reduce their individual risk of cardiovascular disease. Higher levels of HDL (“good” cholesterol) provide extra protection against heart disease. Smoking, being overweight and living a sedentary lifestyle can all result in a lower HDL cholesterol level. To raise their HDL levels, individuals should avoid tobacco smoke, maintain a healthy weight and exercise for at least 30-60 minutes more days than not.
  - **Triglycerides:** Less than 150 mg/dL. Triglycerides are a form of fat. Many people have high triglyceride levels due to being overweight or obese, physical inactivity, cigarette smoking, excess alcohol consumption or a diet very high in carbohydrates (60 percent of more of calories). High triglycerides are a lifestyle-related risk factor; however, underlying
diseases or genetic disorders can be the cause.

冠状动脉疾病: 所有专业的组织，AAPF，AHA和USPSTF，建议与常规筛查
对于心脏疾病与常规

| Electrocardiograms (ECG) | 血脂和总LDL。每一
| Electrocardiogram (ECG or EKG) | 心电图
| Myoglobin | 是氨基酸，对于
| Creatine kinase (CK) | 是一个酶，特定于
| Homocysteine | 是一个氨基酸，被
| C-reactive protein (CRP) | 是一个标志，表明
| Echocardiogram (ECHO) | 是一个非侵入性测试
| Chest radiograph (CXR) | 提供一个
| Electrocardiogram (ECG) | 测量电介质，心率
| Myocardial ischemia | 将导致
| MI (infarction) | 涉及
| Non-Q-wave MI | 诊断为
| Stress test | 是有用的
| Echocardiogram (ECHO) | 是一个无创测试
| Electrocardiogram (ECG or EKG) | 测量电介质

When cardiovascular disease is suspected, a
physician or nurse practitioner will order specific
tests to confirm a potential cardiac diagnosis. If
the patient presents with potential life-threatening
emergency cardiac symptoms, the patient will be
immediately transferred via the ambulance to the
closest emergency room (ER). Other specific tests
that may be ordered are as follows:

- **B-type natriuretic peptide (BNP)** is a
  hormone produced and released by the
  ventricles secondary to volume and pressure
  overload, thus decreasing preload [16, 46].
  BNP increases sodium and water excretion
  and signifies congestive heart failure.
  Therefore, it is a useful test to distinguish
  between congestive heart failure and other
  causes of shortness of breath. A normal
  level of BNP is less than 100 picograms per
  milliliter (pg/mL).

- **C-reactive protein (CRP)** is a marker of
  inflammatory process and may aide in the
  prediction of coronary events and signifies
  atherosclerosis. CRP is a protein produced
  by the liver and the smooth muscle cells
  within the atherosclerotic coronary arteries
[24]. Although the CRP is a good predictor,
  it should not be relied on solely as it is only
  one piece to the puzzle of predicting coronary
  artery disease, myocardial infarction and
  cerebrovascular accident.

- **Cardiac catheterization** is the most
  definitive, invasive diagnostic test to aide
  in the diagnosis of cardiovascular disease.
  During the procedure a thin, flexible tube
  is passed through an artery in the groin or
  arm to reach the coronary arteries to assess
  for any blockage, coronary artery disease,
  myocardial and valvular function.

- **Chest radiograph (CXR)**, provides a picture
  of the organs and structures inside the chest
  to determine the size, silhouette and position
  of the heart.

- **Creatine kinase (CK)** is an enzyme specific
  to cells of the brain, myocardium and skeletal
  muscle. If a patient tests positive for CK, it
  indicates tissue necrosis or injury somewhere
  in the body. However, in order to definitely
  assess for cardiac necrosis or injury, a health
  care professional needs to be familiar with
  the three types of isoenzymes:
  11. CK-MM is the predominant isoenzyme of
  skeletal muscle.
  12. CK-MB is found in the myocardial
  muscle and most specific for
  demonstrating an MI.
  13. CK-BB is found in the brain.

- **Echocardiogram (ECHO)** is a noninvasive test
  that allows cardiologists to assess the function
  of the valves and structure of the heart by visually
  observing and taking measurements via
  an ultrasound device.

- **Electrocardiogram (ECG or EKG)** measures the
  electrical function, rate and
  regularity of the patient’s heart rhythm. The
  ECG is a useful tool to distinguish between
different types of arrhythmias, myocardial
infarction and demonstrates left ventricular
hypertrophy and coronary artery disease.
Any patient who presents with chest pain, is
over 40 or has a history of the major heart
ailments should have an ECG to assess and
differentiate cardiac ischemia, injury, infarct,
myocardial infarction or left ventricular
hypertrophy:

- **Myocardial ischemia** will result in the
  inversion of the T wave.
- **Injury to the myocardial cells is more
  severe than ischemia and is manifested by
  ST segment depression or ST elevation.**
- **MI (infarction) implies necrosis or death of
  the myocardial cells secondary to
  atherosclerosis.** In the majority of cases,
  the left ventricle (LV) is the major site for
  infarction; however, it may occur in the
  right ventricle (RV).
- **Q-wave MI is defined as an initial
  downward deflection of a duration of 40
  msec or more in any lead except III and
  a VR.**
- **Non-Q-wave MI diagnosed in the
  presence of ST depression and T wave
  abnormalities.**

Regardless, the doctor will order cardiac enzymes to assess for MI.
In the absence of enzyme elevation, ST and T wave abnormalities are
interpreted as due to injury or ischemia rather than infarction.
- **Left ventricular hypertrophy** is complex to assess and more
  applicable for the cardiologists to
definitively hypothesize a diagnosis
  based upon the height of the R and
  S wave. It is definitely diagnosed
  based upon the thickness of the wall
  measured during an echocardiogram
  (ECHO).

- **Homocysteine** is an amino acid that is,
produced when proteins are broken down.
An elevated level may be a risk factor
for cardiovascular disease. However, the
correlation is still controversial.
- **Myoglobin** is another early marker of an
MI; however, it is not specific to the heart.
Myoglobin is a low-molecular protein found
in the cardiac and skeletal muscle.
- **A stress test** is useful in assessing for
ischemia caused by fixed coronary lesions,
but it may provide inaccurate readings in
patients at high risk or with coronary artery
disease. Research studies have demonstrated
that patients with coronary artery disease
may have a false-positive, and patients in a
high-risk category for developing it may have
false-negatives. At that time, the patient’s
cardiologists would need to evaluate the
risk and history of the individual to decide
whether further testing is warranted, such as a
cardiac catheterization.

**Prevention of cardiovascular disease**
Due to the significant prevalence of
cardiovascular disease globally, it is imperative
to consider primary prevention before

cardiovascular diseases begin. In order to reduce
the risk of developing cardiovascular disease, it
is imperative to initiate healthy lifestyle choices.
The CDC and WHO say the best way to fight
heart disease is a healthy diet and lifestyle.
Although it may appear difficult, it is all about
making healthy choices to protect the heart and to
be able to live life to the fullest. Healthy lifestyle choices for all people include exercising, not smoking and eating nutritious foods.

There are a few dietary recommendations that overlap, yet all have one goal in mind: protecting the heart. Since 1998, then revised in 2006, the U.S. Department of Health and Human Services has encouraged Americans to adhere to a dietary approach to stop hypertension, called DASH. Another common diet is the cardiac diet initiated by the American Heart Association and updated in 2006. The AHA, CDC and WHO have elaborated upon their diet recommendations by encouraging individuals to do the following:

- Consume a diet high in fruits vegetables, fiber, nuts and whole grains, and low in refined grains. Fruits and vegetables have folate, vitamin B6 and B12 to reduce the total homocysteine level, especially if the patient is at risk for developing cardiovascular disease.
- Choose lean meats and poultry without skin and prepare them without added saturated and trans fat. Limit energy intake from total fats and shift fat consumption away from saturated fats to unsaturated fats and towards the elimination of trans-fatty acids.
- Select fat-free, 1 percent fat and low-fat dairy products.
- Increase consumption of omega-3 fatty acids from fish oil or plant sources at least twice a week. Recent research has demonstrated that eating oily fish containing omega-3 fatty acids (for example, salmon, trout and herring) may help limit an individual’s risk of death from coronary artery disease.
- Limit foods containing partially hydrogenated vegetable oils to reduce trans fat in the diet.
- Limit the total dietary cholesterol in a diet, with the goal to eat less than 300 mg of cholesterol every day.
- Limit the consumption of beverages and foods with added sugars.
- Limit the amount of alcohol consumed to no more than one drink per day for women and two drinks per day for men.
- Choose and prepare foods with little or no salt. Americans should aim to eat less than 2,300 mg of sodium per day (or less than 1,500 mg if there is a higher risk of being affected by hypertension for those already diagnosed).
- The DASH diet restates the CDC and WHO recommendations by further stating that 2,300 mg is the highest level considered acceptable by the National High Blood Pressure Education Program. It is also the highest amount recommended for healthy Americans by the 2005 “U.S. Dietary Guidelines for Americans.” A 1,500 mg level can lower blood pressure further, and more recently is the amount recommended by the Institute of Medicine (IOM) as an adequate intake level and one that most people should try to achieve. In 2009, the CDC said that patients at higher risk of developing cardiovascular disease and/or hypertension (including people 40 or older, African Americans or those currently hypertensive) should limit their total sodium intake to less than 1,500 mg/day. In 2009, a CDC report stated that two out of three (69 percent) of adults in the U.S. fall into these three groups who are at especially high risk for health problems from consuming too much sodium.
- Eating less sodium can help prevent, lower or even control blood pressure. Most of the sodium consumed comes from packaged, processed, store-bought and restaurant foods. Only about 5 percent comes from salt added during cooking, and about 6 percent comes from being added at the table. All nutritional information facts are available on food products at grocers and available at many restaurants.
- Additional research has demonstrated that most Americans eat a lot more than the recommended sodium intake; men currently eat about 4,200 mg a day, and women consume 3,300 mg [45].

The recommended daily nutrient goals in the Third Report of the National Cholesterol Education Program (NCEP) and DASH to reduce the overall weight, blood pressure, lipid profile and to promote a healthy heart are very similar in the specific recommendations:

- Total fat 27 percent of calories (DASH); 25-35 percent (NCEP).
- Saturated fat 6 percent of calories (DASH); less than 7 percent of calories (NCEP).
- Polyunsaturated fat up to 10 percent of calories (NCEP).
- Monounsaturated fat up to 20 percent of calories (NCEP).
- Sodium 2,300 mg; however 1,500 mg is ideal, especially to maintain a healthy blood pressure.
- Potassium 4,700 mg.
- Protein 18 percent of calories (DASH); 15 percent of calories (NCEP).
- Calcium 1, 250 mg.
- Carbohydrates 55 percent of calories (DASH); 50-60 percent of calories (NCEP).
- Magnesium 500 mg.
- Cholesterol 150 mg (DASH); less than 200 mg/day (NCEP).
- Fiber 30 grams (g)/day (DASH); 20-30 g/day (NCEP).

NCEP is supported by the Detection, Evaluation and Treatment of High Blood Cholesterol in Adults; Adult Treatment Plan (ATP III).

Although the majority of patients with cardiovascular disease may be considered overweight or obese based upon their BMI, it may occur in the thin patient as well. Therefore, medical professionals should never assume by the body size alone that an individual is “healthy.” The JNC VII recommends patients should maintain a normal body weight with a BMI of 18.5 to 24.9 kg/m2 to help maintain a normal blood pressure. In addition to eating healthy, all individuals should be encouraged to exercise for at least 30 minutes every day. The NCEP and the AHA have expanded upon their recommendations based upon research.

Regular physical activity reduces very low density lipoprotein (VLDL) levels, raises HDL cholesterol, and in some people, lowers the LDL levels. It also can lower blood pressure, reduce insulin resistance and improve the function of the heart. It should be important for the health care provider to find a level of activity that the patient can accomplish over the long term. The American Academy of Family Physicians (AAFP) recommends a combination of resistance and aerobic exercise, but any activity is better than none, and patients who have been sedentary need to start with walking and gradually increase duration and intensity.

Ideally, the AHA recommends regular aerobic physical activity to increase an individual’s overall fitness level and capacity for exercise. It also plays a role in both primary and secondary prevention of cardiovascular disease. Physical inactivity is a major risk factor for heart disease and stroke and is linked to cardiovascular mortality. Regular physical activity can help control blood lipid abnormalities, diabetes and obesity. Aerobic physical activity can also help reduce blood pressure. Therefore, in order to achieve health benefits to the heart, lungs and circulation, people should perform any moderate-to-vigorous-intensity aerobic activity for at least 30 minutes on most days of the week at 50-85 percent of their maximum heart rate. One can accumulate 30 minutes in 10- or 15-minute sessions. It is important to include physical activity as part of a regular routine.

- Ideal examples of aerobic activities that increase endurance include brisk walking, jumping rope, jogging, bicycling, rowing, swimming, cross-country skiing and dancing.

Treatment
In addition to the lifestyle changes outlined above, additional treatment might be necessary.

Coronary artery disease
Medicines
Medicines may be needed to treat coronary artery disease if lifestyle changes aren’t enough. Medicines can:

- Decrease the workload on the heart and relieve coronary artery disease symptoms.
- Decrease the chance of having a heart attack or dying suddenly.
- Lower cholesterol and blood pressure.
- Prevent blood clots.
- Prevent or delay the need for a special procedure (for example, angioplasty or coronary artery bypass grafting).

Medicines used to treat coronary artery disease include anticoagulants, aspirin and other.
antiplatelet medicines, ACE inhibitors, beta blockers, calcium channel blockers, nitroglycerin, glycprotein IIb-IIIa, statins, and fish oil and other supplements high in omega-3 fatty acids.

**Medical procedures**

Patients may need a medical procedure to treat CAD. Both angioplasty and coronary artery bypass grafting are used as treatments.

- Angioplasty opens blocked or narrowed coronary arteries. During angioplasty, a thin tube with a balloon or other device on the end is threaded through a blood vessel to the narrowed or blocked coronary artery. Once in place, the balloon is inflated to push the plaque outward against the wall of the artery. This widens the artery and restores the flow of blood.

- Angioplasty can improve blood flow to the heart, relieve chest pain, and possibly prevent a heart attack. Sometimes a small mesh tube called a stent is placed in the artery to keep it open after the procedure.

- In coronary artery bypass grafting, arteries or veins from other areas in the body are used to bypass narrowed coronary arteries. The procedure can improve blood flow to the heart, relieve chest pain and possibly prevent a heart attack.

**Cardiac rehabilitation**

A doctor may prescribe cardiac rehabilitation (rehab) for angina or after coronary artery bypass grafting, angioplasty, or a heart attack. Cardiac rehab, when combined with medicine and surgical treatments, can help a patient recover faster, feel better, and develop a healthier lifestyle. Almost everyone with coronary artery disease can benefit from cardiac rehab. The cardiac rehab team may include doctors, nurses, exercise specialists, physical and occupational therapists, dietitians and psychologists or other behavioral therapists. Rehab has two parts:

1. Exercise training. This part helps a patient learn how to exercise safely, strengthen the muscles and improve stamina. An exercise plan will be based on an individual’s abilities, needs and interests.

2. Education, counseling and training. This part of rehab helps people understand their heart condition and find ways to reduce the risk for future heart problems. The cardiac rehab team will help them learn how to cope with the stress of adjusting to a new lifestyle and with their fears about the future.

Taking action to control risk factors can help prevent or delay coronary artery disease. Making lifestyle changes and taking prescribed medicines are important steps.

**Heart failure Medicines**

A doctor will prescribe medicines based on the type of heart failure a person has, how severe it is, and the person’s response to certain medicines. The following medicines are commonly used to treat heart failure:

- Diuretics (water or fluid pills) help reduce fluid buildup in the lungs and swelling in the feet and ankles.

- ACE inhibitors lower blood pressure and reduce strain on the heart. They also may reduce the risk of a future heart attack.

- Aldosterone antagonists trigger the body to get rid of salt and water through urine. This lowers the volume of blood that the heart must pump.

- Angiotensin receptor blockers relax blood vessels and lower blood pressure to decrease the workload on the heart.

- Beta blockers slow the heart rate and lower blood pressure to decrease the workload on the heart.

- Angiotensin-II receptor blockers relax blood vessels and lower blood pressure to decrease the workload on the heart.

- Isosorbide dinitrate/hydralazine hydrochloride helps relax blood vessels so the heart doesn’t work as hard to pump blood. The Food and Drug Administration approved this medicine for use in African Americans after studies showed it worked well for this group.

- Digoxin makes the heart beat stronger and pump more blood.

**Ongoing care**

It’s important to watch for signs that heart failure is getting worse. For example, weight gain may mean that fluids are building up in the body.

**Medical procedures and surgery**

As heart failure worsens, lifestyle changes and medicines may no longer control symptoms. A patient may need a medical procedure or surgery.

If heart damage and severe heart failure symptoms are present, a patient may need a cardiac resynchronization therapy (CRT) device or an implantable cardioverter defibrillator (ICD). In heart failure, the right and left sides of the heart may no longer contract at the same time. This disrupts the heart's pumping. To correct this problem, a doctor may implant a CRT device (a type of pacemaker) near the heart. This device helps both sides of the heart contract at the same time, which may decrease heart failure symptoms.

Some people who have heart failure have very rapid, irregular heartbeats. Without treatment, the problem can cause sudden cardiac arrest. A doctor may implant an ICD near the heart to solve this problem. An ICD checks the heart rate and uses electrical pulses to correct irregular heart rhythms.

People who have severe heart failure symptoms at rest, despite other treatments, may need:

- **A mechanical heart pump**, such as a left ventricular assist device. This device helps pump blood from the heart to the rest of the body. A heart pump may be until surgery or as a long-term treatment.

- **Heart transplant**. A heart transplant is an operation in which a person’s diseased heart is replaced with a healthy heart from a deceased donor. Heart transplants are done as a life-saving measure for end-stage heart failure when medical treatment and less drastic surgery have failed.

**Experimental treatments**. Studies are under way to see whether open-heart surgery or angioplasty (a procedure used to open clogged heart arteries and improve blood flow) can reduce heart failure symptoms.

**Ongoing research**

Researchers continue to learn more about heart failure and how to treat it. As a result, treatments are getting better. People who have heart failure often can be treated as part of research studies. These studies offer top care from heart failure experts and the chance to help advance heart failure knowledge and care.

People with heart failure may want to take part in a heart failure registry, which tracks the course of disease and treatment in large numbers of people. The registry’s data help research move forward. Patients should talk with their health care team to learn more.

**Heart attack**

Early treatment can prevent or limit damage to the heart muscle. Acting fast, at the first symptoms of heart attack, can save a life. Medical personnel can begin diagnosis and treatment even before a person gets to the hospital.

Certain treatments are usually started right away if a heart attack is suspected, even before the diagnosis is confirmed. These include:

- **Oxygen**.

- **Aspirin to prevent further blood clotting**.

- **Nitroglycerin**, to reduce the workload on the heart and improve blood flow through the coronary arteries.

- **Treatment for chest pain**.

Once the diagnosis of heart attack is confirmed or strongly suspected, treatments to try to restore blood flow to the heart are started as soon as possible. Treatments include medicines and medical procedures.

**Medicines**

A number of different kinds of medicines may be used to treat heart attack. They include the following.

- **Thrombolytic medicines**

These medicines (also called clot busters) are used to dissolve blood clots that are blocking the coronary arteries. To be most effective, these medicines must be given within 1 hour after the start of heart attack symptoms.

- **Beta blockers**

These medicines decrease the workload on your heart. Beta blockers also are used to relieve chest pain or discomfort and to help prevent additional heart attacks. Beta blockers also are used to correct arrhythmias (irregular heartbeats).

- **Angiotensin-converting enzyme (ACE) inhibitors**

These medicines lower blood pressure and reduce the strain on the heart. They also help slow down further weakening of the heart muscle.
ANTIPLATELET MEDICINES

These medicines (such as aspirin and clopidogrel) stop platelets from clumping together and forming unwanted clots.

OTHER MEDICINES

May also be given to relieve pain and anxiety, and to treat arrhythmias, which often occur during a heart attack.

MEDICAL PROCEDURES

If medicines can’t stop a heart attack, medical procedures – surgical or nonsurgical – may be used. These procedures, detailed above, include:

- Angioplasty.
- Coronary artery bypass grafting.

Treatment after patients leave the hospital

Most people spend several days in the hospital after a heart attack. When patients leave the hospital, treatment doesn’t stop. At home, treatment may include daily medicines and cardiac rehabilitation (rehab). Lifestyle changes may be recommended to lower chances of having another heart attack. Cardiac rehabilitation also may be prescribed.

CONCLUSION

Ideally, all dentists, physicians and nurses should teach their patients about food choices, smoking cessation and choosing an active lifestyle, regardless of the person’s current risk of developing cardiovascular disease; ultimately, all people are at risk. Although people cannot change smoking cessation and choosing an active lifestyle changes may be recommended to lower chances of having another heart attack. Cardiac rehabilitation also may be prescribed.

References

CHAPTER 5
FACING THE FUTURE: NIDCR RESEARCHERS OFFER THEIR VISION OF THE 21ST CENTURY
(3 CE HOURS)

Learning objectives

- Review scientific research on craniofacial development.
- Identify National Institute of Dental and Craniofacial Research (NIDCR) ideas on the systematic model of craniofacial development.
- Explain how neural crest cells assist in the development of the formation of the craniofacial plate.
- Identify the development of replacement tissues for damaged teeth.
- Discover the future possibilities to regenerate damaged gingival, ligament and bone.

Introduction

This course presents researchers and their views on related studies of dental and oral research that promise giant steps in the future. The material consists of questions and answers from grantees of the National Institute of Dental and Craniofacial Research. These scientists use the latest molecular and genetic tools to conduct research on the full spectrum of topics related to craniofacial, oral and dental health and disease. In this course, you will meet each of these researchers and review some of the challenges they are facing.

The six researchers and grantees are:
- Dr. Marianne Bronner-Fraser, a biologist at the California Institute of Technology in Pasadena, California.
- Dr. Paul Trainor, a scientist at the Stowers Institute for Medical Research in Kansas City, Missouri.
- Dr. Richard Maas, a scientist at Brigham and Women’s Hospital and Harvard Medical School in Boston, Massachusetts.
- Dr. Malcolm Snead, a scientist at the University of Southern California, Los Angeles, California.
- Dr. William Giannobile, a researcher at the University of Michigan in Ann Arbor, Michigan.
- Dr. Pamela Robey, a National Institute of Dental and Craniofacial Research scientist in Bethesda, Maryland.

On its 60th anniversary, the NIDCR looks to the future and the likelihood of a more systematic model of craniofacial development. The pages that follow offer the perspectives of several NIDCR researchers and grantees on the scientific road ahead to meet this challenge. They also portray some of the likely benefits of this research to the nation’s public health. These include a detailed picture of where the molecular glitches might arise in the system, for example, to cleft a lip, omit a tooth bud or malformed a bone. By knowing the most frequent problem spots and, more generally, how healthy craniofacial structures are made, scientists will be in a much better position in the years ahead to dispense molecular medicine and repair more naturally a congenital problem or heal a diseased tissue. They also will be more attuned to the early molecular warning signs of developing disease. This will allow earlier and more accurate diagnoses to correct problems before they become advanced, chronic and destructive.

As part of this glimpse forward, the NIDCR highlights related areas of dental and oral research that hold tremendous promise. These include studies of head and neck cancer, the development of saliva as a diagnostic fluid, more effective control of orofacial pain, and ongoing hands-on efforts in communities across the nation to help translate the fruits of our science into improved health care.

To tell these stories involves a new language of discovery. These include more familiar terms such as genomics, or the study of genes across species, and proteomics, the companion term for proteins. It also includes more recently minted biological pursuits such as the interactome, the complete set of possible protein interactions within a cell, and the microbiome, the complete set of microorganisms that inhabit distinct parts of the body, such as the mouth, and greatly influence our health and susceptibility to disease over time.

These and other terms represent the need for conceptual distinctions in science. While organizationally helpful, they are in many ways artificial. All human biology is one, from head to toe. As NIDCR-supported research unfolds in the years ahead, its lessons will have broad applications throughout science and, more importantly, in hospitals, clinics and dental offices across the land.

One final note: Although the scientists highlighted here are all outstanding, they represent just a cross section of a much larger community of NIDCR researchers and grantees who are making important contributions to their fields and the nation’s public health.

Part I: Neural crest cells: The first mystery of craniofacial development

In 1868, the Swiss embryologist Wilhelm His spotted a thin band of previously undetected cells bunched between fetal ectoderm and the inchoate neural tube of a developing chick. Dr. His called his find the Zwischenstrang, or “the intermediate cord.” By the end of the century, the German word Zwischenstrang had been scrapped for the more descriptive English term “neural crest cells,” denoting the geographic crest of the neural tube as their site of origin. The cells also had become a topic of controversy. Reports had begun to trickle into the scientific literature that neural crest cells in some fish gave rise to neurons and nerve fibers of the cranium, while those in certain salamanders were proposed to produce cartilage of the head and dentin forming cells of the teeth. Many biologists claimed this was preposterous.

“One hundred years ago, claiming that an ectodermal derivative such as the neural crest was in any way involved with the formation of skeletal structures was the embryological and evolutionary equivalent of nailing an additional thesis to the cathedral door,” wrote Langille and Hall in the early 1990s, referring to Martin Luther’s famous Protestant rebellion. “That skeletal structures were mesodermal in origin was dogma, known and accepted by all; an ectodermal origin was heresy.”

Today, the controversy has ebbed. Scientists have solidly established that these short-lived precursor cells come in four distinct types, all of which are programmed to migrate throughout the body and seed new tissue. Among them are the cranial neural crest cells that, as mentioned above, help to generate most of the distinctive skeletal structures of the head and face. Although the mystery of neural crest cells historically has attracted anatomists and evolutionary biologists, the last few decades have brought more molecular and cell biologists to the field. The prospect of increased collaboration among the scientific disciplines coupled with the rapid progress in research technology promises to herald a new era of discovery in craniofacial development.

To take a closer look at neural crest cells, craniofacial development and the research job ahead, two NIDCR grantees offer their thoughts. We start with Dr. Marianne Bronner-Fraser, a biologist at the California Institute of Technology in Pasadena, and Dr. Paul Trainor, a scientist at the Stowers Institute for Medical Research in Kansas City, Missouri.

Marianne Bronner-Fraser

Dr. Marianne Bronner-Fraser
California Institute of Technology
Pasadena, California

In studying craniofacial development, why go all the way back to neural crest cells? In other words, why study the Book of Genesis? Why not just cut to the Book of Revelations and fully formed human tissues?

Think of it like this. You wouldn’t understand the meaning of Tolstoy’s “War and Peace” by flipping to the last few chapters. The same is true here. You’ve got to start as close to the beginning as possible to follow the biological narrative and,
What are some of the early features of the narrative?
Well, the initial generation of neural crest cells. It’s really quite fascinating. The early embryo forms as three distinct layers of tissue – the exterior ectoderm, the middle mesoderm, and the internal endoderm. By day 19, the interaction of ectoderm and mesoderm produces the neural plate, a precursor of the central nervous system.

And neural crest cells form along the neural plate?
Exactly. The interaction between ectoderm and mesoderm is a classic mode of embryonic tissue formation. That’s why the lessons learned here will have relevance to understanding tissue formation elsewhere in the body. That’s also why it’s essential to define the molecular machinery within the neural crest cells that prompt them to migrate. In other words, which molecular gears and sprockets turn on and off to enable neural crest cells to transition from ectoderm to mesoderm? How does this transition enable them to loosen from the neural tube and migrate, for example, to the heart or the cranium? And, of course, in the context of cranial neural crest cells, it’s essential to understand how these cells at first produce what appears to be the same generic, undifferentiated facial primordial in vertebrate species. And yet, neural crest and the surrounding ectodermal cells generate these dynamic development programs that produce vertebrate structures as distinct as the beak of a toucan, the tusk of a boar or the venom-producing salivary gland of a rattle snake.

Your group is looking comparatively up and down the evolutionary ladder not only at vertebrates but also invertebrates, or more primitive creatures that lack a spinal column and thus a head. Why?
That’s where many of the answers to vertebrate evolution will be found. People tend to be so human-centric, and because of that, vertebrate-centric. But if you can piece together and understand some of the evolutionary changes that occurred through the millennia from invertebrate to vertebrate, they can be extremely informative in telling us how something as complex as a human head is assembled. In short, we need to listen to the biology, not impose our own mechanistic thoughts and metaphors upon it.

And by listening to the biology, it also will help to explain where things go wrong to cause a malformation, say a cleft lip?
Sure, I think a lot of the answers to birth defects will lie in the early stages of craniofacial development. One of the things that I’m very interested in is the gene regulatory networks in neural crest cells that help to initiate this self-assembly machine that forms a head. You start development in all species with a single-cell fertilized egg. Without giving any obvious hints, that lone cell gives rise to structures and faces as diverse as those of a human being, a finch and a giraffe.

And yet, as complex as craniofacial development is, it usually is completed without a hitch.
That’s right, craniofacial development goes right in the vast majority of cases. What’s interesting is the same genes that are used early in development also are used later in the process and at multiple times. It seems to be a reiterative process during which you have important genes that are first used to specify a cell type and then later that same gene might be used to tell it to differentiate into a tooth, bone or jaw cell. It’s fascinating to realize that the toolkit is not as vast as we once thought it must be. It’s the way that toolkit is deployed that proves to be especially important.

Has the genetic activity of neural crest cells during the developmental process been catalogued?
We’re getting there. With the full genetic complement, or genomes, of various species now determined, the rate of identifying genes involved in making a head or a heart has increased exponentially. It’s left us wading through a huge amount of data. That’s exciting in that so many more pieces to the puzzle are spread out on the table. The problem is this heavy volume makes assembling the puzzle more complex. If I’m dealing with 500 or 1,000 genes to figure out how they work together to create a cell type or render a neural crest cell migratory, I might be really puzzled. If I have a colleague who is looking at it from an opposite approach but happens to identify a subset of those genes, we can take those 1,000 candidate genes and cut them to 10 and begin thinking about communication nodes and signaling networks. What I’m hoping is that by putting these groups together, we can narrow down the key players more quickly. There’s going to be common themes running through this. Unless you do something comparatively, you can’t see those threads.

And these multidisciplinary groups have been formed and continue to be?
That’s right. For example, the NIDCR soon will launch its FaceBase Project. It will bring together scientists of various research backgrounds and establish collaborative consortia that focus on specific sequences of craniofacial development. That will be very constructive. Our best science is ahead of us, and as more of the metaphorical pieces to the neural-crest puzzle are discovered, I think fitting them into a coherent biological picture of craniofacial development will have profound implications for human health and disease.
lot of what they do is dependent on which tissues they contact during their migration and which signals are received when they reach their final resting place.

**A view of the neural plate and migrating cranial crest cells.**

What I’m wondering, though, does the facial primordial serve as the rough blueprint of a vertebrate head? That may well be. If you look at the different vertebrate species, there are tremendous similarities in the initial formation and migration of neural crest cells into the pharyngeal arches, also called the branchial arches in fish. There’s no doubt about that. But if you fast-forward the developmental process and look at the diversity of cranial structures that arise across the vertebrate spectrum, they are dramatically different from the trunk of an elephant to the tusk of a boar. So what is highly conserved in nature is this early basic blueprint of facial development, and then the diversification themes that take place beyond that time point.

**When you say “diversification themes,” that’s where neural crest cells play such a major role?**

Correct. Neural crest cells are endowed with innate plasticity, or an ability to make developmental modifications. That means the genetic program wired into the neural crest cells don’t need to be modified at the neural tube, that is, the very front end of their life cycle. The modifications can occur throughout the developmental process. By that, I mean cranial neural crest cells can be influenced by molecular factors during their migration to the pharyngeal arches. Or they might arrive there at a new position, where they have multiple tissue interactions that modify their location, orientation, and ultimately their fates.

**When can neural crest cells first be detected during embryonic development?**

In the mouse and chick, we’ve gone all the way back to the induction process, which is the earliest relevant time point [embryonic Day 8 in the mouse, 1.5 in the chick]. If we went back any further, we’d see things that might influence neural crest formation secondarily, such as the development of the neural plate. But they may not be particularly relevant to the actual induction process.

**So, in these species, you can track neural crest cells from just about point A to Z of the developmental process?**

Yes, exactly. What we can’t do is tackle that in humans for technical and ethical reasons. What we do know, if you think about the different phases of neural crest development — whether it be the formation, migration, differentiation phase — if an anomaly arises in any one of those phases, you can end up with a very different craniofacial malformation.

**For example?**

Well, there a number of recognized neural crest-derived malformation syndromes. I’m talking about potentially devastating conditions such as Treacher-Collins syndrome or DiGeorge syndrome. What’s clear is these often-severe syndromes arise within the first eight weeks of pregnancy. At the moment, there is no way that we can detect or visualize them in people during these early, in utero stages based on morphology alone. I think an exceptionally skilled sonographer, even if he or she was specially trained to detect craniofacial anomalies, wouldn’t necessarily be able to do it with 100 percent accuracy, even at 22 to 25 weeks of pregnancy.

I should note that even if one could recognize a potential problem, many craniofacial syndromes are quite similar and overlap in their phenotypes, or visible manifestations. They also vary in severity from child to child. So the precise identification of a specific condition still requires genetic confirmation. It can’t be done visually.

**What needs to change to turn back the detection clock?**

Well, it’s incredibly complex. I guess one is the development of improved technologies to visualize the very early embryo. But that’s only part of it. I think it is very difficult at that early stage to say whether something looked unusual and needed to be monitored and then to try to figure out what it was that was abnormal. It’s not always so clear.

**How will clarity be reached?**

I would say the key is building on the recent progress in biology. If we have good mouse models of individual diseases, we can take all of the genetic network information for neural crest patterning, migration and differentiation and pinpoint the origin of the problem. If it turns out to be something as simple as a wave of cell death – the neural crest cells are being killed off – then the simplistic idea is to find something that will keep them alive, in the same way that some people have found that folic acid somehow confers better viability to neuroepithelial cells and can reduce the incidence of neural tube defects. That’s the approach that we’re taking. We start with a specific syndrome, try to identify its cause, test whether the mechanism may be common to similar syndromes, and see if we can find a way either to chemically or genetically rescue the problem.

**But, as you said, nobody will get anywhere without doing the biology?**

That’s right. Every day presents a new challenge, but we enjoy our work and its potential to benefit substantial numbers of people worldwide.

**Part II: Tooth development**

Is it possible to build a tooth? That’s a question that many giants of 20th century dental research no doubt considered, and it’s a conceptual puzzle that continues to capture the imaginations of the nation’s oral health scientists. But there is a key difference between the musings of then and now. Today’s scientists possess for the first time the needed laboratory tools to plumb the molecular depths and developmental biology of tooth formation, and some already have begun to do so in earnest.

The research follows two broad but complementary tracks. One seeks to define in sequential detail the genetic programs underlying tooth development and, moving to the next biological level of activity, to map the protein biocircuitry in tooth-forming cells that carry out the genetic program. This research delves into the genetics of the initial tooth placode, a thickened patch of ectoderm near the fetal head that arises as migratory neural crest cells arrive early in development. It then tracks the sequential development of the tooth cap, the tooth bud and ultimately, the maturation of the individual dental tissues therein, from enamel down to the cementum of the tooth root.

The other path aims to take this fundamental information and, like a minimalist artist, deconstruct the complexity of tooth development and define its essential molecular requirements. By stripping away the redundancies and other non-essential molecular chaff of the process, scientists hope to match or possibly improve upon nature’s instructions to engineer replacement tissues for damaged teeth.

Offering their perspectives on the road ahead are two NIDCR grantees. They are: Dr. Richard Maas, a scientist at Brigham and Women’s Hospital and Harvard Medical School in Boston, and Dr. Malcolm Snead, a scientist at the University of Southern California in Los Angeles.
As a part of the NIH Roadmap Initiative, you have begun a project that, in part, explores tooth development. Could you tell us about it?

Sure. The project focuses on three structures: the tooth, pancreatic islet cells and the heart valve. The central premise here is we now know enough about organ development to use this knowledge base as a template to assemble a far more comprehensive biological picture of the process.

You want to put more meat on the bone? Exactly. The program’s acronym is SysCODE, which stands for Systems-Based Consortium for Organ Design and Engineering.

So, it’s a systems biology approach, or studying the cell as an integrated system of biological circuits and data processing?

Well, the systems-based aspect arises because we want to integrate the various data sets that the new generation of research tools now can generate. These include comprehensive gene expression profiles; extensive catalogues of protein expression, chip-on-chip analyses to figure out where transcription factors bind in the genome; assembling data on common inherited genetic alterations; and logging the results of RNAi experiments to inhibit an individual gene’s expression and thus study its function and thereby dissect relevant signaling pathways within the system.

What will this data integration produce?

Our hope is a coherent molecular blueprint to build a tooth. The idea is, once the computer and genome scientists have assembled this large body of information in an intelligent format, it will be amenable for tissue engineers to use.

How would they use it?

The set of instructions would be in a user-friendly format for a scientist to say, “Okay, I need to add Factors A, B and C in this particular sequence, at these concentrations and in this particular combination. I need to couple them with a scaffold of extracellular matrix materials X, Y and Z. And because this information is based on how the tooth normally forms, if we reconstruct those types of parameters as best we’re able in vitro, we should have a molecular blueprint that will yield a structure that approximates a tooth.”

The magnitude in the first image is twice that in the second image. From: Kuaraguchi, Wang et al., PLoS Genetics 2, e146, 2006.

How does a tissue engineer do it today?

Well, the current paradigm for tissue engineering consists of taking Factor X, adding it to some cells and seeing what happens. I’m in no way denigrating that approach. I think it’s been incredibly successful. But it is empiric, and a molecular blueprint would be extremely helpful.

In generating the data sets, on one level, wouldn’t you want to tease out the evolutionary biology of the tooth? By analogy, a mechanic needs to know the make and model of an automobile before lifting up the hood.

You certainly want to know how a tooth or any part of the body came to be. So, yes, I agree. And that information is being assembled. From DNA sequencing projects to improved mouse models, a major investment has been made over the last decade or so to perform comparative analyses among species and tease out these evolutionary motifs.

But on another level, how detailed will the instruction manual need to be? In other words, do we need to recapitulate all of the moving parts and redundancies that are built into the system? Or can the process be streamlined in the laboratory and remain functional?

The answer is we probably don’t need to know all of the moving parts. There are some basic organizing principles at work in the tooth bud that can be mastered and hopefully exploited to form enamel, dentin, cementum and the other constituent parts of the tooth. That means we don’t need to account for every last gene in the human genome to build a tooth, and that’s why this is a doable task.

How many genes would make the cut? Well, although there are roughly 23,500 genes in the human genome, probably only one-tenth of those are expressed during tooth development. That is to say, they satisfy the condition of being necessary or sufficient.

And of those genes, some likely will be more critical than others? That’s right. Not all genes and proteins that plug into a developmental pathway are of equal importance. This relates to the structure of networks.

How so?

There are two general types of biological networks hard-wired into our cells. One is called a universal random network, where every component, or node, is equal in importance and weight. The second and more prevalent form is called a scale-free network. In scale-free networks, not all nodes are created the same. There are very important centralized nodes, or hubs, that act as convergence points and processing centers for incoming biological information. Think of the spoke-and-hub system in aviation. If you identify the hubs—the Chicago O’Hares—it’s possible to predict the behavior of the system to a large extent and without needing to piece together every single element of the network.

What might these predictions reveal?

Let me give you an example. We study a gene that, if inactivated, results in the formation of supernumery, or extra, teeth in the mouse. That suggests that this gene and its protein product are very high up in the regulatory cascade that controls tooth development. By manipulating that protein, you wouldn’t necessarily have to control all of the others that are activated subsequently, or downstream, of it. Because that master gene would take care of them for you. You see? So, this shows the great simplification that is possible as some genes turn on entire programs of downstream events.
Are there other basic organizing principles?
There's a corollary principle. I would call it the principle of autonomy. By that I mean, if an early tooth germ reaches a certain developmental stage, it will continue to develop all the way to the latter stages of mineralization. There's actually a precedent for that. Dr. Paul Sharp and colleagues at Guy's Hospital in the UK showed some time ago that if they took what's called a cap-stage tooth germ and grafted it into the jaw of an adult mouse, it will in fact develop much, much further.

That would mean we don't necessarily have to worry about mastering all stages of tooth development. Once a developmental tipping point is reached, biology could take care of the rest? That's right.

What impact might this and related work have on practitioners in the coming years?
Well, let me just say that current prosthetics work relatively well. But millions of Americans still lose a significant number of teeth during their lives, and dental disease remains a significant health problem. So, if we could generate a biomimetic substitute, it would be welcomed. To do that at a reasonable cost and with good efficiency, I think you're looking at least a decade into the future. On the other hand, if you could generate enamel matrix in a test tube from cells that you've programmed, that would be very exciting. How that would figure into clinical practice, dentists no doubt would decide. But, clearly it would be a wonderful natural product.

Malcolm Snead

Dr. Malcolm Snead
University of Southern California
Los Angeles, California

The term “building a tooth” suggests creating a bicuspid or incisor from scratch. But that's not the focus in your laboratory?
Most of my interest and expertise developmentally lie down stream of those initiating events. In other words, I’m not interested in day six or seven of gestation, although I think early development is very interesting. My research focus is on the problems of tissue specification during late gestation and early postnatal development.

How do these problems flow into building a tooth?
In our case, the focus is on learning to engineer new tissue to replace damaged or diseased tooth structures.

Why engineer?
Let me back up a bit. Biology is now in a golden age of discovery. We can knock out a specific gene, modify another gene and ask a variety of profound questions about the circuitry of the cell that just weren’t on the table a decade or so ago.

For example?
Well, you could ask what happens systemically if you remove 100 percent of transforming growth factor X? Does the cell – the biological system – have the ability to compensate for the loss via a redundant signal? If there’s no compensation and thus the effect is uniform within the system, what then happens downstream when the circuit is shut down? It’s kind of like a caveman holding a pocket watch. You smash the pocket watch and say, “Great, look at all of these parts in it.” But can you reassemble the watch? The next step is to go back and say, “Okay, I know that I need this piece, but how far can I turn it down,” so that it functions at 10 percent of its normal level and still get an outcome?

Addition by subtraction?
Right. If you’ve identified all of the pieces, can you also define the ones that you don’t need? It’s a matter of relevance, and that is now framed within the context of our expanded scale of discovery. What I mean is we used to try to understand how the cell worked at some level when we could perform a Western blot assay and detect a protein. We advanced to a Northern blot assay to process RNA, and that gave us greater sensitivity to quantify gene expression. In the 1990s, we entered a PCR state of affairs that enabled us to look at five or six molecules in a cell. Now you must start pulling out the noise, the chaff in the system. What is relevant? And what is spurious noise? It’s oftentimes a matter of understanding what you know relative to how you think you need to know it.

What about something as complex as a tooth root?
It’s a four-in-one proposition with dentin, pulp, cementum and the periodontal ligament. It represents a challenge, but certainly a worthy one. If you can understand root formation, you have a much better handle on regenerating a major cause of tooth loss in adults, which is the loss of supporting bone and ligament. But what’s important here is this is a challenge that we now can productively wrap our minds around.

What about regenerating enamel, one of your major research interests?
Enamel is a tissue in which the whole is greater structurally than its individual parts, in this case, elongated hydroxyapatite crystals. Enamel is a fascinating tissue. I’m actually sitting here holding a chunk of hydroxyapatite in my hand. If you made a tooth out of what’s in my hand, it would fracture and fall apart in a matter of days. Its toughness, hardness and elasticity really are quite different than the hydroxyapatite in the enamel of my teeth. Some of that has to do with the nanoscale that nature works to weave hydroxyapatite crystals into the patterned structure that we know as tooth enamel. Another small part of that is some residual amount of protein. It’s maybe 5/10 of a percent of protein dry weight. It’s likely retained for a very specific function.

After injecting artificial bioactive nanostructures, the mouse incisor expresses the protein integrin alpha-6.

The protein helps to form the enamel matrix.

Green fluorescent proteins illuminate cells in a three-dimensional matrix of artificial bioactive nanostructures.

A close-up of dental enamel.

And it's retained as a remnant of the original protein matrix?
Right. Even though the tooth erupts into the oral cavity as a white, mineralized fossil, it was not a fossil during its formation. Before the hydroxyapatite crystals elongated, properly
orientated themselves and formed mature enamel, they were seeded in an extensive protein matrix that served as a developmental lattice. All of the rules that apply to changes in gene expression, control of protein expression, response of different signaling molecules through membrane-mediated receptor events and secondary signals. All of those are happening. Enamel is very, very much alive as it’s being made.

**But can you go all the way back and track the assembly of, say, the amelogenins in forming the protein matrix?**

Absolutely. In fact, there are 16 different isoforms, or types, of amelogenin. We work on them in vitro analyses, and that tells you certain things. But then you must go back to the organism and say, “In the context of the organism, does it work this way?” That’s where the approach to genetic engineering – the simplicity of a biological outcome as your measure – is very appealing. If you can achieve the same outcome with a lot less moving parts, it suggests that you understand how the system works and know its critical parts.

**How’s the engineering going?**

Quite well. Right now, I’m working on a manuscript that produces almost a two-order reduction in simplicity in proteins of the amelogenin class. We used a genetic knock-in strategy that ends up producing an enamel that has essentially characteristics that are within 20 percent of the natural enamel. So I’ve made this enamel with 16 times less alternative proteins participating. And yet, the system seems to work adequately. Or within 95 percent of the expected values. So this question of how far can we go is one that I share with the rest of the team here at University Southern California and numerous labs around the world.

**And across scientific disciplines.**

Yeah, I think a lot of people in materials sciences, engineering and nanotechnology get quite excited about it. Making a mineral that behaves in the way that enamel does, or the way that the enamel actually bonds to the underlying dentin and dentinoenamel junction, or DEJ, is a phenomenal piece of engineering. When I speak to my engineering colleagues, they would like to know about the DEJ. How does the enamel stay on the dentin?

**That’s of real significance to dentists.**

Right, if you could replicate a dentino enamel junction (DEJ), it would be a first step toward ensuring that fillings lasted longer. Restorations usually fail at the interface. It’s not the filling itself. It’s the bond of the materials. … If a glass-like ceramic material is more compatible with the dentin, you can increase the longevity of the restoration.

**And the data are pouring in.**

Yes, that’s right. It’s pouring in all areas of biology. I was at a nanotechnology meeting recently where people were talking about monitoring 40 channels of data coming out of the cell simultaneously, from their cell receptors to their oxidative state. You could see lots of different parameters of cell biology being reported in a single cell instead of looking at a thousand cells and averaging their behavior for one parameter. You can just imagine what that means. Suddenly you must ask, “Have we been measuring the tops of mountains? There’s a much wider range to how cells respond. We have to see a 20-fold change in its activity before we even start to say we can measure and work with it. When, in fact, the system is much more sensitive, it may be changes of 20 percent that make differences. But we ignore them because we don’t see them.

**Part III: Periodontal disease: Engineering the future of care**

In the 1950s, soon after NIDCR’s founding, millions of Americans often flipped on their black-and-white tube televisions and watched commercials that warned of a tongue-twisting condition called gingivitis. As the ads warned, gingivitis was step one on the road to chronic gum, or periodontal, disease and tooth loss.

Today, researchers now know that gingivitis does not necessarily lead to advanced periodontal disease. However, a confluence of factors can induce chronic inflammation of the gingiva in some people. These factors include lifestyle choices, such as an addiction to tobacco; diabetes or another underlying health condition that compromises one’s ability to heal; a susceptibility to gingival infections; and an over-reactive immune system. If left unchecked, periodontal disease gradually will degrade the four tooth-supporting tissues of the periodontium – gingiva, periodontal ligament, cementum and bone.

As the television ads from the 1950s correctly concluded, advanced periodontal disease will lead to tooth loss.

Today, a trip to the periodontist typically entails anti-inflammatory therapy coupled with scaling and planing of the inflamed tissue. Periodontists also have been eager to employ the latest biological discoveries to regenerate damaged gingiva, ligament and bone. Although today’s tissue regeneration techniques remain works in progress, research on this front continues to progress nicely. Most scientists are optimistic that tissue engineering, with its sophisticated mix of biology and chemistry, will be more predictable in the years ahead. To present the research themes are two scientists with long and productive records of accomplishment in this area: Dr. William Giannobile, a researcher at the University of Michigan in Ann Arbor; and Dr. Pamela Robey, an NIDCR scientist in Bethesda, Maryland.

**Dr. William Giannobile**

**University of Michigan**

**Ann Arbor, Michigan**

You oversee your own laboratory and head a clinical research center at the University of Michigan. You also find the time to see patients in private practice? I’m also a practicing periodontist, and I continue to treat patients in a private practice here in Ann Arbor.

**So you’ve both seeded and directly benefited from the research?**

I think so. As a practitioner, I’ve benefitted from the advancements in biomaterials research, various bone grafting techniques, guiding tissue membranes that separate the bone from the connective tissues, and anti-infective therapies to arrest or slow the progression of periodontal disease.

**But there’s still a ways to go?**

That’s right. Periodontal treatment today remains fairly unpredictable in terms of getting stable, long-term results. That’s especially true for regenerating the various parts of the periodontium – bone, ligament, cementum and mucosa. But there have been some nice advancements, and I just mentioned a few of them. I think the combination of research progress and the continued unpredictability of treatment has to some extent shifted the periodontist’s role.

**How so?**

About 20 years ago, most restorative dentists would contact periodontists with referrals and say, “Do your best. See how many more years you can help this patient eke out of these teeth.” Now, the mindset is much different. Because of the unpredictability of regeneration and the challenge of controlling a chronic immune response, many practitioners don’t want to run the risk of trying to save the teeth. Many advise their patient to have the questionable teeth removed and replaced with dental implants. But as a researcher and periodontist, I continue to support the profession’s founding principles to
save teeth whenever possible. For that reason, I see a lot of areas that we need to explore to develop more predictable therapies, especially when regenerating the damaged tissues of the periodontium.

And the biology is there for the taking? I think so. You can see it in the scientific literature each and every month. You also can see it in the ideas that have entered the clinical research pipeline.

For example? Growth factors. Platelet-derived growth factor and the bone morphogenetic proteins are both now FDA approved and have entered into the clinical arena over the last two years. Although these growth factors have sometimes incorrectly been held up as a panacea for tissue regeneration, they are indeed very important advancements. Keep in mind, though, periodontal disease is an extremely complex condition. Tissue regeneration alone is not the answer. We need to push the anti-infective/host modulation side, too, and ensure that the patient’s immune response doesn’t turn chronic and self-destructive.

And that self destruction is of an inherently complex environment? Absolutely. We essentially have a tooth – an avascular mineralized tissue – that protrudes through soft tissue, where it is under constant microbial attack. The tooth is rooted in bone, anchored by ligament and dependent on supportive tissues in dentin and cementum. These tissues have specific geographic junctions, abilities to bond and load-bearing qualities. What’s more, all of this complexity is rolled into a tight biologic space. We often talk about millimeters of eroded bone. Millimeters are very significant in the support of teeth. There’s just nothing like the periodontium in the rest of the body.

So how do you make tissue regeneration more predictable? I think interdisciplinary collaborations hold the key. We need scientists with training in infectious disease, biomedical engineering, molecular and cell biology, genetics, and clinical research.

What about technology development? Discovery and technology development typically go hand in hand. A good example is the progress in high-resolution imaging techniques. They produce images of bone damage that are so accurate, we literally can construct in the laboratory three dimensional scaffolds that fit perfectly into the periodontal pockets and deliver regenerative factors. This hasn’t yet reached the clinic, but it suggests the following scenario: The surgeon images the tooth/bone lesion and says to the patient, “Okay, I can quickly make this scaffold, and it will be loaded with growth factors or stem cells. We’ll just drop it into the defect.” Right now, the surgeons carve out the decalcified bone as best they can. It’s just not efficient.

We talked a moment ago about the biology being there for the taking. If the scaffolds and their growth-promoting cargo now can be more precisely delivered, that raises the issue of timing. You need to drop in the growth factors at the right time and in the right sequence. That’s an important point. Researchers have begun to look at the process in a more systematic way. But defining the biology is even more important from a diagnostic standpoint. Patients respond differently to treatment.

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The four research areas that hold the key to a future of periodontal tissue engineering and regenerative medicine.

Pamela Robey
National Institutes of Health
Bethesda, Maryland

It’s kind of like reading the Old Testament Book of Numbers. The patriarchal stem cell begets sublineages of cells.

Right, and this theme is played out throughout the body. We see it in bone and cartilage, and we see it in dentin.

What’s the second defining feature? Self renewal. A stem cell must have the ability to produce a new generation of stem cells. So, as they churn out more mature daughter cells, they also must produce daughter cells that remain stem cells. Without self-renewal, the stem cells that populate a given tissue would die their natural deaths and take with them the ability to regenerate and maintain a tissue structure.

Why has the definition of stem cell gone off in all directions? It’s the vagaries of cell culture. Because scientists typically study stem cells in a culture dish, they describe certain characteristics that may or may not relate back to what they do in the body.

For example? Well, two things come to mind. A lot of people say that a stem cell is undifferentiated. But that may be a misnomer. It may be that a fully differentiated cell, under the proper conditions, can revert back and become a precursor cell or maybe even a more primitive cell like a stem cell. As long as a cell has an intact nucleus, nothing is really impossible.

Secondly, some say a stem cell has the ability to replicate almost endlessly. But that isn’t necessarily the case either. Even the best characterized stem cell – the hematopoietic stem cell – is not immortal. Each hematopoietic stem cell can only repopulate blood cells a certain number of times before it becomes exhausted.

How does this “stemness” translate to the periodontium? Let’s start with the periodontal ligament. We
know it’s possible to take a periodontal ligament and treat it with enzymes to release single cells. Within that mixed population of cells, there are some that have the ability to recreate fibers that look a lot like those in a periodontal ligament. Whether the fibers can function as a periodontal ligament I think is still on the table for discussion. These cells were discovered here at NIDCR about four years ago, and this lead is actively being pursued. It’s also not clear where the cell comes from and whether it’s truly a stem cell or a useful progenitor cell. I think that is something that we need to take into consideration.

What do you mean?
Having a stem cell is a wonderful thing. Knowing about it is a wonderful thing. But the slightly more committed progenitors also can do wonderful things. We shouldn’t dismiss them just because they don’t self-renew or produce more than one cell type. If they’re useful in a regenerative way, that’s fine. They don’t have to be a stem cell to be useful.

What about alveolar bone of the tooth socket?
Stem cells that make bone have been under study since the mid-1990s. Obviously, they have great potential in regenerating the periodontium. If you don’t have bone to anchor the tooth, you have no foundation. But we really need to know how this type of bone is different from the axial and appendicular bone found elsewhere in the body. They have a different embryonic origin, and their properties appear to be slightly different. We don’t know how that is. Nor do we know the impact of these differences. For example, can we take bone marrow from the iliac crest of the pelvis and use it to regenerate craniofacial bone, including alveolar bone? That’s a huge question, and we really don’t know much about it.

What about cementum?
Well, I just mentioned the periodontal ligament cells. They also make something that appears to be cementum. In addition, a number of years ago, we took shavings of cementum and could get cells to grow out of those shavings in a clonal fashion. When we took the cells, put them in a scaffold and transplanted them into our animal model, they formed tissue that resembled cementum. The problem is we don’t really know whether cementum is different from bone. We don’t have any cementum specific markers to answer that question. It may just be that osteogenic cells form a cementum-like structure when they are in close proximity to dentin-forming cells. So, the boundaries between cementum and bone are very subtle. It’s difficult to say that they are truly two distinct entities. Maybe under the right conditions, cells that normally would be osteogenic could be made to be cementogenic.

Are you confident that the regeneration of the periodontium will be doable down the road?
I am confident. We have cells that we can begin to use to try and create a viable tooth. But there is a major hurdle in trying to construct a root that will provide a solid anchor within the jawbone. And we need to bring a broader array of expertise to the table. We need more people with expertise in bioinformatics, biomaterials, biochemistry and clinicians to help us design appropriate animal models that mimic a given human disease. There can be a perception that it’s only a tooth. It’s not going to kill you if you don’t have one. But try to tell that to somebody with a bad toothache. Dental problems cut across all aspects of society, and their solutions potentially benefit everyone. Secondly, the mouth is readily accessible, unlike the body’s internal organs such as the pancreas or liver. The lessons learned in the oral cavity might not be a perfect fit in learning to better treat osteoporosis or kidney cancer, but they will have applicability.

Conclusion
There are many challenges in the study of the human molecular genetics, and researchers are involved from many different areas and in many different ways. We have learned from the interviews above that researchers are confident that eventually they will be able to engineer or build a tooth, and will see tissue regeneration or self renewal from stem cells that have the ability to produce a new generation of stem cells. Additional scientific progress in the neurosciences will have broad implications for the diagnosis and treatment of diseases and disorders of the craniofacial system. The approach to design and fabricate bioelectronics to be used in the replacement of human enamel or dentin of the surfaces of teeth is another scientific breakthrough. The continued study of the fabrication of biomaterials to be used in the advances toward repair and regeneration of cartilage, bone, muscle, teeth, (cementum, dentin, enamel and periodontal ligament) offers another focus. Dental professionals are indeed ready to face the future.

Reference
* www.nidcr.nih.gov/facingthefuture.htm National Institute of Dental and Craniofacial Research

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FACING THE FUTURE: NIDCR RESEARCHERS OFFER THEIR VISION OF THE 21ST CENTURY

Final Examination Questions

Choose True or False for questions 1 through 5 and mark your answers online at www.onlinedentalCE.com.

1. The interaction between ectoderm and mesoderm is a classic mode of embryonic tissue formation.
   - True
   - False

2. Neural crest and the surrounding ectodermal cells generate the development programs that produce vertebrate structures as distinct as the beak of a toucan, the tusk of a boar or the gland of a rattlesnake.
   - True
   - False

3. The pharyngeal arches are also called the branchial arches in fish.
   - True
   - False

4. Neural crest cells are endowed with an innate plasticity but cannot make developmental modifications.
   - True
   - False

5. Tooth enamel is an organism that is dead when it is being made.
   - True
   - False
CHAPTER 6
NITROUS OXIDE – N₂O
(6 CE Hours)

Learning objectives
▶ Review the history of nitrous oxide.
▶ Describe the production of nitrous oxide.
▶ List the uses of nitrous oxide.
▶ Explain the use of nitrous oxide in dental operatories.
▶ Describe the hazards in the workplace.
▶ Review the methods of engineering control and training.

Introduction
Sedation dentistry, sometimes called relaxation dentistry, refers to the way dentists manage pain and anxiety during dental appointments.

Conscious sedation is defined as a minimally depressed level of consciousness that retains the patient’s ability to independently and continuously maintain an airway and respond appropriately to physical stimulation and verbal command that is produced by pharmacological or nonpharmacologic method or a combination of both. Nitrous oxide is only one of the 14 different ways that sedation drugs can be administered.

There are three primary ways that sedation is administered in the dental office: IV sedation, enteral conscious sedation and inhalation conscious sedation or nitrous oxide.

Inhalation conscious sedation or the use of nitrous oxide, commonly known as laughing gas, is a chemical compound with the formula N₂O. It is an oxide of nitrogen. At room temperature, it is a colorless non-flammable gas with a pleasant, slightly sweet odor and taste. It is used in surgery and dentistry for its anesthetic and analgesic effects. It is known as “laughing gas” because of the euphoric effects of inhaling it, a property that has led to its recreational use as a dissociative hallucinogen. It is also used as an oxidizer in rocketry and in motor racing to increase the power output of engine. At elevated temperatures, nitrous oxide is a powerful oxidizer similar to molecular oxygen. For example, nitrous oxide in a test tube will re-ignite a smoldering split.

Nitrous oxide reacts with ozone and is the main naturally occurring regulator of stratospheric ozone. It is also a major greenhouse gas and air pollutant. Considered over a 100-year period, it has 298 times more impact per unit weight than carbon dioxide.

History
The gas was first synthesized by English chemist and Unitarian minister Joseph Priestley in 1772, who called it phlogistinated nitrous air. Priestley published his discovery in the book “Experiments and Observations on Different Kinds of Air” (1775), where he described how to produce the preparation of “nitrous air diminished” by heating iron filings dampened with nitric acid.

Early use (1794-1843)
The first important use of nitrous oxide was made possible by Thomas Beddoes and the renowned engineer James Watt, who worked together to publish the book “Considerations on the Medical Use and on the Production of Factitious Air” (1794). This book was important for two reasons. First, James Watt had invented a novel machine to produce “factitious airs” (i.e. nitrous oxide) and a novel “breathing apparatus” to inhale the gas. Second, the book also presented the new medical theories by Thomas Beddoes, that tuberculosis and other lung diseases could be treated by inhalation of factitious airs.

The machine to produce factitious airs was comprised of three parts: a furnace to burn the needed material, a vessel with water where the produced gas passed through in a spiral pipe (in order for impurities to be “washed off”), and finally the gas cylinder with a gasometer where the produced air could be tapped into portable air bags (made of airtight oily silk). The breathing apparatus was one of the portable air bags connected with a tube to a mouthpiece. With this new equipment engineered and produced already in 1794, the way was now paved for clinical trials, which began when Thomas Beddoes in 1798 established the Pneumatic Institution for Relieving Diseases by Medical Airs in Clifton (Bristol). In the basement of the building, a large-scale machine was producing the gases under the supervision of a young Humphry Davy, who was encouraged to experiment with new gases for patients to inhale. The first important work of Davy was to examine the nitrous oxide, with the results being published in his book: “Researches, Chemical and Philosophical” (1800).

Despite the valuable finding made by Davy, that inhalation of nitrous oxide could relieve a conscious person from pain, another 44 years would elapse before doctors attempted to use it for anesthesia.

Anesthetic use
At a “popular science” exhibition in Hartford, Connecticut, where volunteers inhaled nitrous oxide, local dentist Horace Wells noted one of them, a man who had injured his leg, seemed unaware of any pain from the injury. Thus was born the first use of nitrous oxide as anesthetic drug. Wells himself, with assistance by Gardner Quincy Colton and John Mankey Riggs, demonstrated insensitivity to pain from a dental extraction in December 1844. In the following weeks, Wells treated the first 12–15 patients with nitrous oxide in Hartford, and according to his own record, only failed in two cases. In spite of these convincing results reported by Wells to the medical society in Boston in December 1844, this new method was not immediately adopted by other dentists. This probably was because in January 1845, Wells had been partly unsuccessful at his first public demonstration of the use of nitrous oxide for the medical faculty in Boston, leaving his colleagues doubtful regarding its efficacy and safety.

The method did not come into general use until 1863, when Colton successfully started to use it in all his Colton Dental Association clinics, which he just had established in New Haven and New York City. Over the following three years, Colton and his associates successfully administered nitrous oxide to more than 25,000 patients. With its efficacy and safety now demonstrated by large numbers, the usage of nitrous oxide rapidly became the preferred anesthetic method in dentistry. Because the gas is mild enough to keep a patient in a conscious and conversational state but in most cases is strong enough to suppress the pain caused by dental work, it remains the preferred agent in dentistry today.

In hospitals, however, nitrous oxide was found not to be a strong enough for use in large operations. A stronger and more potent anesthetic, sulfuric ether, was instead demonstrated and accepted for use in October 1846, along with chloroform in 1847. When Joseph Thomas Clover invented the “gas-ether inhaler” in 1876, it became a common practice at hospitals to initiate all anesthetic treatments with a mild flow of nitrous oxide, and then gradually increase the anesthesia with the stronger ether/chloroform. Clover’s gas-ether inhaler was designed to supply the patient with nitrous oxide and ether at the same time, with the exact mixture controlled by the operator of the device. It remained in use by many hospitals until the 1930s. Although hospitals today are using a more advanced anesthetic machine, these machines still use the same principle launched with Clover’s gas-ether inhaler, to initiate the anesthesia with nitrous oxide before the administration of a more powerful anesthetic.

Production
Nitrous oxide is most commonly prepared by careful heating of ammonium nitrate, which decomposes into nitrous oxide and water vapor. The addition of various phosphates favors formation of a purer gas at slightly lower temperatures. One of the earliest commercial producers was George Poe in Trenton, New Jersey.

- NH₄NO₃ (s) → 2 H₂O (g) + N₂O (g)
- This reaction occurs between 170–240 degrees C, temperatures where ammonium nitrate is a moderately sensitive explosive and a very powerful oxidizer. Above 240 degrees C, the exothermic reaction may accelerate to the point of detonation, so the mixture must be cooled to avoid such a disaster. Superheated steam is used to reach reaction temperature in some turnkey production plants.

Downstream, the hot, corrosive mixture of gases must be cooled to condense the steam and filtered to remove higher oxides of nitrogen. Ammonium nitrate smoke, as an extremely persistent colloid, will also have to be removed. The cleanup is
often done in a train of three gas washes, base, acid and base again. However, significant amounts of nitric oxide (NO) may not necessarily be absorbed directly by the base (sodium hydroxide) washes. The nitric oxide impurity is sometimes chelated out with ferrous sulfate, reduced with iron metal or oxidized and absorbed in base as a higher oxide. The first base wash may (or may not) react out much of the ammonium nitrate smoke. However, this reaction generates ammonia gas, which may have to be absorbed in the acid wash.

**Other routes**

The direct oxidation of ammonia may someday rival the ammonium nitrate pyrolysis synthesis of nitrous oxide mentioned above. This capital-intensive process, which originates in Japan, uses a manganese dioxide-bismuth oxide catalyst: 

- \(2 \text{NH}_2\text{SO}_3 + 2 \text{O}_2 \rightarrow \text{N}_2\text{O} + 2 \text{H}_2\text{SO}_4\) 
- Higher oxides of nitrogen are formed as impurities. In comparison, uncatalyzed ammonia oxidation (i.e. combustion or explosion) goes primarily to \(\text{N}_2\) and \(\text{H}_2\text{O}\).

Nitrous oxide can be made by heating a solution of sulfamic acid and nitric acid. Many gases are made this way in Bulgaria.

- \(\text{HNO}_3 + \text{NH}_2\text{SO}_3 \rightarrow \text{N}_2\text{O} + \text{H}_2\text{SO}_4 + \text{H}_2\text{O}\)
- There is no explosive hazard in this reaction if the mixing rate is controlled. However, as usual, toxic higher oxides of nitrogen are formed.

Nitrous oxide is produced in large volumes as a byproduct in the synthesis of adipic acid, one of the two reactants used in nylon manufacture. This might become a major commercial source, but will require the removal of higher oxides of nitrogen and organic impurities. Currently, much of the gas is decomposed before release for environmental protection. Greener processes may prevail that substitute hydrogen peroxide for nitric acid oxidation; hence no generation of oxide of nitrogen by-products.

Hydroxylammonium chloride can react with sodium nitrite to produce \(\text{N}_2\text{O}\) as well:

- \(\text{NH}_2\text{OH}^+\text{Cl}^- + \text{NaNO}_2 \rightarrow \text{N}_2\text{O} + \text{NaCl} + 2 \text{H}_2\text{O}\)
- If the nitrite is added to the hydroxylamine solution, the only remaining byproduct is salt water. However, if the hydroxylamine solution is added to the nitrite solution (nitrite is in excess), then toxic higher oxides of nitrogen are also formed.

**Applications**

**Rocket motors**

Nitrous oxide can be used as an oxidizer in a rocket motor. This has the advantages over other oxidizers that it is non-toxic, and because of its stability at room temperature, easy to store and relatively safe to carry on a flight. As a secondary benefit, it can be readily decomposed to form breathing air. Its high density and low storage pressure enable it to be highly competitive with stored high-pressure gas systems.

In a 1914 patent, American rocket pioneer Robert Goddard suggested nitrous oxide and gasoline as possible propellants for a liquid-fueled rocket. Nitrous oxide has been the oxidizer of choice in several hybrid rocket designs (using solid fuel with a liquid or gaseous oxidizer). The combination of nitrous oxide with hydroxyl-terminated polybutadiene fuel has been used by SpaceShipOne and others. It is also notably used in amateur and high power rocketry with various plastics as the fuel.

Nitrous oxide can also be used in a monopropellant rocket. In the presence of a heated catalyst, \(\text{N}_2\text{O}\) will decompose exothermically into nitrogen and oxygen, at a temperature of approximately 1,300 degrees C. Because of the large heat release, the catalytic action rapidly becomes secondary as thermal autodecomposition becomes dominant. In a vacuum thruster, this can provide a monopropellant specific impulse (isp) of much as 180s. While noticeably less than the isp available from hydrazine thrusters (monopropellant or bipropellant with nitrogen tetroxide), the decreased toxicity makes nitrous oxide an option worth investigating.

Specific impulse \(I_e\) can be improved by blending a hydrocarbon fuel with the nitrous oxide inside the same storage tank, becoming a nitrous oxide fuel blend (NOFB) monopropellant. This storage mixture does not incur the danger of spontaneous ignition because \(\text{N}_2\text{O}\) is chemically stable. When the nitrous oxide decomposes by a heated catalyst, high-temperature oxygen is released and rapidly ignites the hydrocarbon fuel blend. NOFB monopropellants are capable of \(I_e\) greater than 300 seconds, while avoiding the toxicity associated with hypergolic propulsion systems. The low freezing point of NOFB eases thermal management compared to hydrazine and dinitrogen tetroxide – a valuable property for space storable propellants.

**Internal combustion engine**

In vehicle racing, nitrous oxide (often referred to as just “nitrous” or as NOS after the name of the brand Nitrous Oxide Systems) allows the engine to burn more fuel and air, resulting in a more powerful combustion. The gas itself is not flammable, but it delivers more oxygen than atmospheric air by breaking down at elevated temperatures.

Nitrous oxide is stored as a compressed liquid; the evaporation and expansion of liquid nitrous oxide in the intake manifold causes a large drop in intake charge temperature, resulting in a denser charge, further allowing more air/fuel mixture to enter the cylinder. Nitrous oxide is sometimes injected into (or prior to) the intake manifold, whereas other systems directly inject right before the cylinder (direct port injection) to increase power.

The technique was used during World War II by Luftwaffe aircraft with the GM-1 system to boost the power output of aircraft engines. Originally meant to provide the Luftwaffe standard aircraft with superior high-altitude performance, technological considerations limited its use to extremely high altitudes. Accordingly, it was only used by specialized planes like high-altitude reconnaissance aircraft, high-speed bombers and high-altitude interceptor aircraft.

One of the major problems of using nitrous oxide in a reciprocating engine is that it can produce enough power to damage or destroy the engine. Very large power increases are possible, and if the mechanical structure of the engine is not properly reinforced, the engine may be severely damaged or destroyed during this kind of operation. It is very important with nitrous oxide augmentation of internal combustion engines to maintain proper operating temperatures and fuel levels to prevent “pre-ignition” or “detonation” (sometimes referred to as “knocking” or “pinging”). Most problems that are associated with nitrous do not come from mechanical failure due to the power increases. Since nitrous allows a much denser charge into the cylinder, it dramatically increases cylinder pressures. The increased pressure and temperature can cause problems, such as melting the piston or valves. It may also crack or warp the piston or head and cause pre-ignition due to uneven heating.

**Aerosol propellant**

The gas is approved for use as a food additive (also known as E942), specifically as an aerosol spray propellant. Its most common uses in this context are in aerosol whipped cream canisters, cooking sprays and as an inert gas used to displace oxygen and inhibit bacterial growth when filling packages of potato chips and other similar snack foods.

The gas is extremely soluble in fatty compounds. In aerosol whipped cream, it is dissolved in the fatty cream until it leaves the can, when it becomes gaseous and thus creates foam. Used in this way, it produces whipped cream four times the volume of the liquid, whereas whipping air into cream only produces twice the volume. If air were used as a propellant, oxygen would accelerate rancidification of the butterfat; nitrous oxide inhibits such degradation. Carbon dioxide cannot be used for whipped cream because it is acidic in water, which would curdle the cream and give it a seltzer-like “sparkling” sensation. However, the whipped cream produced with nitrous oxide is unstable and will return to a liquid state within half an hour to one hour. Thus, the method is not suitable for decorating food that will not be immediately served.

Similarly, cooking spray, which is made from various types of oils combined with lecithin (an emulsifier), may use nitrous oxide as a propellant; other propellants used in cooking spray include food-grade alcohol and propane.

Users of nitrous oxide for recreational use as a euphoria-inducing inhalant drug, often obtain it from whipped cream dispensers that use nitrous oxide as a propellant. It is not harmful in small doses, but risks due to lack of oxygen do exist (see Recreational section).
Recreational use

Nitrous oxide (N₂O) is a dissociative drug that can cause analgesia, depersonalization, dizziness, euphoria and some sound distortion. Research has also found that it increases suggestibility and imagination. Inhalation of nitrous oxide for recreational use to cause euphoria and slight hallucinations began as a phenomenon for the British upper class in 1799 at "laughing gas parties." When equipment became more widely available for dentistry and hospitals, most countries also restricted the legal access to buy pure nitrous oxide gas cylinders to those sectors. A low availability of equipment to produce the gas combined with a low usage of the gas for medical purposes meant recreational use was a relatively rare phenomenon that mainly took place among students at medical universities. That apparently continued into the 20th century. A poll taken in 1979 indicated that between 1 and 2 percent of medical and dental students used nitrous oxide for recreational purposes, according to Theodore J. Jastak in a 1991 article in the Journal of the American Dental Association.

In the 1960 and '70s, the recreational use of inhalants became somewhat fashionable again, according to a Consumers Union report in 1972 based on reports of use in Maryland and Vancouver and a survey at the University of Michigan in 1970.

According to the Michigan survey: “It was not uncommon [in the interviews] to hear from individuals who had been to parties where a professional (doctor, nurse, scientist, inhalation therapist, researcher) had provided nitrous oxide. There also were those who work in restaurants who used the N₂O stored in tanks for the preparation of whip cream. Reports were received from individuals who used the gas contained in aerosol cans both of food and non-food products. At a rock festival, nitrous oxide was widely sold for 25 cents a balloon. Contact was made with a ‘mystical-religious’ group that used the gas to accelerate arriving at their transcendent-al-meditative state of choice. Although a few more sophisticated users employed nitrous oxide—oxygen mixes with elaborate equipment, most users employed balloons or plastic bags. They either held a breath of N₂O or rebreathed the gas. There were no adverse effects reported in the more than 100 individuals surveyed.”

Although recreational use is believed to be somewhat limited today, government data on substance abuse of youths shows that inhalants, including nitrous oxide, are being used by young people.

The Substance Abuse and Mental Health Services Administration (SAMHSA) said in its 2007 report on trends in drug use that almost 1 million youth had used inhalants within the past year. The percentage of young people aged 12-17 who had used all inhalants within the past year was lower in 2007 (3.9 percent) than in 2003 (4.5 percent), in 2004 (4.6 percent), and in 2005 (4.5 percent). Among first-time users, the rate of use of nitrous oxide, or “whippets” – usually canisters of the propellants to create whipped cream – declined between 2002 and 2007 among males (40.2 percent to 20.2 percent) and females (22.3 percent to 21.2 percent).

However, an investigation in 2009 by the Bristol (Va.) Herald Courier reported that the records of 46 health care professionals in the area – including doctors, nurses, pharmacists and dentists – were “marred by substance abuse, and in some cases, criminal convictions.” The Herald Courier told the story of a Big Stone Gap, Va., dentist who “huffed nitrous oxide in the mid-1970s and quit only after a temporary loss of feeling in his hands.” From there, the dentist descended into alcoholism and took Valium and Hydrocodone from his office, the newspaper said.

A grassroots drug-recovery group of Virginia dentists directed the man to a rehab program. The state board of dentistry got an anonymous call about his situation. Instead of disciplinary action, the board helped monitor his recovery. According to the newspaper, keeping additions confidential is at the discretion of either a Department of Health Professions investigator or a licensing board.

A board of medicine official said the policy protected the public by “making sure the individual is identified and investigated, set for an evaluation and treatment, and continue with monitoring. They (the Virginia monitoring program) will not OK a doctor to go back into practice until he or she is believed to be safe.”

That is a common practice. The Federation of State Physician Health Programs Inc. (FSPHP) evolved in 1990 from an initiative of the American Medical Association and individual state physician health programs that focus upon rehabilitation and monitoring of physicians with psychotoxic substance abuse disorders as well as mental and physical illness. The nonprofit organization includes members from 42 state programs.

FSPHP serves as a resource for state programs; helps to establish monitoring standards; serves as an informational source; advocates for physicians and their health issues at local state and national levels; and helps states in their quest to protect the public. The organization promotes confidentiality for health care professionals who chose to address their substance problems and submit to rigorous monitoring of their progress.

A 2003 report in the Journal of the California Dental Association [Malamed and Clark] cited concerns about abuse of nitrous oxide by health care professionals. The authors said nitrous oxide causes euphoria and can include “sexual phenomena,” including increased feelings of sexuality and arousal, and therefore has the potential for abuse. “This abuse is usually not as addictive as some drugs, but nonetheless can be a steppingstone to other drugs and can cause incapacitation of the affected person. Nitrous oxide should be given the same respect as all drugs.”

The typical abuser of nitrous oxide is older and middle- or upper class, they said. If the abuser has an inhalation sedation unit available, it may have been altered to deliver a higher concentrate of gas, they said.

The authors noted there have been reports of sexual abuse of patients under anesthetics, including nitrous oxide. They noted there are three elements that put a practitioner at risk: treating a patient without an assistent in the operatory, high concentrations of nitrous oxide, and failure to titrate the patient to avoid extension of therapeutic sedation.

“Nitrous oxide should be employed with confidence. Employing simple guidelines will ensure there are no difficulties with sexual issues and the administrator of nitrous oxide,” they said.

In medicine

Nitrous oxide has been used for anesthesia in dentistry since December 1844, when Horace Wells made the first dental operations with the gas in Hartford. Its debut as a generally accepted method came in 1863, when Gardner Quincy Colton introduced it more broadly at all the Colton Dental Association clinics. The first devices used in dentistry to administer the gas, known as nitrous oxide inhalers, were designed in a very simple way, with the gas stored and breathed through a breathing bag made of rubber cloth, without a scavenger system and flow meter, and with no addition of oxygen/air.

Today these simple and somewhat unreliable inhalers, of course, have been replaced by the more modern relative analgesia machine, which is an automated machine designed to deliver a precisely dosed and breath-actuated flow of nitrous oxide mixed with oxygen for the patient to inhale safely. The machine used in dentistry is designed as a more simplified version of the larger anesthetic machine used by hospitals, and it doesn’t feature the additional anesthetic vaporizer and medical ventilator. The machine allows for a more simple design, because it only delivers a mixture of nitrous oxide and oxygen for the patient to inhale to depress the feeling of pain while keeping the patient in a conscious state.

The relative analgesia machine typically features a constant-supply flow meter, which allows the proportion of nitrous oxide and the combined gas flow rate to be individually adjusted. The gas is administered by dentists through a demand-valve inhaler over the nose, which will only release gas when the patient inhales through the nose. Because nitrous oxide is minimally metabolized in humans (with a rate of 0.004 percent), it retains its potency when exhaled into the room by the patient and can pose an intoxicating and prolonged exposure hazard to the clinic staff if the room is poorly ventilated. Where nitrous oxide is administered, a continuous-flow fresh-air ventilation system or nitrous scavenger system is used to prevent a waste-gas buildup.

Hospitals are administering nitrous oxide as one of the anesthetic drugs delivered by anesthetic.
molecules. Nitrous oxide is a weak general anesthetic, and so is generally not used alone in general anesthesia. In general anesthesia it is used as a carrier gas in a 2:1 ratio with oxygen for more powerful general anesthetic drugs such as sevoflurane or desflurane. It has a MAC (minimum alveolar concentration) of 105 percent and a blood gas partition coefficient of 0.46.

When nitrous oxide is inhaled as the only anesthetic drug, it is normally administered as a mixture with 30 percent gas and 70 percent oxygen.

**Neuropharmacology**
The pharmacological mechanism of action of N₂O in medicine is not fully known. However, it has been shown to directly modulate a broad range of ligand-gated ion channels, and this likely plays a major role in many of its effects. It moderately blocks NMDA and β₂-subunit-containing nACh channels; weakly inhibits AMPA, kainate, GABAₐ, and 5-HT receptors; and slightly potentiates GABAₐ and glycine receptors. It has also been shown to activate two-pore-domain K⁺ channels. While N₂O affects quite a few ion channels, its anesthetic, hallucinogenic and euphoriant effects are likely caused predominantly or fully via inhibition of NMDAR-mediated currents. In addition to its effects on ion channels, N₂O may act to imitate nitric oxide (NO) in the central nervous system as well, and this may relate to its analgesic and anxiolytic properties.

**Anxiolytic effect**
In behavioral tests of anxiety, a low dose of N₂O is an effective anxiolytic, and this anti-anxiety effect is associated with enhanced activity of GABAₐ receptors as it is partially reversed by benzodiazepine receptor antagonists. Mirroring this, animals that have developed tolerance to the anxiolytic effects of benzodiazepines are partially tolerant to N₂O. Indeed, in humans given 30 percent N₂O, benzodiazepine receptor antagonists reduced the subjective reports of feeling “high,” but did not alter psychomotor performance in human clinical studies.

**Analgesic and anti-nociceptive effect**
The analgesic effects of N₂O are linked to the interaction between the endogenous opioid system and the descending noradrenergic system. When animals are given morphine chronically, they develop tolerance to its pain-killing effects, and this also renders the animals tolerant to the analgesic effects of N₂O. Administration of antibodies that bind and block the activity of some endogenous opioids (not β-endorphin) also block the anti-nociceptive effects of N₂O. Drugs that inhibit the breakdown of endogenous opioids also potentiate the anti-nociceptive effects of N₂O. Several experiments have shown that opioid receptor antagonists applied directly to the brain block the anti-nociceptive effects of N₂O but these drugs have no effect when injected into the spinal cord.

Conversely, α₂-adrenoceptor antagonists block the anti-nociceptive effects of N₂O when given directly to the spinal cord, but not when applied directly to the brain. Indeed, α₂-adrenoceptor knockout mice or animals depleted in norepinephrine are nearly completely resistant to the anti-nociceptive effects of N₂O. It seems N₂O-induced release of endogenous opioids causes disinhibition of brain stem noradrenergic neurons, which release norepinephrine into the spinal cord and inhibit pain signaling. Exactly how N₂O causes the release of endogenous opioid peptides is still uncertain.

**Euphoric effect**
In rats, N₂O stimulates the mesolimbic reward pathway via inducing dopamine release and activating dopaminergic neurons in the ventral tegmental area and nucleus accumbens, presumably through antagonization of NMDA receptors localized in the system. This action has been implicated in its euphoric effects, and notably, appears to augment its analgesic properties as well.

However, it is remarkable that in mice, N₂O blocks amphetamine-induced and dopamine release in the nucleus accumbens and behavioral sensitization, abolishes the conditioned place preference (CPP) of cocaine and morphine, and does not produce reinforcing (or aversive) effects of its own. Studies on CPP of N₂O in rats is mixed, consisting of reinforcement, aversion and no change. In contrast, it is a positive reinforcer in squirrel monkeys, and is well known as a drug of abuse in humans. These discrepancies in response to N₂O may reflect specie variations or methodological differences. It is noteworthy that in human clinical studies, N₂O was found to produce mixed responses similarly to rats, reflecting high subjective individual variability.

**Neurotoxicity**
Similarly to other NMDA antagonists like ketamine, N₂O has been demonstrated to produce neurotoxicity in the form of Olney’s lesions (damage to the posterior cingulate and retrosplenial cortices) in rodents upon prolonged (e.g., several hours) exposure. However, it also simultaneously exerts widespread neuroprotective effects via inhibiting glutamate-induced and it has been argued that on account of its very short duration under normal circumstances, N₂O may not share the neurotoxicity of other NMDA antagonists. Indeed, in rodents, short-term exposure results in only mild injury that is rapidly reversible, and permanent neuronal death only occurs after constant and sustained exposure.

**Safety**
The major safety hazards of nitrous oxide come from the fact that it is a compressed liquefied gas, an asphyxiation risk and a dissociative anesthetic. Exposure to nitrous oxide causes short-term decreases in mental performance, audiovisual ability and manual dexterity. Long-term exposure can cause vitamin B₁₂ deficiency, numbness, reproductive side effects and other problems.

The National Institute for Occupational Safety and Health recommends that workers’ exposure to nitrous oxide should be controlled during the administration of anesthetic gas in medical, dental and veterinary operators.

**Chemical/physical**
At room temperature (20 degrees C), the saturated vapor pressure is 58.5 bar, rising up to 72.45 bar at 36.4 degrees C – the critical temperature. The pressure curve is thus unusually sensitive to temperature. Liquid nitrous oxide acts as a good solvent for many organic compounds; liquid mixtures may form shock-sensitive explosives.

As with many strong oxidizers, contamination of parts with fuels have been implicated in rocketry accidents, where small quantities of nitrous/fuel mixtures explode due to “water hammer-like” effects (sometimes called “dieseling” – heating caused by adiabatic compression of gases that can reach decomposition temperatures). Some common building materials, such as stainless steel and aluminum, can act as fuels with strong oxidizers such as nitrous oxide, as can contaminants, which can ignite due to adiabatic compression.

There have also been accidents where nitrous oxide decomposition in plumbing has led to the explosion of large tanks.

**Biological**
Nitrous oxide inactivates the cobalamin form of vitamin B₁₂ by oxidation. Symptoms of vitamin B₁₂ deficiency, including sensory neuropathy and encephalopathy, can occur within days or weeks of exposure to nitrous oxide anesthesia in people with subclinical vitamin B₁₂ deficiency. Symptoms are treated with high doses of vitamin B₁₂, but recovery can be slow and incomplete. People with normal vitamin B₁₂ levels have stores to make the effects of nitrous oxide insignificant, unless exposure is repeated and prolonged (nitrous oxide abuse). Vitamin B₁₂ levels should be checked in people with risk factors for vitamin B₁₂ deficiency prior to using nitrous oxide anesthesia.

A study of workers and several experimental animal studies indicate that adverse reproductive effects for pregnant females may also result from chronic exposure to nitrous oxide.

**Flammability**
Nitrous oxide is a non-flammable gas at room temperature.

The National Fire Protection Association has not assigned a flammability rating to nitrous oxide:
- Flash point: Not applicable.
- Autoignition temperature: Not applicable.
- Flammable limits in air: Not applicable.
- Extinguishing: For small fires, use dry chemical or carbon dioxide. Use water spray, fog or standard foam to fight large fires involving nitrous oxide.
Fires involving nitrous oxide should be fought upwind from the maximum distance possible. Keep unnecessary people away; isolate the hazard area and deny entry. Isolate the area for ½-mile in all directions if a tank, rail car or tank truck is involved in the fire. For a massive fire in a cargo area, use unmanned hose holders or monitor nozzles; if this is impossible, withdraw from the area and let the fire burn. Emergency personnel should stay out of low areas and ventilate closed spaces before entering. Vapors are an explosion hazard indoors, outdoors or in sewers. Containers of nitrous oxide may explode in the heat of the fire and should be moved from the fire area if it is possible to do so safely. If this is not possible, cool fire-exposed containers from the sides with water until well after the fire is out. Stay away from the ends of containers. Firefighters should wear a full set of protective clothing and self-contained breathing apparatus when fighting fires involving nitrous oxide.

Environmental
Nitrous oxide is a greenhouse gas, accounting for about 6 percent of the heating effect of greenhouse gases in the atmosphere. According to 2006 data from the United States Environmental Protection Agency, industrial sources make up only about 20 percent of all anthropogenic sources, and include the production of nylon and the burning of fossil fuel in internal combustion engines. Human activity is thought to account for 30 percent; tropical soils and oceanic release account for 70 percent. However, a 2008 study by Nobel Laureate Paul Crutzen suggests that the amount of nitrous oxide release attributable to agricultural nitrate fertilizers has been seriously underestimated, most of which would presumably come under soil and oceanic release in the Environmental Protection Agency data. Nitrous oxide also causes ozone depletion. A recent study suggests that N₂O emission currently is the single most important ozone-depleting substance (ODS) emission and is expected to remain the largest throughout the 21st century.

Legality
In the United States, possession of nitrous oxide is legal under federal law and is not subject to DEA purview. It is, however, regulated by the Food and Drug Administration under the Food Drug and Cosmetics Act; prosecution is possible under its “misbranding” clauses, prohibiting the sale or distribution of nitrous oxide for the purpose of human consumption.

Many states have laws regulating the possession, sale and distribution of nitrous oxide. Such laws usually ban distribution to minors or limit the amount of nitrous oxide that may be sold without special license. In the state of California, possession for recreational use is prohibited and qualifies as a misdemeanor.

In some countries, it is illegal to have nitrous oxide systems plumbed into an engine’s intake manifold. These laws are ostensibly used to prevent street racing and to meet emission standards. Nitrous oxide is entirely legal to possess and inhale in the United Kingdom, although supplying it to others to inhale, especially minors, is more likely to end up with a prosecution under the Medicines Act.

In New Zealand, the Ministry of Health has warned that nitrous oxide is a prescription medicine, and its sale or possession without a prescription is an offense under the Medicines Act. This statement would seemingly prohibit all non-medical uses of the chemical, though it is implied that only recreational use will be legally targeted.

In India, for general anesthesia purposes, nitrous oxide is available as nitrous oxide IP. India’s gas cylinder rules (1985) permit the transfer of gas from one cylinder to another for breathing purposes. This law benefits remote hospitals, which would otherwise suffer because of India’s geographic immensity. Nitrous oxide IP is transferred from bulk cylinders (17,000 liters capacity gas) to smaller pin-indexed valve cylinders (1,800 liters of gas), which are then connected to the yoke assembly of Boyle’s machines. Because India’s Food and Drug Authority (FDA-India) rules state that transferring a drug from one container to another (refilling) is equivalent to manufacturing, anyone found doing so must possess a drug-manufacturing license.

Nitrous oxide in dental operatories
The Engineering Control Technology Branch (ECTB) of the Division of Physical Sciences and Engineering studies the aspects of health hazard prevention and control in the workplace. Nitrous oxide (N₂O) mixed with oxygen has been used in dentistry as an analgesic and as a sedative for more than 100 years. Today, more than 424,000 workers who practice dentistry (such as dentists, dental assistants and dental hygienists) in the United States are potentially exposed to N₂O.

In a technical report published in 1977, the National Institute for Occupational Safety and Health recommended controlling exposure limits of nitrous oxide waste to 25 parts per million (ppm) of air during dental surgery. The report presented methods for limiting the waste during administration, based on the technical feasibility of existing controls. Since publication of this technical report, data collected by NIOSH have shown occupational exposures as high as 300 ppm in hospital operating rooms and exposures higher than 1,000 ppm in dental operatories equipped with scavenging systems (properly operating scavenging systems have been shown to reduce N₂O concentrations by more than 70 percent). The scavenging systems use local exhaust ventilation to collect waste gases from anesthetic breathing systems and remove them from the workplace.

Effects of exposure to high concentrations
Animal studies have shown adverse reproductive effects in female rats exposed to airborne concentrations of N₂O. Data from these studies indicate that exposure to N₂O during gestation can produce adverse health effects in the offspring.

Several studies of workers have shown that occupational exposure to N₂O causes adverse effects such as reduced fertility, spontaneous abortions and neurologic, renal and liver disease. A recent study reported that female dental assistants exposed to unscavenged N₂O for five or more hours per week had a significant risk of reduced fertility compared with unexposed female dental assistants. The exposed assistants had a 59 percent decrease in probability of conception for any given menstrual cycle compared with the unexposed assistants. For dental assistants who used scavenging systems during N₂O administration, the probability of conception was not significantly different from that of the unexposed assistants. Because environmental exposures were not measured during these epidemiologic studies, no dose-effect relationship could be established.

Exposure to high concentrations of waste anesthetic gases – even for a short time – may cause the following health effects:

- Headache.
- Irritability.
- Fatigue.
- Nausea.
- Drowsiness.
- Difficulties with judgment and coordination.
- Liver and kidney disease.

Workers exposed
In 1983, the American Dental Association (ADA) reported that 35 percent of all dentists used N₂O to control pain and anxiety in their patients [ADA 1983]. The ADA 1991 Survey of Dental Practice indicated that 58 percent of dentists reported having N₂O anesthetic equipment, and 64 percent of those practitioners also reported having a scavenging system. The percentage of pediatric dentists using N₂O increased from 65 percent in 1980 to 88 percent in 1988.

Occupational exposure limits
The Occupational Safety and Health Administration (OSHA) does not currently have a standard for N₂O.

The NIOSH recommended exposure limit (REL) for N₂O is 25 ppm as a time-weighted average (TWA) during the period of anesthetic administration [NIOSH 1977b]. This REL is intended to prevent decreases in mental performance, audiovisual ability and manual dexterity during exposures to N₂O. A recommended exposure limit to prevent adverse reproductive effects cannot be established until more data are available.

The American Conference of Governmental Industrial Hygienists' (ACGIH) threshold limit value (TLV) for N₂O is 50 ppm as an eight-hour time-weighted average [ACGIH 1993]. The 1991 Documentation of the Threshold Limit Values and Biological Exposure Indices states that "control to this level should prevent embryo-fetal toxicity in humans and significant decrements in human psychomotor and cognitive functions..."
or other adverse health effects in exposed personnel” [ACGIH 1991].

Medical surveillance
OSHA is currently developing requirements for medical surveillance. When these requirements are promulgated, readers should refer to them for additional information and to determine whether employers whose employees are exposed to nitrous oxide are required to implement medical surveillance procedures.

Medical screening
Workers who may be exposed to chemical hazards should be monitored in a systematic program of medical surveillance that is intended to prevent occupational injury and disease. The program should include education of employees and workers about work-related hazards, early detection of adverse health effects and referral of workers for diagnosis and treatment. The occurrence of disease or other work-related adverse health effects should prompt immediate evaluation of primary preventive measures (e.g., industrial hygiene monitoring, engineering controls, and personal protective equipment). A medical surveillance program is intended to supplement, not replace, such measures. To detect and control work-related health effects, medical evaluations should be performed (1) before job placement, (2) periodically during the term of employment, and (3) at the time of job transfer or termination.

Preplacement medical evaluation
Before a worker is placed in a job with a potential for exposure to nitrous oxide, a licensed health care professional should evaluate and document the worker’s baseline health status with thorough medical, environmental and occupational histories, a physical examination, and physiologic and laboratory tests appropriate for the anticipated occupational risks. These should concentrate on the function and integrity of the respiratory, reproductive, central nervous and hematological systems. Medical surveillance for respiratory disease should be conducted using the principles and methods recommended by the American Thoracic Society. A preplacement medical evaluation is recommended to assess medical conditions that may be aggravated or may result in increased risk when a worker is exposed to nitrous oxide at or below the prescribed exposure limit. The health care professional should consider the probable frequency, intensity and duration of exposure as well as the nature and degree of any applicable medical condition. Such conditions (which should not be regarded as absolute contraindications to job placement) include a history and other findings consistent with diseases of the respiratory, reproductive, central nervous or hematological systems.

Periodic medical evaluations
Occupational health interviews and physical examinations should be performed at regular intervals during the employment period, as mandated by any applicable federal, state or local standard. Where no standard exists and the hazard is minimal, evaluations should be conducted every three to five years or as frequently as recommended by an experienced occupational health physician. Additional examinations may be necessary if a worker develops symptoms attributable to nitrous oxide exposure. The interviews, examinations and medical screening tests should focus on identifying the adverse effects of nitrous oxide on the respiratory, reproductive, central nervous or hematological systems. Current health status should be compared with the baseline health status of the individual worker or with expected values for a suitable reference population.

Termination medical evaluations
The medical, environmental and occupational history interviews; the physical examination; and selected physiologic or laboratory tests that were conducted at the time of placement should be repeated at the time of job transfer or termination to determine the worker’s medical status at the end of his or her employment. Any changes in the worker’s health status should be compared with those expected for a suitable reference population.

Biological monitoring
Biological monitoring involves sampling and analyzing body tissues or fluids to provide an index of exposure to a toxic substance or metabolite. No biological monitoring test acceptable for routine use has yet been developed for nitrous oxide.

Workplace monitoring and measurement
Determination of a worker’s exposure to airborne nitrous oxide can be made using one of the following techniques:
- A Landauer Passive Dosimeter badge, which can be used for a minimum sampling duration of one hour (maximum duration 40 hours). Analysis is performed by the manufacturer of the badge as described in the OSHA Computerized Information System.
- An ambient air or bag sample with a minimum collection volume of two spectrophotometer cell volumes. Analysis is conducted using a long-path-length portable infrared spectrophotometer as described in NIOSH Method No. 6600.

Personal hygiene procedures
If liquid nitrous oxide contacts the skin, workers should flush the affected areas immediately with tepid water to reduce the likelihood of frostbite.

A large population of health care workers is potentially exposed to N2O and NIOSH has documented cases in which exposures substantially exceed existing recommended exposure limits. NIOSH has concluded that exposure to N2O causes decreases in mental performance, audiovisual ability and manual dexterity. Data from animal studies demonstrate that exposure to N2O may cause adverse reproductive effects. Studies of workers exposed to N2O have reported adverse health effects such as reduced fertility, spontaneous abortion, and neurological, renal, and liver disease. The recommendations in a 1994 NIOSH alert should therefore be followed to minimize worker exposures.

Recommendations
Engineering controls, work practices and respirators (when necessary) should be used to minimize the exposure of workers to N2O. Employers should ensure that their workers are adequately protected from N2O exposure by taking the following steps:
- Monitor airborne concentrations of N2O.
- Implement appropriate engineering controls, work practices and maintenance procedures.
- Institute a worker education program that:
  - Describes standard operating procedures for all tasks that may expose workers to N2O.
  - Informs workers about proper work practices, controls, equipment and protective gear that should be used when working with N2O.
- Use the guidelines in the following section to minimize worker exposures to N2O.

Guidelines for minimizing worker exposures

Exposure monitoring
Exposure monitoring should be the first step in developing work practices and worker education programs, because measurements of N2O are needed to determine the type and extent of controls that are necessary. Follow the guidelines below to minimize worker exposures:
- Monitor for N2O when the anesthetic equipment is installed and every three months thereafter. Include the following types of monitoring:
  - Leak testing of equipment.
  - Monitoring of air in the worker’s personal breathing zone.
  - Environmental (room air) monitoring.
- Prepare a written monitoring and maintenance plan for each facility that uses N2O. This plan should be developed by knowledgeable persons who consider the equipment manufacturers’ recommendations, frequency of use and other circumstances that might affect the equipment.
- Perform air monitoring by gasbag sampling or real-time sampling.
- When real-time sampling is conducted to obtain personal exposure data, attach the sampling train to the lapel of the worker on the side closest to the patient; N2O concentrations in this location are most representative of those in the worker’s breathing zone. Diffusive samplers (referred to as passive dosimeters) are commercially available and may be useful as initial indicators of exposures.

Engineering controls and maintenance procedures
The following engineering controls and maintenance procedures have been shown to be feasible and effective in reducing exposure to N2O during anesthetic administration.

 Elite CME
Anesthetic delivery. Excessive exposure to N₂O may occur as a result of leaks from the anesthetic delivery system during administration. The rubber and plastic components of the anesthetic equipment are potential sources of N₂O leakage because they may be degraded by the N₂O and the oxygen as well as by repeated sterilization.

Take the following steps to control N₂O exposure from anesthetic delivery systems:
- Use connection ports with different-diameter hoses for N₂O and O₂ to reduce the possibility of incorrectly connecting the gas delivery and scavenging hoses.
- Check all rubber hoses, connections, tubing and breathing bags daily and replace them when damaged or when recommended by the manufacturer.
- Following visual inspection, perform leak testing of the equipment and connections by using a soap solution to check for bubbles at high-pressure connections. For a more thorough inspection of all connectors, use a portable infrared spectrophotometer (such as a Miran 1A or 1B) calibrated for N₂O detection.
- Check both high- and low-pressure connections (such as O-rings) regularly, as they may become worn; replace them periodically, according to the manufacturer’s recommendations.
- Evaluate the N₂O and oxygen mixing system for leaks when it is first installed and periodically thereafter, according to the manufacturer’s recommendations.
- Ensure that gas cylinders are safely handled, used and stored as specified by the National Research Council and as required by OSHA Federal Code Rule Title 29, 1910.101.
- Sec. 1910.101 Compressed gases (general requirements).
- (a) Inspection of compressed gas cylinders. Each employer shall determine that compressed gas cylinders under his control are in a safe condition to the extent that this can be determined by visual inspection. Visual and other inspections shall be conducted as prescribed in the Hazardous Materials Regulations of the Department of Transportation (49 CFR parts 171-179 and 14 CFR part 103). Where those regulations are not applicable, visual and other inspections shall be conducted in accordance with Compressed Gas Association Pamphlets C-6-1968 and C-8-1962, which is incorporated by reference as specified in Sec. 1910.6.

Scavenging systems. Control of N₂O at the scavenging mask is the next priority after control of N₂O leakage from the anesthetic equipment. Leakage from the scavenging mask can be one of the most significant sources of N₂O exposure because the breathing zone of a dentist or dental assistant is within inches of the mask. NIOSH research has reported breathing-zone concentrations of N₂O above 1,000 ppm.

Take the following steps to control N₂O exposure from anesthetic scavenging systems:
- Supply scavenging masks in a variety of sizes so that the mask always fits comfortably and securely over the patient’s nose or face.
- Use an automatic interlock system to assure that the N₂O cannot be turned on unless the scavenging system is also activated. N₂O should never be used without a properly operating scavenging system.
- Make sure that the scavenging system exhaust rates (flow rates) are approximately 45 liters per minute (L/min) to minimize leakage of N₂O. Flow rates of less than 40 L/min may result in significant leakage around the mask. Monitor the flow rate with a flow meter that is:
  - Validated to measure airflow within 5 percent of actual airflow.
  - Permanently connected to the scavenging system vacuum line.
  - Positioned so that it is always visible to the operator.
- Maintain the flow meter by cleaning and recalibrating it according to the manufacturer’s recommendations.
- Use scavenging vacuum pumps that are powerful enough to maintain a scavenging flow rate of at least 45 L/min at each nasal mask, regardless of the number of scavenging units in use at one time.
- Vent N₂O from all scavenging vacuum pumps to the outside of the building away from fresh air intakes, windows or walkways. Scavenging system exhaust should not be vented into a recirculating ventilation system.

Room ventilation. Take the following steps to assure that the ventilation system effectively removes waste N₂O:
- If concentrations of N₂O are above 25 ppm in work areas, increase the airflow into the room or increase the percentage of outside air to allow for more air mixing and further dilution of the anesthetic gas. Maintain a balanced air supply and exhaust system so that N₂O does not contaminate adjacent areas.
- If concentrations of N₂O are still above 25 ppm, use supplementary local ventilation in conjunction with a scavenging system to reduce N₂O exposure in the operatory. The effectiveness of this ventilation depends on its location with respect to the patient and the airflow rates. Do not work between the patient and the exhaust duct, where contaminated air would be drawn through the worker’s breathing zone.
- Dilute N₂O and remove contaminated air from the work area by placing fresh-air vents in the ceiling; direct the supply of fresh air toward the floor and the operating area. Place exhaust-air vents at or near the floor.

Work practices
Use the following work practices to control N₂O exposures:
- Inspect the anesthetic delivery systems and all connections before starting anesthetic gas administration. Make sure that breathing bags, hoses and clamps are in place before turning on the anesthetic machine.
- Connect the scavenging mask properly to the gas delivery hose and the vacuum system.
- Do not turn on the machine delivering N₂O until:
  - The vacuum system scavenging unit is operating at the recommended flow rate of 45 L/min.
  - The scavenging mask is secured over the patient’s nose or face.
- Fasten the mask according to the manufacturer’s instructions to prevent leaks around the mask during gas delivery.
- Do not fill the breathing bag to capacity with N₂O; an overinflated bag can cause excessive leakage from the scavenging mask. The breathing bag should collapse and expand as the patient breathes. This bag activity shows that the proper amounts of N₂O and air are being delivered to the patient.
- Flush the system of N₂O after surgery by administering oxygen to the patient through the anesthetic equipment for at least five minutes before disconnecting the gas delivery system.
- Encourage patients to minimize talking and mouth-breathing during dental surgery. When mouth-breathing is apparent, avoid the patient’s breathing zone to the extent possible.

Respiratory protection
Workers should wear respiratory protection when N₂O concentrations are not consistently below 25 ppm; however, practical considerations may prevent them from wearing such protection. Therefore, it is essential that employers use the engineering controls and work practices described in a 1994 NIOSH alert to reduce N₂O concentrations below 25 ppm.

When N₂O concentrations are not consistently below 25 ppm, workers should take the following steps to protect themselves:
- Wear air-supplied respirators. Air-purifying respirators (that is, respirators that remove N₂O from the air rather than supply air from a clean source) should not be used because respirator filters do not efficiently remove N₂O.
- As specified by the NIOSH respirator standards, the minimum level of protection for an air-supplied respirator is provided by a half-mask respirator operated in the demand or continuous-flow mode. More protective air-supplied respirators are described in the NIOSH respirator decision logic.
- When respirators are used, the employer must establish a comprehensive respiratory protection program as outlined in the NIOSH Guide to Industrial Respiratory Protection [NIOSH 1987a] and as required by the OSHA respiratory protection standard [29 CFR 1910.134]. Important elements of this standard are:
  - An evaluation of the worker’s ability to perform the work while wearing a respirator.
Regular training of personnel.
Periodic environmental monitoring.
Respirator fit testing.
Maintenance, inspection, cleaning and storage.
Selection of proper NIOSH-approved respirators.
The respiratory protection program should be evaluated regularly by the employer.

Signs and symptoms of exposure
- Acute exposure: The signs and symptoms of acute exposure to nitrous oxide include dizziness, difficult breathing, headache, nausea, fatigue and irritability. Acute exposure to nitrous oxide concentrations of 400,000 to 800,000 ppm may cause loss of consciousness.
- Chronic exposure: The signs or symptoms of chronic overexposure to nitrous oxide may include tingling, numbness, difficulty in concentrating, interference with gait, and reproductive effects.

Storage
Nitrous oxide should be stored in a cool, dry, well-ventilated area in tightly sealed containers that are labeled in accordance with OSHA’s Hazard Communication Standard [29 Code of Federal Regulations (CFR)1910.1200]. Containers of nitrous oxide should be protected from physical damage and should be stored separately from cylinders containing oxygen. Nitrous oxide should also be stored separately from aluminum, boron, hydrazine, lithium hydride, phenyllithium, phosphine, sodium, tungsten carbide, hydrogen, hydrogen sulfide, organic peroxides, ammonia and carbon monoxide.

Spills and leaks
In the event of a spill or leak involving nitrous oxide (liquid or gas), persons not wearing protective equipment and clothing should be restricted from contaminated areas until cleanup has been completed. The following steps should be undertaken following a spill or leak:
- Do not touch the spilled material; stop the leak if it is possible to do so without risk.
- Use water spray to protect persons attempting to stop the leak.
- Notify safety personnel of large spills or leaks.
- Minimize all sources of ignition because a fire may cause nitrous oxide to accelerate the burning of other combustibles; keep combustible materials (wood, paper, oil, etc.) away from the spilled material.
- Isolate the area until the gas has dispersed.

Special requirements
United States Environmental Protection Agency (EPA) requirements for emergency planning, reportable quantities of hazardous releases, community right-to-know and hazardous waste management may change over time. Users are therefore advised to determine periodically whether new information is available.

Emergency planning requirements
Nitrous oxide is not subject to EPA emergency planning requirements under the Superfund Amendments and Reauthorization Act (SARA) (Title III) in 42 CFR 11022.

Reportable quantity requirements for hazardous releases
Employers are not required by the emergency release notification provisions in 40 CFR Part 355.40 to notify the National Response Center of an accidental release of nitrous oxide; there is no reportable quantity for this substance.

Community right-to-know requirements
Employers are not required by EPA in 40 CFR Part 372.30 to submit a Toxic Chemical Release Inventory form (Form R) to EPA reporting the amount of nitrous oxide emitted or released from their facility annually.

Hazardous waste management requirements
EPA considers a waste to be hazardous if it exhibits any of the following characteristics: ignitability, corrosivity, reactivity or toxicity as defined in 40 CFR 261.21-261.24. Under the Resource Conservation and Recovery Act (RCRA) [40 USC 6901 et seq.], EPA has specifically listed many chemical wastes as hazardous. Although nitrous oxide is not specifically listed as a hazardous waste under RCRA, EPA requires employers to treat waste as hazardous if it exhibits any of the characteristics discussed above. Providing detailed information about the removal and disposal of specific chemicals is beyond the scope of this guideline. The U.S. Department of Transportation, EPA, and state and local regulations should be followed to ensure that removal, transport and disposal of this substance are conducted in accordance with existing regulations. To be certain that chemical waste disposal meets EPA regulatory requirements, employers should address any questions to the RCRA hotline at (703) 412-9810 (in the Washington, D.C. area) or toll-free at 800-424-9346 (outside Washington, D.C.). In addition, relevant state and local authorities should be contacted for information on any requirements they may have for the waste removal and disposal of this substance.

Respiratory protection
Conditions for respirator use
Good industrial hygiene practice requires that engineering controls be used where feasible to reduce workplace concentrations of hazardous materials to the prescribed exposure limit. However, some situations may require the use of respirators to control exposure. Respirators must be worn if the ambient concentration of nitrous oxide exceeds prescribed exposure limits. Respirators may be used (1) before engineering controls have been installed, (2) during work operations such as maintenance or repair activities that involve unknown exposures, (3) during operations that require entry into tanks or closed vessels, and (4) during emergencies. Workers should only use respirators that have been approved by NIOSH and the Mine Safety and Health Administration (MSHA).

Respiratory protection program
Employers should institute a complete respiratory protection program that, at a minimum, complies with the requirements of OSHA's Respiratory Protection Standard [29 CFR 1910.134]. Such a program must include respirator selection, an evaluation of the worker’s ability to perform the work while wearing a respirator, the regular training of personnel, respirator fit testing, periodic workplace monitoring, and regular respirator maintenance, inspection and cleaning. The implementation of an adequate respiratory protection program (including selection of the correct respirator) requires that a knowledgeable person be in charge of the program and that the program be evaluated regularly. For additional information on the selection and use of respirators and on the medical screening of respirator users, consult the latest edition of the NIOSH Respirator Decision Logic [NIOSH 1987b] and the NIOSH Guide to Industrial Respiratory Protection [NIOSH 1987a].

Personal protective equipment
Workers should use appropriate personal protective clothing and equipment that must be carefully selected, used and maintained to be effective in preventing skin contact with liquid nitrous oxide. The selection of the appropriate personal protective equipment (PPE) (e.g., gloves, sleeves, encapsulating suits) should be based on the extent of the worker’s potential exposure to liquid nitrous oxide and the PPE material’s ability to protect workers from frostbite. There are no published reports on the resistance of various materials to permeation by liquid nitrous oxide.

To evaluate the use of PPE materials with liquid nitrous oxide, users should consult the best available performance data and manufacturers’ recommendations. Significant differences have been demonstrated in the chemical resistance of generically similar PPE materials (e.g., butyl) produced by different manufacturers. In addition, the chemical resistance of a mixture may be significantly different from that of any of its neat components.

Any chemical-resistant clothing that is used should be periodically evaluated to determine its effectiveness in preventing dermal contact. Safety showers and eye wash stations should be located close to operations that involve nitrous oxide.

Splash-proof chemical safety goggles or face shields (20 to 30 cm long, minimum) should be worn during any operation in which a solvent, caustic or other toxic substance may be splashed into the eyes.

In addition to the possible need for wearing protective outer apparel (e.g., aprons, encapsulating suits), workers should wear work uniforms, coveralls or similar full-body coverings that are laundered each day. Employers should provide lockers or other closed areas to store...
work and street clothing separately. Employers should collect work clothing at the end of each work shift and provide for its laundering. Laundry personnel should be informed about the potential hazards of handling contaminated clothing and instructed about measures to minimize their health risk.

Protective clothing should be kept free of oil and grease and should be inspected and maintained regularly to preserve its effectiveness.

Protective clothing may interfere with the body’s heat dissipation, especially during hot weather or during work in hot or poorly ventilated work environments.

More on personal protective equipment

- Personal protective equipment should not be used as a substitute for engineering, work practice and/or administrative controls in anesthetizing locations and post anesthesia care units (PACUs). In fact, exposure to waste gases is not effectively reduced by gloves, goggles and surgical masks. A negative-pressure, high-efficiency particulate air (HEPA) filter used for infection control is also not appropriate to protect workers from waste gases. Air-supplied respirators with self-contained air source are ideal for eliminating exposure but are not a practical alternative.

- During cleanup and containment of spills of liquid anesthetic agents, personal protective equipment should be used in conjunction with engineering, work practice and administrative controls to provide for employee safety and health. Gloves, goggles, face shields and chemical protective clothing (CPC) are recommended to ensure worker protection. Respirators, where needed, should be selected based on the anticipated contamination level.

- When selecting gloves and chemical protective clothing, some of the factors to be considered include material chemical resistance, physical strength and durability, and overall product integrity. Permeation, penetration and degradation data should be consulted if available. Among the most effective types of gloves and body protection are those made from Viton®, neoprene and nitrile. Polyvinyl alcohol (PVA) is also effective, but it should not be exposed to water or aqueous solutions.

- When the gloves and the CPC being used have not been tested under the expected conditions, they may fail to provide adequate protection. In this situation, the wearer should observe the gloves and the chemical protective clothing during use and treat any noticeable change (e.g., color, stiffness, chemical odor inside) as a failure until proved otherwise by testing. If the work must continue, new CPC should be worn for a shorter exposure time, or be of a different generic material. The same thickness of a generic material such as neoprene or nitrile supplied by different manufacturers may provide significantly different levels of protection because of variations in the manufacturing processes or in the raw materials and additives used in processing.

- Professional judgment must be used in determining the type of respiratory protection to be worn. For example, where spills of halogenated anesthetic agents are small, exposure time brief and sufficient ventilation present, NIOSH-approved chemical cartridge respirators for organic vapors should provide adequate protection during cleanup activities.

- Where large spills occur and there is insufficient ventilation to adequately reduce airborne levels of the halogenated agent, respirators designed for increased respiratory protection should be used. The following respirators, to be selected for large spills, are ranked in order from minimum to maximum respiratory protection:
  - Any type C supplied-air respirator with a full facepiece, helmet or hood operated in continuous-flow mode.
  - Any type C supplied-air respirator with a full facepiece operated in pressure-demand or other positive-pressure mode.
  - Any self-contained breathing apparatus with a full facepiece operated in pressure-demand or other positive-pressure mode.

Workplace exposures

Workplace exposures to anesthetic gases occur in hospital-based and stand-alone operating rooms, recovery rooms, dental operatories and veterinary facilities. Engineering, work practice and administrative controls that help reduce these exposures in all anesthetizing locations are identified and discussed. Sources of leaks in anesthesia equipment systems, components, and accessories are identified, and appropriate methods are described that limit excessive leaks. Inhaled anesthetic agents include two different classes of chemicals: nitrous oxide and halogenated agents. Halogenated agents currently in use include halothane (Fluothane®), enflurane (Ethrane®), isoflurane (Forane®), desflurane (Suprane®), and sevoflurane (Ultane®). Methoxyflurane (Penthrane®), once in general use, is now only infrequently used, primarily in veterinary procedures. At present, OSHA has no permissible exposure limits regulating these agents.

The basic anesthesia machine

An anesthesia machine is an assembly of various components and devices that include medical gas cylinders in machine hanger yokes, pressure regulating and measuring devices, valves, flow controllers, flow meters, vaporizers, CO2 absorbers, canisters, and breathing circuit assembly. The basic two-gas anesthesia machine has more than 700 individual components.

The anesthesia machine is a basic tool of the anesthesiologist/anesthetist and serves as the primary work station. It allows the anesthesia provider to select and mix measured flows of gases, to vaporize controlled amounts of liquid anesthetic agents, and thereby to administer safely controlled concentrations of oxygen and anesthetic gases and vapors to the patient via a breathing circuit. The anesthesia machine also provides a working surface for placement of drugs and devices for immediate access and drawers for storage of small equipment, drugs, supplies and equipment instruction manuals. Finally, the machine serves as a frame and source of pneumatic and electric power for various accessories such as a ventilator, and monitors that observe or record vital patient functions or that are critical to the safe administration of anesthesia.

Gas flow in the anesthesia machine and breathing system

The internal piping of a basic two-gas anesthesia machine is shown in Figure 1 (located at end of this chapter). The machine has many connections and potential sites for leaks. Both oxygen and N2O may be supplied from two sources (Figure 2, located at end of this chapter): a pipeline supply source (central piping system from bulk storage) and a compressed gas cylinder supply source. In hospitals, the pipeline supply source is the primary gas source for the anesthesia machine. Pipeline-supplied gases are delivered through wall outlets at a pressure of 50-55 psig through diameter indexed safety system (DISS) fittings or through quick-connect couplings that are gas-specific within each manufacturer’s patented system.

Because pipeline systems can fail and because the machines may be used in locations where piped gases are not available, anesthesia machines are fitted with reserve cylinders of oxygen and N2O. The oxygen cylinder source is regulated from approximately 2,200 psig in the tanks to approximately 45 psig in the machine high-pressure system, and the N2O cylinder source is regulated from 745 psig in the tanks to approximately 45 psig in the machine high-pressure system.

Figure 1 (located at end of chapter)

The flow arrangement of a basic two-gas anesthesia machine. A. The fail-safe valve in Ohmeda machines is termed a pressure sensor shut-off valve; in Dräger machines it is the oxygen failure protection device (OFPD). B. Second-stage oxygen pressure regulator is used in Ohmeda (but not Dräger Narkomed) machines. C. Second-stage nitrous oxide pressure regulator is used in Ohmeda machines except Modulus II Plus and Modulus CD models; not used in Dräger machines. E. Outlet check valve used in Ohmeda machines except Modulus II Plus and Modulus CD models; not used in Dräger machines. The oxygen take-off for the anesthesia ventilator driving gas circuit is downstream of the main on/off switch in Dräger machines, as shown here. In Ohmeda machines, the take-off is upstream of the main on/off switch. (Adapted from Check-out: a guide for preoperative inspection of an anesthesia machine, ASA, 1987. Reproduced by permission of the American Society of Anesthesiologists, 520 N. Northwest Highway, Park Ridge, Ill.)
Figure 2 (located at end of chapter)
The supply of nitrous oxide and oxygen may come from two sources: the wall (pipeline) supply and the reserve cylinder supply. (Reproduced by permission of Datex-Ohmeda, Madison, Wisconsin). Compressed gas cylinders of oxygen, N₂O, and other medical gases are attached to the anesthesia machine through the hanger yoke assembly. Each hanger yoke is equipped with the pin index safety system, a safeguard introduced to eliminate cylinder interchanging and the possibility of accidentally placing the incorrect gas tank in a yoke designed for another gas tank.

Figure 3 (located at end of this chapter) shows the oxygen pathway through the flow meter, the agent vaporizer, and the machine piping, and into the breathing circuit. Oxygen from the wall outlet or cylinder pressurizes the anesthesia delivery system. Compressed oxygen provides the needed energy for a pneumatically powered ventilator, if used, and it supplies the oxygen flush valve used to supplement oxygen flow to the breathing circuit. Oxygen also “powers” an in-line pressure-sensor shutoff valve (“fail-safe” valve) for other gases to prevent their administration if pressure-limiter (APL) or “pop-off” valve circuit. The ventilator bellows functionally replaces the ventilator (ventilator) circuit selector switch. The ventilator connects to the machine inlet. Therefore, gas-scavenging is (are) reassembled. The exhaust from a side-stream sampling respiratory gas analyzer and/or capnograph should also be connected to the waste gas scavenging system because the analyzed gas sample may contain N₂O or halogenated vapors.

Sources of leaks within the anesthesia machine and breathing system

No anesthesia machine system is totally leak-free (Emergency Care Research Institute 1991). Leakage may originate from both the high-pressure and low-pressure systems of the anesthesia or analgesia machine.

The high-pressure system consists of all piping and parts of the machine that receive gas at cylinder or pipeline supply pressure. It extends from the high-pressure gas supply (i.e., wall supply or gas cylinder) to the flow control valves. Leaks may occur from the high-pressure connections where the supply hose connects to the wall outlet or gas cylinder and where it connects to the machine inlet. Therefore, gas-supply hoses should be positioned to prevent strain on the fittings (ASTM Standard F1161-88; Dorsch and Dorsch 1994) and conducted from supply-hose materials designed for high-pressure gas flow and minimal kinking (Bowie and Huffman 1985). High-pressure leakage may also occur within the anesthesia machine itself. Other potential sources of leaks include quick-connect fittings, cylinder valves, absent or worn gaskets, missing or worn yoke plugs in a dual yoke assembly, and worn hoses.

The low-pressure system of the anesthesia machine (in which the pressure is slightly above atmospheric) consists of components downstream of the flow-control valves. It therefore includes the flow meter tubes, vaporizers, common gas outlet and breathing circuit, (i.e., from the common gas outlet to the patient). Low-pressure system leaks may occur from the connections and components anywhere between the anesthesia gas flow control valves and the airway. This leakage may occur from loose-fitting connections, defective and worn seals and gaskets, worn or defective breathing bags, hoses, and tubing, loosely assembled or deformed slip joints and threaded connections, and the moisture drainage port of the CO₂ absorber, which may be in the “open” position.

Low-pressure system leaks also may occur at the gas analysis sensor (i.e., circuit oxygen analyzer) and gas sampling site(s), face mask, the tracheal tube (especially in pediatric patients where a leak is required around the uncuffed tracheal tube), laryngeal mask airway (over the larynx), and connection points for accessory devices such as a humidifier, temperature probe, or positive end-expiratory pressure (PEEP) valve. Inappropriate installation of a calibrated vaporizer(s) or misalignment of a vaporizer on its manifold can also contribute to anesthetic gas leakage.

Minute absorbent particles that may have been spilled on the rubber seal around the absorber canister(s) may also prevent a gas-tight seal when the canister(s) in the carbon dioxide absorber is (are) reassembled. The exhaust from a sidestream sampling respiratory gas analyzer and/or capnograph should also be connected to the waste gas scavenging system because the analyzed gas sample may contain N₂O or halogenated vapors.

Checking anesthesia machines

Prior to induction of anesthesia, the anesthesia machine and its components/accessories should be made ready for use. All parts of the machine should be in good working order with all accessory equipment and necessary supplies on hand. The waste gas disposal system should be connected, hoses visually inspected for obstructions or kinks, and proper operation determined. Similarly, the anesthesia breathing system should be tested to verify that it can maintain positive pressure. Leaks should be identified and corrected before the system is used. The ability of the anesthesia system to maintain constant pressure is tested not only for the safety of the patient dependent on a generated positive pressure ventilation but also to test for leaks and escape of anesthetic gases, which may expose health-care personnel to waste anesthetic gases.

General workplace controls

Occupational exposures can be controlled by the application of a number of well-known principles, including engineering and work practice controls, administrative controls, personal protective equipment and monitoring. These principles may be applied at or near the hazard source, to the general workplace environment, or at the point of occupational exposure to individuals. Controls applied at the source of the hazard, including engineering and work practice controls, are generally the preferred and most effective means of control. In anesthetizing locations and PACUs, where employees are at risk of exposure to waste
anesthetic gases, exposure may be controlled by some or all of the following: (1) effective anesthetic gas scavenging systems that remove excess anesthetic gas at the point of origin; (2) effective general or dilution ventilation; (3) good work practices on the part of the health care workers, including the proper use of controls; (4) proper maintenance of equipment to prevent leaks; and (5) periodic personnel exposure and environmental monitoring to determine the effectiveness of the overall waste anesthetic gas control program.

The following is a general discussion of engineering controls, work practices, administrative controls, and personal protective equipment that can reduce worker exposure to waste anesthetic gases. However, not every control listed in this section may be feasible in all settings.

**Engineering controls**

The collection and disposal of waste anesthetic gases in operating rooms and non-operating room settings is essential for reducing occupational exposures. Engineering controls such as an appropriate anesthetic gas scavenging system are the first line of defense and the preferred method of control to protect employees from exposure to anesthetic gases. An effective anesthetic gas scavenging system traps waste gases at the site of overflow from the breathing circuit and disposes of these gases to the outside atmosphere. The heating, ventilating and air conditioning (HVAC) system also contributes to the dilution and removal of waste gases not collected by the scavenging system or from other sources such as leaks in the anesthetic apparatus or improper work practices.

The exhalation of residual gases by patients in the PACU may result in significant levels of waste anesthetic gases when appropriate work practices are not used at the conclusion of the anesthetic or inadequate ventilation exists in the PACU. A nonrecirculating ventilation system can reduce waste gas levels in this area. Waste gas emissions to the outside atmosphere must meet local, state, and Environmental Protection Agency (EPA) regulatory requirements.

A scavenging system consists of five basic components (ASTM, F 1343 - 91):
- A gas collection assembly, such as a collection manifold or a distensible bag (i.e., Jackson-Rees pediatric circuit), which captures excess anesthetic gases at the site of emission, and delivers it to the transfer tubing.
- Transfer tubing, which conveys the excess anesthetic gases to the interface.
- The interface, which provides positive (and sometimes negative) pressure relief and may provide reservoir capacity. It is designed to protect the patient’s lungs from excessive positive or negative scavenging system pressure.
- Gas disposal assembly tubing, which conducts the excess anesthetic gases from the interface to the gas disposal assembly.
- The gas disposal assembly, which conveys the excess gases to a point where they can be discharged safely into the atmosphere. Several methods in use include a nonrecirculating or recirculating ventilation system, a central vacuum system, a dedicated (single-purpose) waste gas exhaust system, a passive duct system and an adsorber.

In general, a machine-specific interface must be integrated with a facility’s system for gas removal. The interface permits excess gas to be collected in a reservoir (bag or canister) and limits the pressure within the bag or canister. A facility’s gas disposal system receives waste anesthetic gases from the interface and should vent the waste gases outside the building and away from any return air ducts or open windows, thus preventing the return of the waste gases back into the facility.

Removal of excess anesthetic gases from the anesthesia circuit can be accomplished by either active or passive scavenging. When a vacuum or source of negative pressure is connected to the scavenging interface, the system is described as an active system. When a vacuum or negative pressure is not used, the system is described as a passive system. With an active system, there will be a negative pressure in the gas disposal tubing. With a passive system, this pressure will be increased above atmospheric (positive) by the patient exhaling passively, or manual compression of the breathing system reservoir bag.

Use of a central vacuum system is an example of an active system: The waste anesthetic gases are moved along by negative pressure. Venting waste anesthetic gas via the exhaust grille or exhaust duct of a nonrecirculating ventilation system is an example of a passive system: The anesthetic gas is initially moved along by the positive pressure from the breathing circuit until it reaches the gas disposal assembly.

**Active systems**

Excess anesthetic gases may be removed by a central vacuum system (servicing the ORs in general) or an exhaust system dedicated to the disposal of excess gases. When the waste anesthetic gas scavenging system is connected to the central vacuum system (which is shared by other users, e.g., surgical suction), exposure levels may be effectively controlled. The central vacuum system must be specifically designed to handle the large volumes of continuous suction from OR scavenging units. If a central vacuum system is used, a separate, dedicated gas disposal assembly tubing should be used for the scavenging system, distinct from the tubing used for patient suctioning (used for oral and nasal gastric sources as well as surgical suctioning).

Similarly, when a dedicated exhaust system (low velocity) is used, excess gases can also be collected from one or more ORs and discharged to the outdoors. The exhaust fan must provide sufficient negative pressure and air flow so that cross-contamination does not occur in the other ORs connected to this system. Active systems are thought to be more effective than passive systems at reducing excess waste anesthetic gas concentrations because leaks in the scavenging system do not result in an outward loss of gas.

**Passive systems**

HVAC systems used in health-care facilities are of two types: nonrecirculating and recirculating. Nonrecirculating systems, also termed “one-pass” or “single-pass” systems, take in fresh air from the outside and circulate filtered and conditioned air (i.e., controlled for temperature and humidity) through the room. Whatever volumes of fresh air are introduced into the room are ultimately exhausted to the outside. Waste anesthetic gases can be efficiently disposed of via this nonrecirculating system.

When a nonrecirculating ventilation system serves through large-diameter tubing and terminating the tubing at the room’s ventilation exhaust as the disposal route for excess anesthetic gases, disposal involves directing the waste gases grate. The sweeping effect of the air flowing into the grate carries the waste gases away. Because all of the exhausted air is vented to the external atmosphere in this type of system, the excess anesthetic gases can be deposited into the exhaust stream either at the exhaust grate or further downstream in the exhaust duct.

Concern for fuel economy has increased the use of systems that recirculate air. Recirculating HVAC/ventilation systems return part of the exhaust air back into the air intake and recirculate the mixture through the room. Thus, only a fraction of the exhaust air is discharged of to the outside. To maintain minimal levels of anesthetic exposure, air that is to be recirculated must not contain anesthetic gases. Consequently, recirculating systems employed as a disposal pathway for waste anesthetic gases must not be used for gas waste disposal. The exception is an arrangement that transfers waste gases into the ventilation system at a safe distance downstream from the point of recirculation to ensure that the anesthetic gases will not be circulated elsewhere within the building.

Under certain circumstances, a separate duct for ventilating anesthetic gases directly outside the building without the use of a fan may be an acceptable alternative. By this technique, excess anesthetic gases may be vented through the wall, window, ceiling or floor, relying only on the slight positive pressure of the gases leaving the gas collection assembly to provide the flow. However, several limitations are apparent. A separate line would be required for each OR to prevent the cross-contamination with anesthetic gases among the ORs. A safe disposal site would be necessary. The possible effects of variations in wind velocity and direction would require a means for preventing a reverse flow in the disposal system. Occlusion of the outer portion of such a passive system by ice or by insect or bird nests is also possible. The outside opening of a through-wall, window, ceiling or floor disposal assembly should be directed downward, shielded and screened to prevent the entrance of foreign
matter or ice buildup. Despite these limitations, the separate duct without the use of a fan may be ideal in older facilities constructed with windows that cannot be opened and in the absence of nonrecirculating air conditioning.

Absorbers can also trap most excess anesthetic gases. Canisters of varying shapes and capacities filled with activated charcoal have been used as waste gas disposal assemblies by directing the gases from the gas disposal tubing through them. Activated charcoal canisters will effectively adsorb the vapors of halogenated anesthetics, but not N₂O. The effectiveness of individual canisters and various brands of charcoal vary widely. Different potient inhaled volatile agents are adsorbed with varying efficiencies. The efficiency of adsorption also depends on the rate of gas flow through the canister. The canister is used where portability is necessary. The disadvantages are that they are expensive and must be changed frequently. Canisters must be used and discarded in the appropriate manner, as recommended by the manufacturer.

General or dilution ventilation
An effective room HVAC system when used in combination with an anesthetic gas scavenging system should reduce, although not entirely eliminate, the contaminating anesthetic gases. If excessive concentrations of anesthetic gases are present, then airflow should be increased in the room to allow for more air mixing and further dilution of the anesthetic gases. Supply register louvers located in the ceiling should be designed to direct the fresh air toward the floor and toward the health care workers to provide dilution and removal of the contaminated air from the operatory or PACU. Exhaust register louvers should be properly located (usually low on the wall near the floor level) in the room to provide adequate air distribution. They should not be located near the supply air vents because this will short-circuit the airflow and prevent proper air mixing and flushing of the contaminants from the room.

Work practices
Work practices, as distinct from engineering controls, involve the way in which a task is performed. OSHA has found that appropriate work practices can be a vital aid in reducing the exposures of OR personnel to waste anesthetic agents. In contrast, improper anesthetizing techniques can contribute to increased waste gas levels. These techniques can include an improperly selected and fitted face mask, an insufficiently inflated tracheal tube cuff, an improperly positioned laryngeal mask, or other airway, and careless filling of vaporizers and spillage of liquid anesthetic agents.

General work practices recommended for anesthetizing locations include the following:

- A complete anesthesia apparatus checkout procedure should be performed each day before the first case. An abbreviated version should be performed before each subsequent case. The FDA Anesthesia Apparatus Checkout Recommendations should be considered in developing inspection and testing procedures for equipment checkout prior to administering an anesthetic.

- If a face mask is to be used for administration of inhaled anesthetics, it should be available in a variety of sizes to fit each patient properly. The mask should be pliable and provide as effective a seal as possible against leakage into the surrounding air.

- Tracheal tubes, laryngeal masks, and other airway devices should be positioned precisely and the cuffs inflated adequately.

- Vaporizers should be filled in a well-ventilated area and in a manner to minimize spillage of the liquid agent. This can be accomplished by using a specialized “key-fill” spout to pour the anesthetic into the vaporizer instead of pouring from a bottle into a funnel-fill vaporizer. When feasible, vaporizers should be filled at the location where the anesthetic will be administered and, when filled electively, with the fewest possible personnel present in the room. Vaporizers should be turned off when not in use.

- Spills of liquid anesthetic agents should be cleaned up promptly.

- Before extubating the patient’s trachea or removing the mask or other airway management device, one should administer non-anesthetic gases/agents so that the washed-out anesthetic gases can be removed by the scavenging system. The amount of time allowed for this should be based on clinical assessment and may vary from patient to patient. When possible, flushing of the breathing system should be achieved by exhausting into the scavenging system rather than into the room air.

- Work practices performed by biomedical engineers and technicians also contribute significantly to the efficacy of managing waste gas exposure. It is, therefore, important for this group of workers to do the following:
  - Monitor airborne concentrations of waste gases by sampling, measuring, and reporting data to the institution’s administration. Air monitoring for waste anesthetic gases should include both personal sampling (i.e., in a health-care worker’s breathing zone) and area sampling.
  - Assist in identifying sources of waste/leaking gases and implementing corrective action.
  - Determine whether the scavenging system is designed and functioning properly to remove the waste anesthetic gases from the breathing circuit, and ensure that the gases are vented from the workplace in such a manner that occupational exposure does not occur (e.g., smoke trail tests of exhaust grilles used with passive scavenging systems).
  - Ensure that operatory and PACU ventilation systems provide sufficient room air exchange to reduce ambient waste gas levels.

Administrative controls
Administrative controls represent another approach for reducing worker exposure to waste gases other than through the use of engineering controls, work practices, or personal protective equipment. Administrative controls may be thought of as any administrative decision that results in decreased anesthetic-gas exposure. For workers potentially exposed to waste anesthetic gases, the program administrator should establish and implement policies and procedures to:

- Institute a program of routine inspection and regular maintenance of equipment in order to reduce anesthetic gas leaks and to have the best performance of scavenging equipment and room ventilation. Preventive maintenance should be performed by trained individuals according to the manufacturer’s recommendations and at intervals determined by equipment history and frequency of use. Preventive maintenance includes inspection, testing, cleaning, lubrication and adjustment of various components. Worn or damaged parts should be repaired or replaced. Such maintenance can result in detection of deterioration before an overt malfunction occurs. Documentation of the maintenance program should be kept indicating the nature and date of the work performed, as well as the name of the trained individual servicing the equipment.

- Implement a monitoring program to measure airborne levels of waste gases in the breathing zone or immediate work area of those most heavily exposed (e.g., anesthesiologist, nurse anesthetist, oral surgeon) in each anesthetizing location and PACU. Periodic monitoring (preferably at least semiannually) of waste gas concentrations is needed to ensure that the anesthesia delivery equipment and engineering/environmental controls work properly and that the maintenance program is effective. Monitoring may be performed effectively using conventional time-weighted average air sampling or real-time air sampling techniques.

- Encourage or promote the use of scavenging systems in all anesthetizing locations where inhaled agents are used, recognizing that a waste gas scavenging system is the most effective means of controlling waste anesthetic gases.

- Implement an information and training program for employees exposed to anesthetic agents that complies with OSHA’s Hazard Communication Standard (29 CFR 1910.1200) so that employees can meaningfully participate in, and support, the protective measures instituted in their workplace.

- Define and implement appropriate work practices to help reduce employee exposure. Training and educational programs covering appropriate work practices to minimize levels of anesthetic gases in the operating room should be conducted at least annually. Employers should emphasize the importance of implementing these practices and should
ensure that employees are properly using the appropriate techniques on a regular basis.

- Implement a medical surveillance program for all workers exposed to waste gases.
- Ensure the proper use of personal protective equipment during cleanup and containment of major spills of liquid anesthetic agents.
- Manage disposal of liquid agents, spill containment, and air monitoring for waste gases following a spill.
- Comply with existing federal, state, and local regulations and guidelines developed to minimize personnel exposure to waste anesthetic gases, including the proper disposal of hazardous chemicals.

**Location-specific workplace controls**

This section describes engineering and work practice controls specific to hospital ORs, PACUs, dental operatories and veterinary clinics and hospitals. Operational procedures relating to engineering controls are also discussed where appropriate.

**Hospital operating rooms**

For years, anesthesia providers tolerated exposure to waste anesthetic gases and regarded it as an inevitable consequence of their work. Since the 1970s, anesthesiologists have steadily worked to improve equipment and technique to reduce workplace exposures to waste anesthetic gases, and significant progress has been made. In early delivery equipment, waste gases were exhausted through the APL or “pop-off” valve into the face of the anesthesia provider and were distributed into the room air. Present practice, which utilizes an efficient scavenging system, avoids this type of contamination by collecting the excess gases immediately at the APL valve.

**Engineering controls**

Waste gas evacuation is required for every type of breathing circuit configuration with the possible exception of a closed circuit, because most anesthesia techniques typically use more fresh gas flow than is required. Appropriate waste gas evacuation involves collection and removal of waste gases, detection and correction of leaks, consideration of work practices, and effective room ventilation. To minimize waste anesthetic gas concentrations in the operating room, the recommended air exchange rate (room dilution ventilation) is a minimum total of 15 air changes per hour with a minimum of 3 air changes of outdoor air (fresh air) per hour. Operating room air containing waste anesthetic gases should not be recirculated to the operating room or other hospital locations.

**Work practices**

In most patients, a circle absorption system is used and can be easily connected to a waste gas scavenging system. In pediatric anesthesia, systems other than those with a circle absorber may be used. Choice of the breathing circuit that best meets the needs of pediatric patients may alter a clinician’s ability to scavenge waste gas effectively. Breathing circuits frequently chosen for neonates, infants and small children are usually valveless, have low resistance and limit rebreathing. The Mapleson D system and the Jackson-Rees modification of the Ayre’s T-piece are examples of limited rebreathing systems that require appropriate scavenging equipment.

The following work practices may be employed with any of the above breathing circuits:

- Empty the contents of the reservoir bag directly into the anesthetic gas scavenging system and turn off the flow of N₂O and any halogenated anesthetic agent prior to disconnecting the patient circuit.
- Turn off the flow of N₂O and the vaporizer, if appropriate, when the patient circuit is disconnected from the patient, for example, for oral or tracheal suctioning.
- Test daily for low-pressure leaks throughout the entire anesthesia system. All leaks should be minimized before the system is used. Starting anesthetic gas flow before the actual induction of anesthesia begins is not acceptable. For techniques to rapidly induce anesthesia using inhaled agents (single-breath mask induction), the patient connector should be occluded when filling the breathing circuit with nitrous oxide or halogenated agent prior to applying the mask to the patient’s face.

If the circle absorber system (Figure 6 - located at end of this chapter) is used, the following additional work practices can be employed:

- Adjust the vacuum needle valve as needed to regulate the flow of waste anesthetic gases into the vacuum source in an active scavenging system. Adjustments prevent the bag from overdistending by maintaining the volume in the scavenging system reservoir bag between empty and half-full. In machines that use an open reservoir to receive waste gas, a flow meter is used to adjust the rate of gas flow to the vacuum system.
- Cap any unused port in a passive waste gas scavenging configuration.

**Postanesthesia care in hospitals and stand-alone facilities**

Because the patient is the main source of waste anesthetic gases in the PACU, it becomes more difficult to control health-care workers’ exposures to waste anesthetic gases. The unique PACU environment coupled with the patient’s immediate condition upon arrival from surgery require different work practices than those routinely used in ORs. Patients undergoing general anesthesia usually have their airways secured using a tracheal tube with an inflatable cuff that seals the tube within the trachea. The seal between the tracheal tube cuff and the trachea (or between the face mask and the face) is essential for maintaining a gas-tight system that permits effective scavenging in the OR. The tracheal tube connects the patient with the breathing circuit that is connected to the scavenging system in the OR. Once the patient reaches the PACU, scavenging systems such as those used in the OR are no longer effective, since the patient is no longer connected to the breathing circuit. Other less-effective methods of waste gas removal are thus relied upon.

**Engineering controls**

As a result of using appropriate anesthetic gas scavenging in ORs, the levels of contamination have been decreased. In the PACU, however, the principle of scavenging as practiced in the OR is not widely accepted due to medical considerations and consequently is infrequently employed as a source-control method for preventing the release of waste anesthetic gases into the PACU environment. Most PACUs provide care to multiple patients in beds without walls between them, and convective currents move the gases from their source to other areas. Therefore, in the PACU, a properly designed and operating dilution ventilation system should be relied upon to minimize waste anesthetic gas concentrations. This system should provide a recommended minimum total of 6 air changes per hour with a minimum of 2 air changes of outdoor air per hour to adequately dilute waste anesthetic gases. Room exhaust containing waste anesthetic gases should not be recirculated to other areas of the hospital.

**Work practices**

PACU managers should consider:

- Periodic exposure monitoring with particular emphasis on peak gas levels in the breathing zone of nursing personnel working in the immediate vicinity of the patient’s head. Methods using random room sampling to assess ambient concentrations of waste anesthetic gases in the PACU are not an accurate indicator of the level of exposure experienced by nurses providing bedside care. Because of the closeness of the PACU nurse to the patient, such methods would consistently underestimate the level of waste anesthetic gases in the breathing zone of the bedside nurse.
- Application of a routine ventilation system maintenance program to keep waste gas exposure levels to a minimum.

**Dental operatory**

Mixtures of N₂O and oxygen have been used in dentistry as general anesthetic agents, analgesics and sedatives for more than 100 years. The usual analgesia equipment used by dentists includes a N₂O and O₂ delivery system, a gas mixing bag and a nasal mask with a positive pressure relief valve. The analgesia machine is usually adjusted to deliver more of the analgesic gas mixture than the patient can use. Analgesia machines for dentistry are designed to deliver up to 70 percent (700,000 ppm) N₂O to a patient during dental surgery. The machine restricts higher concentrations of N₂O from being administered to protect the patient from hypoxia. In most cases, patients receive between 30 and 50 percent N₂O during surgery. The amount of time N₂O is administered to a patient depends on the dentist’s judgment of patient needs and the complexity of the surgery. The most common route of N₂O delivery and exhaust is through a nasal scavenging mask applied to the patient.

Some dentists administer N₂O at higher concentrations at the beginning of the operation,
then decrease the amount as the operation progresses. Others administer the same amount of N\textsubscript{2}O throughout the operation. When the operation is completed, the N\textsubscript{2}O is turned off. Some dentists turn the N\textsubscript{2}O on only at the beginning of the operation, using N\textsubscript{2}O as a sedative during the administration of local anesthesia, and turn it off before operating procedures. Based on variations in dental practices and other factors in room air, N\textsubscript{2}O concentrations can vary considerably for each operation and also vary over the course of the operation.

Unless the procedure is performed under general anesthesia in an OR, halogenated anesthetics are not administered, nor does the patient undergo laryngoscopy and tracheal intubation. In the typical dental office procedure, the nasal mask is placed on the patient, fitted and adjusted prior to administration of the anesthetic agent. The mask is designed for the nose of the patient because access to the patient’s mouth is essential for dental procedures.

A local anesthetic, if needed, is typically administered after the N\textsubscript{2}O takes effect. The patient’s mouth is opened and the local anesthetic is injected. The dental procedure begins after the local anesthetic takes effect. The patient opens his/her mouth but is instructed to breathe through the nose. Nonetheless, a certain amount of mouth breathing frequently occurs. The dentist may periodically stop the dental procedure for a moment to allow the patient to close the mouth and breathe deeply to re-establish an appropriate concentration of N\textsubscript{2}O in the patient’s body before resuming the procedure. Depending on the nature of the procedure, high velocity suction is regularly used to remove intraoral debris and, when used, creates a negative air flow and captures some of the gas exhaled by the patient.

At the end of the procedure, the nosepiece is left on the patient while the N\textsubscript{2}O is turned off and the oxygen flow is increased. The anesthetic mixture diffuses from the circulating blood into the lungs and is exhaled. Scavenging is continued while the patient is eliminating the N\textsubscript{2}O.

The dental office or operatory should have a properly installed N\textsubscript{2}O delivery system. This includes appropriate scavenging equipment with a readily visible and accurate flow meter (or equivalent measuring device), a vacuum pump with the capacity for up to 45 L/min of air per workstation, and a variety of sizes of masks to ensure proper fit for individual patients.

A common nasal mask, shown in Figure 7 (located at the end of this chapter), consists of an inner and a slightly larger outer mask component. The inner mask has two hoses connected that supply anesthetic gas to the patient. A relief valve is attached to the inner mask to release excess N\textsubscript{2}O into the outer mask. The outer mask has two smaller hoses connected to a vacuum system to capture waste gases from the patient and excess gas supplied to the patient by the analgesia machine. The nasal mask should fit over the patient’s nose as snugly as possible without impairing the vision or dexterity of the dentist. Gases exhaled orally are not captured by the nasal mask. A flow rate of approximately 45 L/min has been recommended as the optimum rate to prevent significant N\textsubscript{2}O leakage into the room air.

A newer type of mask is a frequent choice in dental practice, a single-patient-use nasal hood. This mask does not require sterilization after surgery because it is used by only one patient and is disposable.

In a dental operatory, a scavenging system is part of a high-volume evacuation system used with a dental unit. The vacuum system may dispose of a combination of waste gases, oral fluid and debris, and is not limited to waste gas removal. The exhaust air of the evacuation system should be vented outside the building and away from fresh-air inlets and open windows to prevent re-entry of gas into the operatory.

The general ventilation should provide good room air mixing. In addition, auxiliary (local) exhaust ventilation used in conjunction with a scavenging system has been shown to be effective in reducing excess N\textsubscript{2}O in the breathing zone of the dentist and dental assistant, from nasal mask leakage and patient mouth breathing. This type of ventilation captures the waste anesthetic gases at their source. However, there are practical limitations in using it in the dental operatory. These include proximity to the patient, interference with dental practices, noise, and installation and maintenance costs. It is most important that the dentist not work between the patient and a free-standing local exhaust hood. Doing so will cause the contaminated air to be drawn through the dentist’s breathing zone. These auxiliary ventilation systems are not now commercially available. The Academy of General Dentistry also emphasizes properly installed and maintained analgesia delivery systems.

Work practices

- Prior to first use each day of the N\textsubscript{2}O machine and every time a gas cylinder is changed, the low-pressure connections should be tested for leaks. High-pressure line connections should be tested for leaks quarterly. A soap solution may be used to test for leaks at connections. Alternatively, a portable infrared spectrophotometer can be used to detect an insidious leak.
- Prior to first use each day, inspect all N\textsubscript{2}O equipment (e.g., reservoir bag, tubing, mask, connectors) for worn parts, cracks, holes, or tears. Replace as necessary.
- Connect mask to the tubing and turn on vacuum pump. Verify appropriate flow rate (i.e., up to 45 L/min or manufacturer’s recommendations).
- A properly sized mask should be selected and placed on the patient. A good, comfortable fit should be ensured. The reservoir (breathing) bag should not be over- or underinflated while the patient is breathing oxygen (before administering N\textsubscript{2}O).
- Encourage the patient to minimize talking, mouth breathing and facial movement while the mask is in place.
- During N\textsubscript{2}O administration, the reservoir bag should be periodically inspected for changes in tidal volume, and the vacuum flow rate should be verified.
- On completing anesthetic administration and before removing the mask, non-anesthetic gases/agents should be delivered to the patient for a sufficient time based on clinical assessment that may vary from patient to patient. In this way, both the patient and the system will be purged of residual N\textsubscript{2}O. Do not use an oxygen flush.

Cleanup and disposal of liquid anesthetic agent spills

Small volumes of liquid anesthetics such as halothane, enfurane, isoflurane, desflurane, and sevoflurane evaporate readily at normal room temperatures, and may dissipate before any attempts to clean up or collect the liquid are initiated. However, when large spills occur, such as when one or more bottles of a liquid agent break, specific cleaning and containment procedures are necessary and appropriate disposal is required. The recommendations of the chemical manufacturer’s material safety data sheet (MSDS) that identify exposure reduction techniques for spills and emergencies should be followed.

In addition, OSHA Standard for Hazardous Waste Operations and Emergency Response would apply if emergency response efforts are performed by employees. The employer must determine the potential for an emergency in a reasonably predictable worst-case scenario, and plan response procedures accordingly. Only adequately trained and equipped workers may respond to spills. When the situation is unclear or data are lacking on the exposure level, the response needs to be the same as for high levels of exposure. Responses to incidental releases of liquid anesthetic agents where the substance can be absorbed, neutralized or otherwise controlled at the time of release by employees in the immediate release area, or by maintenance personnel do not fall within the scope of this standard.

Because of the volatility of liquid anesthetics, rapid removal by suctioning in the OR is the preferred method for cleaning up spills. Spills of large volumes in poorly ventilated areas or in storage areas should be absorbed using an absorbent material, sometimes called a sorbent, that is designed for cleanup of organic chemicals. “Spill pillows” commonly used in hospital laboratories, vermiculite, and carbon-based sorbents are some of the materials commercially available and regularly used for this purpose. Caution should be exercised if broken glass bottles pose a hazard.

Both enfurane and desflurane are considered hazardous wastes under the EPA regulations because these chemicals contain trace amounts of
chloroform (a hazardous substance), a byproduct of the manufacturing process. Consequently, sorbents that have been saturated with enfurane or desflurane should be managed as an EPA hazardous waste material due to the trace concentrations of chloroform present. Isoflurane and halothane do not contain trace amounts of chloroform or any other regulated substance and are therefore not considered hazardous wastes by EPA.

To minimize exposure to all liquid anesthetic agents during cleanup and to limit exposure during disposal procedures, the following general guidelines are recommended. The waste material should be placed in a container, tightly sealed, properly labeled, and disposed of with other chemical wastes sent to a facility’s incinerator or removed by a chemical waste contractor. After a large spill has occurred and the appropriate response action taken, airborne monitoring should be conducted to determine whether the spill was effectively contained and cleaned up.

Determination of appropriate disposal procedures for each facility is the sole responsibility of that facility. Empty anesthetic bottles are not considered regulated waste and may be discarded with ordinary trash or recycled. Furthermore, the facility as well as the waste handling contractor must comply with all applicable federal, state, and local regulations.

To minimize exposure to waste liquid anesthetic agents during cleanup and disposal, the following general guidelines are recommended by the manufacturers of liquid anesthetic agents:

- Wear appropriate personal protective equipment. Where possible, ventilate area of spill or leak. Appropriate respirators should be worn.
- Restrict persons not wearing protective equipment from areas of spills or leaks until cleanup is complete.
- Collect the liquid spilled and the absorbent materials used to contain a spill in a glass or plastic container. Tightly cap and seal the container and remove it from the anesthetizing location. Label the container clearly to indicate its contents.
- Transfer the sealed containers to the waste disposal company that handles and hauls waste materials.
- Health-care facilities that own or operate medical waste incinerators may dispose of waste anesthetics by using an appropriate incineration method after verifying that individual incineration operating permits allow burning of anesthetic agents at each site.

**Air monitoring**

Air monitoring is one of the fundamental tools used to evaluate workplace exposures. Accordingly, this section presents some of the appropriate methods that can be used to detect and measure the concentration of anesthetic gases that may be present in the health care environment. The data provided by monitoring are necessary to establish proper engineering, work practice, and administrative controls to ensure the lowest reasonably achievable gas levels in the operatory and PACU room air.

OSHA recommends that air sampling for anesthetic gases be conducted every six months to measure worker exposures and to check the effectiveness of control measures. Furthermore, OSHA recommends that only the agents most frequently used need to be monitored, since proper engineering controls, work practices, and control procedures should reduce all agents proportionately. However, the decision to monitor only selected agents could depend not only on the frequency of their use, but on the availability of an appropriate analytical method and the cost of instrumentation. ASA emphasizes regular maintenance of equipment and scavenging systems, daily check-out procedures for anesthesiology equipment, and education to ensure use of appropriate work practices. It does not believe that a routine monitoring program is necessary when these actions are being carried out. ASA prefers to use monitoring when indicated, such as in the event of known or suspected equipment malfunction.

Three fundamental types of air samples can be taken in order to evaluate the workplace: personal, area and source samples. Personal samples give the best estimate of a worker’s exposure level because they represent the actual airborne contaminant concentration in the worker’s breathing zone during the sampling period. This is the preferred method for determining a worker’s time-weighted average (TWA) exposure and should be used to assess personal exposures during anesthetic administration and in the PACU. Where several healthcare workers perform the same job, on the same shift, and in the same work area, and the length, duration, and level of waste gas exposures are similar, an employer may sample a representative fraction of the employees instead of all employees.

Area sampling is useful for evaluating overall air contaminant levels in a work area and for investigating cross-contamination with other areas in the health care facility. Source sampling can be used to detect leaks in the anesthesiology delivery and scavenging systems as well as ineffective capture by the scavenging system. Thus, how samples are taken is a critical point in any safety program.

The OSHA Chemical Information Manual contains current sampling technology for several of the anesthetic gases that may be present in anesthetizing locations and PACUs. Some of the sampling methods available are summarized below.

**Time-integrated sampling**

- **Nitrous oxide**
  
  Personal N2O exposures can be determined by using the VAPOR-TRAK nitrous oxide passive monitor (sometimes called a “passive dosimeter” or “diffusive sampler”) as referenced in the 2000 OSHA Chemical Information Manual under IMIS:1953.
  
  The minimum sampling duration for the dosimeter is 15 minutes; however, it can be used for up to 16 hours of passive sampling. This sampler has not been validated by OSHA. Other dosimeters are commercially available and can be used. Although not validated by OSHA at this time, they may be validated in the future. Five liter, 5-layer aluminized gas sampling bags can also be used to collect a sample.

- **Halogenated agents**

  Three chlorofluorocarbon-based anesthetic agents (halothane, enfurane, and isoflurane) and one fluorocarbon-based agent (desflurane) are listed in the Chemical Information Manual. The OSHA sampling procedure for halothane is listed under IMIS:0395; for enfurane, under IMIS:1038; for isoflurane, under IMIS:F118; and for desflurane, under IMIS:R218.

  The current recommended media sampling for halothane, enfurane and isoflurane requires an Anasorb 747 tube (140/70 mg sections) or an Anasorb CMS tube (150/75 mg sections). The sample can be taken at a flow rate of 0.5 L/min. Total sample volumes not exceeding 12 liters are recommended. The current recommended sampling media for desflurane requires an Anasorb 747 tube (140/70 mg sections). The sample can be taken at a flow rate of 0.05 L/min. Total sample volumes not exceeding 3 liters are recommended. All four sampling methodologies are fully validated analytical procedures.

**Real-time sampling**

Sampling that provides direct, immediate, and continuous (real-time) readout of anesthetic gas concentrations in ambient air utilizes a portable infrared spectrophotometer. Since this method provides continuous sampling and instantaneous feedback, sources of anesthetic gas leakage and effectiveness of control measures can be immediately determined.

**Additional sampling guidelines**

If it should ever become necessary to enter an operating room to conduct air sampling, the following guidelines provide the information needed. Individuals performing air sampling should be familiar with and follow all OR procedures for access into and out of the surgical suite with particular attention to sterile and nonsterile areas. The patient is the center of the sterile field, which includes the areas of the patient, operating table, and furniture covered with sterile drapes and the personnel wearing sterile attire. Sampling in the breathing zone of surgeons and other nursing or technical personnel who work in the sterile field must conform to the principles of sterile field access. Strict adherence to sound principles of sterile technique and recommended practices is mandatory for the safety of the patient.

Generally speaking, each hospital has its own guidelines for proper OR attire and other safety...
procedures. These rules should be strictly followed by anyone entering the OR. There are standard uniform guidelines that apply to all hospitals. Only clean and/or freshly laundered OR attire is worn in the OR. Proper attire consists of body covers such as a two-piece pantsuit (scrub suit), head cover (cap or hood), mask, and shoe covers. A sterile gown is worn over the scrub suit to permit the wearer to come within the sterile field. Other attire such as gloves and eyewear may be required. Some hospitals, but not all, may allow persons coming into the OR to wear a clean gown (in addition to the cap, the mask, and the shoe covers) over their street clothes if they are not going to remain in the OR for longer than 10-15 minutes.

In regard to decontaminating outside equipment, each hospital has its own policy. However, the common practice is to “wipe off” all surfaces with a chemical disinfectant. Most hospitals use Wescodyne or other phenolic solutions. Good physical cleaning before disinfection helps reduce the number of microorganisms present and enhances biocidal action.

Any person not familiar with the OR is usually instructed by a scrub nurse on all the safety procedures pertaining to the hospital. The scrub nurse will also provide instructions on hand scrubbing and other procedures that may be necessary. Persons entering the OR must follow these guidelines and instructions.

In addition, it should be recognized that the patient’s welfare, safety, and rights of privacy are paramount.

**Hazard communication**

In accordance with the Hazard Communication Standard (29 CFR 1910.1200), employers in health care facilities must develop, implement and maintain at the workplace a written, comprehensive hazard communication program that includes provisions for container labeling, collection and availability of material safety data sheets (MSDSs), and an employee training and information program. The standard also requires a list of hazardous chemicals in the workplace as part of the written hazard communication program.

Any chemicals subject to the labeling requirements of the FDA are exempt from the labeling requirements under the Hazard Communication Standard. This includes such chemicals as volatile liquid anesthetics and compressed medical gases. However, containers of other chemicals not under the jurisdiction of the FDA must be labeled, tagged or marked with the identity of the material and must show appropriate hazard warnings as well as the name and address of the chemical manufacturer, importer, or other responsible party. The hazard warning can be any type of message – words, pictures, or symbols – that conveys the hazards of the chemical(s) in the container. Labels must be legible, in English (plus other languages if desired), and prominently displayed.

Each MSDS must be in English, although the employer may maintain copies in other languages as well, and must include information regarding the specific chemical identity of the anesthetic gases or hazardous chemical and its common names. In addition, information must be provided on the physical and chemical characteristics of the hazardous chemical, known acute and chronic health effects and related health information, primary route(s) of entry, exposure limits, precautionary measures, emergency and first-aid procedures, and the identification of the organization responsible for preparing the sheet. As a source of detailed information on hazards, copies of the MSDS for each hazardous chemical must be readily accessible during each work shift to employees when they are in their work area(s).

Employers must prepare a list of all hazardous chemicals in the workplace, and the list should be checked to verify that MSDSs have been received for each chemical. If there are hazardous chemicals used for which no MSDS has been received, the employer must contact the supplier, manufacturer or importer to obtain the missing MSDS.

Health care employers must establish a training and information program for all personnel who are involved in the handling of, or who have potential exposure to, anesthetic gases and other hazardous chemicals to apprise them of the hazards associated with these chemicals in the workplace. Training relative to anesthetic gases should place an emphasis on reproductive risks. Training and information must take place at the time of initial assignment and whenever a new hazard is introduced into the work area. At a minimum, employees must be informed of the following:

- Any operations and equipment in the work area where anesthetic agents and hazardous chemicals are present.
- Location and availability of the written hazard communication program including the required lists of hazardous chemicals and the required MSDS forms.

The employee training program must consist of the following elements:

- How the hazard communication program is implemented in the workplace, how to read and interpret information on the MSDS and label of each hazardous chemical, and how employees can obtain and use the available hazard information.
- The physical and health hazards of the chemicals in the work area.
- Measures employees can take to protect themselves from these hazards, including specific procedures put into effect by the employer to provide protection such as engineering controls, appropriate work practices, emergency procedures for spill containment, and the use of personal protective equipment.
- Methods and observations that may be used to detect the presence or release of anesthetic gases and other hazardous chemicals in the work area (such as monitoring conducted by the employer, continuous monitoring devices, and the appearance or odor of chemicals when released).

Personnel training records are not required to be maintained, but such records would assist employers in monitoring their programs to ensure that all employees are appropriately trained. Employers can provide employees information and training through whatever means are found appropriate and protective. Although there would always have to be some training on-site (such as informing employees of the location and availability of the written program and MSDSs), employee training may be satisfied in part by general training about the requirements of the hazard communication standard and about chemical hazards on the job which is provided by, for example, professional associations, colleges, universities, and training centers. In addition, previous training, education and experience of a worker may relieve the employer of some of the burdens of informing and training that worker. The employer, however, maintains the responsibility to ensure that employees are adequately trained and are equipped with the knowledge and information to do their jobs safely.

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<tr>
<th>Step</th>
<th>Procedure</th>
<th>Control</th>
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<tbody>
<tr>
<td>1</td>
<td>Visually inspect all N₂O equipment (reservoir bag, hoses, mask, connectors) for worn parts, cracks, holes, or tears.</td>
<td>Replace defective equipment and/or parts.</td>
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<tr>
<td>2</td>
<td>Turn on the N₂O tank and check all high- to low-pressure connections for leaks. Use a non-oil-based soap solution to check for bubbles at high pressure connectors, or use a portable infrared gas analyzer.</td>
<td>Determine leak source and fix. If tank valve leaks, replace tank; if O-rings, gaskets, valves, hoses, or fittings, replace. Contact the manufacturer for parts replacement. For threaded pipe fittings, use Teflon tape. Do not use this tape on compression fittings.</td>
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### 3. Select scavenging system and mask. Mask should come in various sizes to patients. Scavenging systems should operate at air flow rate of 45 lpm.

Provide a range of mask sizes for patients. Check to see that noise levels at the mask are acceptable when the scavenging system exhaust rate is operated at 45 lpm.

### 4. Connect mask to hose and turn on vacuum pump before turning on N₂O. Scavenging system vacuum pump must have capacity to scavenge 45 lpm per dental operation.

Determine proper vacuum pump size for maintaining 45 lpm flow rates, especially when interconnected with other dental scavenging systems. If undersized, replace pump.

### 5. Place mask on patient and assure a good, comfortable fit. Make sure reservoir bag is not over- or under-inflated while the patient is breathing.

Secure mask with “slip” ring for “good activity” from patient breathing.

### 6. Check general ventilation for good room air mixing. Exhaust vents should not be close to air supply vents (use smoke tubes to observe air movement in room.)

If smoke from smoke tubes indicate room air mixing is poor, then increase the airflow or redesign. If exhaust vents are close to air supply vents, relocate (check with ventilation engineers to make adjustments).

### 7. Conduct personal sampling of dentist and dental assistant for N₂O exposure. Use diffusive sampler or infrared gas analyzer (see sampling methods).

If personal exposures exceed 150 ppm during administration, improve mask fit and make sure it is secure over the patient’s nose. Minimize patient talking while N₂O is administered.

### 8. Repeat procedure in step 7.

If personal exposures are less than 150 ppm but greater than 25 ppm, implement auxiliary exhaust ventilation near the patient’s mouth. Capture distance should no greater than 10 inches from the patient’s nose and mouth area and exhaust no less than 250 cfm at the hood opening. Avoid getting between the auxiliary exhaust hood and patient’s mouth and nose area.

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**Conclusion**

Nitrous oxide is used in many dental and medical offices and should be used with care. It is the most frequently used sedation method used in dentistry. All bodily functions remain normal, and the patient is able to breathe on his/her own. The patient will not fall asleep and will not have memory loss. It is best used for mildly anxious patients who wish only a small amount of sedation to “take the edge off” or to make them less nervous. The patient is able to respond appropriately to physical stimulation and verbal commands. It is a way for the dentist to manage pain and anxiety during dental appointments, but they must also administer it wisely and with caution. Each dental or medical office should establish its own comprehensive training program on how to maintain the equipment and proper safety standards. This course should help you to review your office routines and make sure you are setting the way to achieve the best safety standards for your patients and for your employees.

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### Final Examination Questions

1. Long-term exposure to nitrous oxide can cause reproductive side effects.

   - True
   - False

2. The National Institute for Occupational Safety and Health recommended, in a technical report published in 1977, controlling exposure limits of nitrous oxide waste to 35 parts per million (ppm) of air during dental surgery.

   - True
   - False

3. Inhaled anesthetic agents include two different classes of chemicals.

   - True
   - False

4. Venting waste anesthetic gas via the exhaust grille or exhaust duct of a non-recirculating ventilation system is an example of an active system.

   - True
   - False

5. Three fundamental types of air samples can be taken to evaluate the workplace; they are personal, area and source samples.

   - True
   - False

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**Bibliography**


**"46 Health Care Professionals Linked to Substance Abuse," Bristol Herald Courier, April 20, 2009.**


**"Nitrous oxide. A new look at an old technique,””** Stanley F. Malamed, FDL06NOE12

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**DFL06NOE12**
CHAPTER 6 - NITROUS OXIDE – N₂O

Figures 1 through 7 in chapter

Figure 1

Figure 2

Figure 3

Figure 4

Figure 5

Figure 6

Figure 7
Heart and blood vessel disease can lead to heart attacks and strokes. But a lot can be done to prevent or slow down diabetes problems.

Guide your patients to a healthier lifestyle and give them these suggestions.
- Work with a dietitian to design a healthy eating plan.
- Create an exercise program that works with daily activities. Discuss this with a medical doctor. Being active at least 30 minutes every day will make a big difference.
- Always take medication as directed.
- Check blood glucose every day or as directed by a medical doctor.
- Keep a record of blood glucose; write it in a book or on a notepad.
- Check feet every day for cuts, blisters, sores, swelling, redness or sore toenails.
- Brush and floss teeth daily.
- Control blood pressure and cholesterol.
- Don’t smoke.

How can diabetes hurt the teeth and gums?
High blood glucose helps bacteria grow in the mouth, which can cause the patient to develop red, sore and swollen gums that bleed when they brush their teeth.

People with diabetes can have tooth and gum problems more often if their blood glucose stays high, and it can make tooth and gum problems worse or cause tooth loss.

Smoking makes it more likely for the patient to get a bad case of gum disease, especially for a person with diabetes or one who is age 45 or older. Red, sore and bleeding gums are the first sign of gum disease.

Some diabetes medicine can cause low blood glucose, called hypoglycemia. A dentist might want to talk with a patient’s medical doctor before the person’s visit about the best way to take care of his or her blood glucose during the dental work. The patient may need to bring some diabetes medicine and food to your office to help maintain a level blood glucose.

If the mouth is sore after the dental work, the patient may not be able to eat or chew for several hours or days. For guidance on how to adjust their normal routine while their mouth is healing, check with the medical doctor or dietitian and plan the following:
- What foods and drinks the patient should have.
- Whether the patient should change diabetes medicine routines.
- How often the patient should check his or her blood glucose during the day of and the days following the dental procedure.

Diabetes can cause serious problems in the mouth.
If you have a patient with diabetes, discuss this with the person and make sure he or she stays on a routine schedule with your office.
People with diabetes are at risk for mouth infections, especially periodontal disease, which can lead to painful chewing problems.

Other problems diabetes can cause are dry mouth and a fungal infection called thrush. Dry mouth happens when a person does not have enough saliva. Diabetes may also cause the glucose level in saliva to increase. Together, these problems may lead to thrush, which causes painful white patches in the mouth.

Impress upon your diabetic patients that by controlling their blood glucose, brushing and flossing every day and visiting a dentist regularly, they can prevent periodontal disease.

Cancer treatment and oral health
Most people are aware of common side effects of cancer treatment like nausea and hair loss. But many don’t realize that more than one-third of people treated for cancer develop complications that affect the mouth. These problems may interfere with cancer treatment and diminish the patient’s quality of life.

Oral complications of cancer treatment
With more than 1.4 million new cases of cancer diagnosed each year and a shift to outpatient management, you will likely see some of these patients in your practice. Because cancer treatment can affect the oral tissues, you need to know about potential oral side effects.

Preexisting or untreated oral disease can also complicate cancer treatment. Your role in patient management can extend benefits beyond the oral cavity.

Oral complications from radiation to the head and neck or chemotherapy for any malignancy can compromise patients’ health and quality of life, and affect their ability to complete planned cancer treatment. For some patients, the complications can be so debilitating that they may tolerate only lower doses of therapy, postpone scheduled treatments or discontinue treatment entirely. Oral complications can also lead to serious systemic infections. Medically necessary oral care before, during and after cancer treatment can prevent or reduce the incidence and severity of oral complications, enhancing both patient survival and quality of life.

Oral complications related to cancer treatment
Oral complications of cancer treatment arise in various forms and degrees of severity, depending on the individual and the cancer treatment. Chemotherapy often impairs the function of bone marrow, suppressing the formation of white blood cells, red blood cells and platelets.
During radiation therapy

Some cancer treatments are described as stomatotoxic because they have toxic effects on the oral tissues. Both chemotherapy and radiation therapy come with specific complications. You will need to consider the possibility of these complications each time you evaluate a patient with cancer.

Head and neck radiation, chemotherapy, and blood and marrow transplantation can cause oral complications ranging from dry mouth to life-threatening infections.

Head and neck radiation therapy

Patients receiving radiation therapy to the head and neck are at risk for developing oral complications. Because of the risk of osteonecrosis in irradiated fields, oral surgery should be performed before radiation treatment begins.

Before head and neck radiation therapy

- Conduct a pretreatment oral health examination and prophylaxis.
- Schedule dental treatment in consultation with the radiation oncologist.
- Extract teeth in the proposed radiation field that may be a problem in the future.
- Prevent tooth demineralization and caries:
  - Fabricate custom gel-applicator trays for the patient.
  - Prescribe a 1.1 percent neutral pH sodium fluoride gel or a 0.4 percent stannous, unflavored fluoride gel (not fluoride rinses).
  - Use a neutral fluoride for patients with porcelain crowns or resin or glass ionomer restorations.
  - Be sure that the trays cover all tooth structures without irritating the gingival or mucosal tissues.
  - Instruct the patient in home application of fluoride gel. Several days before radiation therapy begins, the patient should start a daily 10-minute application.
  - Have patients brush with a fluoride gel if using trays is difficult.
- Allow at least 14 days of healing for any oral surgical procedures.
- Conduct prosthetic surgery before treatment, because elective surgical procedures are contraindicated on irradiated bone.

During radiation therapy

- Monitor the patient’s oral hygiene.
- Watch for mucositis and infection.
- Advise against wearing removable appliances during treatment.

After radiation therapy

- Recall the patient for prophylaxis and home-care evaluation every four to eight weeks or as needed for the first six months after cancer treatment.
- Reinforce the importance of optimal oral hygiene.
- Monitor the patient for trismus; check for pain or weakness in masticating muscles in the radiation field. Instruct the patient to exercise three times a day, opening and closing the mouth as far as possible without pain; repeat 20 times.
- Consult with the oncology team about use of dentures and other appliances after mucositis subsides. Patients with friable tissues and xerostomia may not be able to wear them again.
- Watch for demineralization and caries. Lifelong, daily applications of fluoride gel are needed for patients with xerostomia.
- Advise against elective oral surgery on irradiated bone because of the risk of osteonecrosis. Tooth extraction, if unavoidable, should be conservative, using antibiotic coverage and possibly hyperbaric oxygen therapy.

Chemotherapy

The oral complications of chemotherapy depend upon the drugs used, the dosage, the degree of dental disease and the use of radiation. Chemoradiation therapy carries a significant risk for mucositis.

Before chemotherapy

- Conduct a pretreatment oral health examination and prophylaxis.
- Schedule dental treatment in consultation with the oncologist.
- Schedule oral surgery at least seven to 10 days before myelosuppressive therapy begins.
- Consult the oncologist before conducting any oral procedures in patients with hematologic cancers; do not conduct procedures in patients who are immunosuppressed or have thrombocytopenia.

During chemotherapy

- Consult the oncologist before any dental procedure, including prophylaxis.
- Ask the oncologist to order blood work 24 hours before oral surgery or other invasive procedures. Postpone when:
  - The platelet count is less than 75,000/mm³ or abnormal clotting factors are present.
  - Absolute neutrophil count is less than 1,000/mm³ or consider prophylactic antibiotics. (American Heart Association)
- Check for oral source of viral, bacterial or fungal infection in patients with fever of unknown origin.
- Encourage consistent oral hygiene measures.
- Consult the oncologist about the need for antibiotic prophylaxis before any dental procedures in patients with central venous catheters.

### Normal complete blood count

<table>
<thead>
<tr>
<th>Blood Type</th>
<th>Male: 4.7 – 6.1 million cells/mL</th>
<th>Female: 4.2 – 5.4 million cells/mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemoglobin</td>
<td>Male: 13.8 – 17.2 gm/dL</td>
<td>Female: 12.1 – 15.1 gm/dL</td>
</tr>
<tr>
<td>Hematocrit</td>
<td>Males: 40.7 – 50.3 percent</td>
<td>Female: 36.1 – 44.3 percent</td>
</tr>
</tbody>
</table>

### Platelets

<table>
<thead>
<tr>
<th>Blood Type</th>
<th>150,000 – 400,000/mm³</th>
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</thead>
</table>

### White blood cells

<table>
<thead>
<tr>
<th>Blood Type</th>
<th>4,500 – 10,000 cells/mL</th>
</tr>
</thead>
</table>

### Differential white blood cell (WBC) count

<table>
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<tr>
<th>Blood Type</th>
<th>Percent</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neutrophils (PMNs)</td>
<td>40 – 60 percent</td>
<td>(3000 – 6000/mm³)</td>
</tr>
<tr>
<td>Neutrophils (Bands)</td>
<td>0 – 3 percent</td>
<td>(0 – 300/mm³)</td>
</tr>
<tr>
<td>Eosinophils</td>
<td>1 – 4 percent</td>
<td>(50 – 400/mm³)</td>
</tr>
<tr>
<td>Basophils</td>
<td>0.5 – 1 percent</td>
<td>(15 – 15/mm³)</td>
</tr>
<tr>
<td>Lymphocytes</td>
<td>20 – 40 percent</td>
<td>(1200 – 3000/mm³)</td>
</tr>
<tr>
<td>Monocytes</td>
<td>2 – 8 percent</td>
<td>(100 – 600/mm³)</td>
</tr>
</tbody>
</table>

### Absolute neutrophil count = WBC x ( percent PMNs + percent bands)

Source: A.D.A.M. Medical Encyclopedia (Internet) http://www.nimnih.gov/medlineplus/ency/article/003643.htm

### After chemotherapy

- Place the patient on a dental recall schedule when chemotherapy is completed and all side effects, including immunosuppression, have resolved.
- Confirm normal hematologic status prior to dental treatment.
- Ask whether the patient has received intravenous bisphosphonate therapy.

### Oral complications common to both chemotherapy and radiation

- **Oral mucositis**: Inflammation and ulceration of the mucous membranes; can increase the risk for pain, oral and systemic infection, and nutritional compromise. Culture lesions to identify secondary infection. Prescribe topical anesthetics and system analgesics. Consult the oncologist about prescribing antimicrobial agents for known infections. Have the patient avoid rough-textured foods and report oral problems early.

- **Infection**: Viral, bacterial and fungal; results from myelosuppression, xerostomia and/or damage to the mucosa from chemotherapy or radiotherapy.

- **Xerostomia/salivary gland dysfunction**: Dryness of the mouth due to thickened, reduced or absent salivary flow; increases the risk of infection and compromises speaking, chewing and swallowing. Medications other than chemotherapy can also cause salivary gland dysfunction. Persistent dry mouth increases the risk for dental caries. Advise the patient to soften or thin foods with liquid, chew sugarless gum, or suck ice chips or sugar-free hard candies. Suggest using commercial saliva substitutes or prescribe a saliva stimulant.

- **Functional disabilities**: Impaired ability to eat, taste, swallow and speak because of mucositis, dry mouth, trismus and infection.
Taste alterations: Changes in taste perception of foods, ranging from unpleasant to tasteless. Refer to a dietician.

Nutritional compromise: Poor nutrition from eating difficulties caused by mucositis, dry mouth, dysphagia and loss of taste.

Abnormal dental development: Altered tooth development, craniofacial growth, or skeletal development in children secondary to radiotherapy and/or high doses of chemotherapy before age 9.

Etched enamel: Advise the patient to rinse the mouth with water and baking soda solution after vomiting to protect enamel.

Other complications of chemotherapy
Neurotoxicity: Persistent, deep aching and burning pain that mimics a toothache, but for which no dental or mucosal source can be found. This complication is a side effect of certain classes of drugs, such as the vinca alkaloids. Provide analgesics or systemic pain relief.

Bleeding: Oral bleeding from the decreased platelets and clotting factors associated with the effects of therapy on bone marrow. Advise the patient to clean teeth thoroughly with a toothbrush softened in warm water; to avoid flossing the areas that are bleeding but to keep flossing the other teeth.

Other complications of radiation therapy
Demineralization and radiation caries: Prescribe daily fluoride gel applications before treatment starts. Continue for the patient’s lifetime if changes in quality or quantity of saliva persist.

Radiation caries: Lifelong risk of rampant dental decay that may begin within three months of completing radiation treatment if changes in either the quality or quantity of saliva persist.

Trismus/tissue fibrosis: Loss of elasticity of masticatory muscles that restrict normal ability to open the mouth. Instruct the patient on stretching exercises for the jaw to prevent or reduce the severity of fibrosis.

Osteonecrosis: Blood vessel compromise and necrosis of bone exposed to high-dose radiation therapy; results in decreased ability to heal if traumatized. Avoid invasive procedures involving irradiated bone, particularly the mandible.

Who has oral complications?
Oral complications occur in virtually all patients receiving radiation for head and neck malignancies, in approximately 80 percent of hematopoietic (blood-forming) stem cell transplant recipients, and in nearly 40 percent of patients receiving chemotherapy. Risk for oral complications can be classified as low or high:

Lower risk: Patients receiving minimally myelosuppressive or nonmyelosuppressive chemotherapy.

Higher risk: Patients receiving stomatotoxic chemotherapy resulting in prolonged myelosuppression, including patients undergoing hematopoietic stem cell transplantation; and patients undergoing head and neck radiation for oral, pharyngeal and laryngeal cancer.

Some complications occur only during treatment; others, such as xerostomia, may persist for years. Unfortunately, patients with cancer often do not receive oral care until serious complications develop.

The role of pretreatment oral care
A thorough oral evaluation by a knowledgeable dentist before cancer treatment begins is important to the success of the regimen. Pretreatment oral care achieves the following:

- Reduces the risk and severity of oral complications.
- Allows for prompt identification and treatment of existing infections or other problems.
- Improves the likelihood that the patient will successfully complete planned cancer treatment.
- Prevents, eliminates or reduces oral pain.
- Minimizes oral infections that could lead to potentially serious systemic infections.
- Prevents or minimizes complications that compromise nutrition.
- Prevents or reduces later incidence of bone necrosis.
- Preserves or improves oral health.
- Provides an opportunity for patient education about oral hygiene during cancer therapy.
- Improves the quality of life.
- Decreases the cost of care.

With a pretreatment oral evaluation, the dental team can identify and treat problems such as infection, fractured teeth or restorations, or periodontal disease that could contribute to oral complications when cancer therapy begins. The evaluation also establishes baseline data for comparing the patient’s status in subsequent examinations.

Before the exam, you will need to obtain the patient’s cancer diagnosis and treatment plan, medical history and dental history. Open communication with the patient’s oncologist is essential to ensure that each provider has the information necessary to deliver the best possible care.

Patient evaluation
Ideally, a comprehensive oral evaluation should take place one month before cancer treatment starts to allow adequate time for recovery from any required invasive dental procedures. The pretreatment evaluation includes a thorough examination of hard and soft tissues as well as appropriate radiographs to detect possible sources of infection and pathology. Also take the following steps before cancer treatment begins:

- Identify and treat existing infections, carious and other compromised teeth, and tissue injury or trauma.
- Stabilize or eliminate potential sites of infection.
- Extract teeth in the radiation field that are nonrestorable or may pose a future problem to prevent later extraction-induced osteonecrosis.

Conduct a prosthodontic evaluation if indicated. If a removable prosthesis is worn, make sure that it is clean and well adapted to the tissue. Instruct the patient not to wear the prosthesis during treatment, if possible; or at the least, not to wear it at night.

Perform oral prophylaxis if indicated.

Time oral surgery to allow at least two weeks for healing before radiation therapy begins. For patients receiving radiation treatment, this is the best time to consider surgical procedures. Oral surgery should be performed at least seven to 10 days before the patient receives myelosuppressive chemotherapy. Medical consultation is indicated before invasive procedures.

Remove orthodontic bands and brackets if highly stomatotoxic chemotherapy is planned or if the appliances will be in the radiation field.

Consider extracting highly mobile primary teeth in children, and teeth that are expected to exfoliate during treatment.

Prescribe an individualized oral hygiene regimen to minimize oral complications. Patients undergoing head and neck radiation therapy should be instructed on the use of supplemental fluoride.

Supplemental fluoride
Fluoride rinses are not adequate to prevent tooth demineralization. Instead, a high-potency fluoride gel, delivered via custom gel-applicator trays, is recommended. Several days before radiation therapy begins, patients should start a daily 10-minute-application of a 1.1 percent neutral pH sodium fluoride gel or a 0.4 percent stannous fluoride (unflavored) gel. Patients with porcelain crowns or resin or glass ionomer restorations should use a neutral pH fluoride. Be sure that the trays cover all tooth structures without irritating the gingival or mucosal tissues.

For patients reluctant to use a tray, a high-potency fluoride gel should be brushed on the teeth following daily brushing and flossing. Either 1.1 percent neutral pH sodium or 0.4 percent stannous fluoride gel is recommended, based on the patient’s type of dental restorations.

Questions to ask the medical oncologist
1. What is the patient’s complete blood count, including absolute neutrophil and platelet counts?
2. If an invasive dental procedure needs to be done, are there adequate clotting factors?
3. Does the patient have a central venous catheter?
4. What is the scheduled sequence of treatments so that safe dental treatment can be planned?
5. Is radiation therapy also planned?

Questions to ask the radiation oncologist
1. What parts of the mandible/maxilla and salivary glands are in the field of radiation?
2. What is the total dose of radiation the patient will receive, and what will be the impact on these areas?
3. Has the vascularity of the mandible been previously compromised by surgery?
4. How quickly does the patient need to start radiation treatment?
5. Will there be induction chemotherapy with the radiation treatment?

Hematopoietic stem cell transplantation
Most stem cell transplant patients develop acute oral complications, especially patients with graft-versus-host disease.

Before transplantation
- Conduct a pretreatment oral health examination and prophylaxis.
- Consult the oncologist about scheduling dental treatment.
- Schedule oral surgery at least seven to 10 days before myelosuppressive therapy begins.
- Prevent tooth demineralization and radiation caries:
  - Instruct the patient in home application of fluoride gel (not fluoride rinses).
  - Explain the necessary oral hygiene regimen to the patient.

After transplantation
- Consult the oncologist before any dental procedure, including prophylaxis.
- Monitor the patient’s oral health for plaque control, tooth demineralization, dental caries and infection.
- Watch for infections on the tongue and oral mucosa. Herpes simplex and Candida albicans are common oral infections.
- Delay elective oral procedures for one year.
- Follow patients for long-term oral complications. Such problems are strong indicators of chronic graft-versus-host disease.
- Monitor transplant patients carefully for second malignancies in the oral region.

Advice for your patients
- Brush teeth, gums and tongue gently with an extra-soft toothbrush and fluoride toothpaste after every meal and at bedtime. If brushing hurts, soften the bristles in warm water.
- Floss teeth gently every day. If gums bleed and hurt, avoid the areas that are bleeding or sore but keep flossing your other teeth.
- Follow instructions for fluoride gel applications.
- Avoid mouthwashes containing alcohol.
- Rinse the mouth several times a day with a baking soda and salt solution, followed by a plain water rinse. Use ¼ teaspoon each of baking soda and salt in 1 quart of warm water. Omit salt during mucositis.
- Try the following if dry mouth is a problem:
  - Sip water frequently.
  - Suck ice chips or use sugar-free gum or candy.
  - Use saliva substitute spray or gel or a prescribed saliva stimulant if appropriate.
  - Avoid glycercin swabs.
  - Exercise the jaw muscles three times a day to prevent and treat jaw stiffness from radiation treatment.

Special care for children
Children receiving chemotherapy and/or radiation therapy are at risk for the same oral complications as adults. Other actions to consider in managing pediatric patients include:
- Before the cancer treatment begins, extract loose primary teeth and teeth expected to exfoliate during cancer treatment.
- Remove orthodontic bands and brackets if highly stomatotoxic chemotherapy is planned or if the appliances will be in the radiation field.
- Monitor craniofacial and dental structures for abnormal growth and development.

Oral complications and the heart with infective endocarditis
Endocarditis is a sometimes life-threatening infection of the inner surface of the heart and/or its valves. Of the approximately 15,000 cases of endocarditis reported each year in the United States, many likely arise when bacteria that naturally attach to our teeth are displaced and pass into the bloodstream during a dental procedure, flossing, or even chewing food.

These microbes, while relatively harmless in the mouth, have an affinity for damaged endothelial cells or blood clots in the heart, where they attach, multiply and form larger bacterial colonies that trigger the endocarditis. Scientists have shown that immune cells called monocytes are prominently found in early inflammatory lesions linked to endocarditis. What’s been puzzling is the monocytes tend to disappear from the lesions over time without becoming macrophages, a scavenging immune cell formed from monocytes that removes debris from tissues, such as the damaged, bacteria-laden cells linked to endocarditis.

In a report in the journal Infection and Immunity, NIDCR grantees show that the usual monocyte-macrophage transformation rarely occurs because monocytes infected in studies with the well-known oral bacterium Streptococcus mutans instead become dendritic cells, a type of immune cell that initiates an inflammation-producing immune response upon interaction with this bacterium. This finding indicates that oral streptococci-mediated changes in a person’s normal immune response can contribute to endocarditis. It also suggests that an effective future strategy to treat endocarditis might involve learning to turn off the destructive immune response and/or reprogram the monocytes to produce macrophages to clear away the disease-causing bacterial colonies from the heart.

Endocarditis is an infection of the inner lining of the heart chambers and valves. This lining is called the endocardium. The condition also is called infective endocarditis (IE).

Infective endocarditis occurs if bacteria, fungi, or other germs invade the bloodstream and attach to abnormal areas of the heart. The infection can damage the heart and cause serious and sometimes fatal complications. It can develop quickly or slowly; it depends on what type of germ is causing it and whether the patient has an underlying heart problem. When it develops quickly, it is called acute infective endocarditis. When it develops slowly, it is called subacute infective endocarditis.

The disease mainly affects people who have:
- Damaged or artificial (man-made) heart valves.
- Congenital heart defects (defects present at birth).
- Implanted medical devices in the heart or blood vessels.

People who have normal heart valves also can have this disease. However, the condition is much more common in people who have abnormal hearts.

Certain factors make it easier for bacteria to enter the bloodstream. These factors put the patient at higher risk for infective endocarditis. For example, poor dental hygiene and unhealthy teeth and gums increase the risk for the infection.

Other risk factors include using intravenous (IV) drugs, having a catheter (tube) or another medical device in the body for long periods, and having a history of infective endocarditis.

Common symptoms of infective endocarditis are fever and other flu-like symptoms. Because the infection can affect people in different ways, the signs and symptoms vary. The disease may cause problems in many other parts of the body besides the heart.

What causes endocarditis?
The disease occurs if bacteria, fungi or other germs invade the bloodstream and attach to abnormal areas of the heart. A common underlying factor in infective endocarditis is a structural heart defect, especially faulty heart valves. Usually the immune system will kill germs in the bloodstream. If the heart has a rough lining or abnormal valves, the invading germs can attach and multiply in the heart.

Other factors also can play a role in causing the disease. Common activities, such as brushing the teeth or having certain dental procedures, can allow bacteria to enter the bloodstream. This is even more likely to happen if the teeth and gums are in poor condition.

Having a catheter, tube or other medical device inserted through the skin, especially for long periods, can allow bacteria to enter the bloodstream. People who use intravenous (IV) drugs also are at risk for infective endocarditis because of the germs on needles and syringes.

Bacteria may spread to the blood and heart from infections in other parts of the body such as the gut, skin or genitals.
Endocarditis complications
- This disease can cause many complications; the most common is problems with the heart. They occur in one-third to one-half of all people who have the infection. These problems may include:
  - A heart murmur.
  - Heart failure.
  - Heart valve damage.
  - Heart block.
  - Heart attack.
- Complications of the central nervous system occur in as many as 20 to 40 percent of people who have infective endocarditis. The central nervous system complications most often occur when bits of the vegetation called emboli break away and lodge in the brain. The emboli can cause local infections called brain abscesses. They also can cause a more widespread brain infection called meningitis.
- Emboli can cause strokes or seizures. This happens if they block blood vessels or affect the brain’s electrical signals.
- These complications can cause long-term brain damage or even be fatal.
- Infective endocarditis can affect other organs in the body, such as the lungs, kidneys and spleen.
  - The lungs are at risk when the endocarditis affects the right side of the heart.
  - The kidneys can become abscessed and the infection can inflame the internal filtering structures of the kidneys.
  - The spleen can become enlarged, especially in people with long-term infective endocarditis. Sometimes emboli can damage the spleen.

How can endocarditis be prevented?
To help your patients prevent endocarditis, always take steps to maintain infection control in your office and advise your patients to:
- Let you know if they are at risk for endocarditis. (These patients may need an antibiotic before routine dental exams and certain other dental and medical procedures.)
- Brush and floss their teeth regularly.
- Have regular dental checkups.
- Avoid body piercing, tattoos and other procedures that may allow germs to enter the bloodstream.
- Be alert to the signs and symptoms of infective endocarditis. (Advise the patient to see a medical doctor if any of these symptoms persist.)
  - Flu-like symptoms, such as fever chills, fatigue (tiredness), aching muscles and joints, night sweat and headaches.
  - Shortness of breath or a cough that won’t go away.
  - A new heart murmur or a change in an existing heart murmur.
  - Skin changes such as:
    - Overall paleness.
    - Small, painful, red purplish bumps under the skin on the fingers or toes.
    - Tiny spots under the fingernails, on the whites of the eyes, on the roof of the mouth and inside of the cheeks, or on the chest. These spots are from broken blood vessels.
  - Nausea, vomiting, a decrease in appetite, a sense of fullness with discomfort on the upper left side of the abdomen or weight loss with or without a change in appetite.
  - Blood in the urine.
  - Swelling in the feet, legs or abdomen.

Sjögren’s syndrome
In the early 20th century, Swedish physician Henrik Sjögren (SHOW-gren) first described a group of women whose chronic arthritis was accompanied by dry eyes and dry mouth. Today rheumatologists know more about the syndrome that is named for Sjögren and, most significantly for patients, can provide advice about how to live with it.
- Sjögren’s syndrome sometimes develops as a complication of another autoimmune disorder.
- Symptoms vary in type and intensity, but many people with Sjögren’s are able to live normal lives.
- Although serious complications are rare, regular medical care is important.

What is Sjögren’s syndrome?
Sjögren’s syndrome is an inflammatory disease that can affect many different parts of the body, but most often affects the tear and saliva glands. Patients with this condition may notice irritation, a gritty feeling or painful burning in the eyes. Dry mouth or difficulty eating dry foods and swelling of the glands around the face and neck are also common. Some patients experience dryness of other mucous membranes (such as the nasal passages, throat and vagina) and skin.

“Primary” Sjögren’s syndrome occurs in people with no other rheumatologic disease. “Secondary” Sjögren’s occurs in people who do have another rheumatologic disease, most often lupus and rheumatoid arthritis.
Most of the complications of Sjögren’s syndrome occur because of decreased tears and saliva. Patients with dry eyes are at increased risk for infections around the eye and may have damage to the cornea. Dry mouth may cause an increase in dental decay, gingivitis (gum inflammation), and oral yeast infections (thrush) that may cause pain and burning. Some patients have episodes of painful swelling in the saliva glands around the face.
Complications in other parts of the body occur rarely in patients with Sjögren’s syndrome. Pain and stiffness in the joints with mild swelling may occur in some patients, even in those without rheumatoid arthritis or lupus. Rashes on the arms and legs related to inflammation in small blood vessels (vasculitis) and inflammation in the lungs, liver, and kidney may occur rarely and be difficult to diagnose. Neurological complications that cause symptoms such as numbness, tingling and weakness have also been described in some patients.

What causes Sjögren’s syndrome?
The cause of Sjögren’s syndrome is not known, but it is considered an autoimmune disorder. People with this disease have abnormal proteins in their blood suggesting that their immune system, which normally functions to protect the body against cancers and invading infections, is reacting against their own tissue. The decreased production of tears and saliva seen in Sjögren’s syndrome occurs when the glands that produce these fluids are damaged by inflammation.
Research suggests that genetic factors and possibly viral infections (as yet unidentified) may predispose people to developing this condition.

Who gets Sjögren’s syndrome?
Between 400,000 and 3.1 million adults have Sjögren’s syndrome. This condition can affect people of any age, but symptoms usually appear between the ages of 45 and 55. It affects 10 times as many women as men. About half of affected patients also have rheumatoid arthritis or other connective tissue diseases, such as lupus.

How is Sjögren’s syndrome diagnosed?
Diagnosis depends on a combination of symptoms, physical findings, blood tests and sometimes special studies. Dry eyes and mouth may be early signs of the condition but require further investigation because these symptoms can be caused by many other conditions or medications. Special tests may be used to assess any decrease in tear or saliva production (an example would be the Schirmer test for tear production). An eye examination is helpful in detecting any eye changes seen in Sjögren’s.
Blood tests can determine the presence of antibodies (immune system cells that help destroy foreign invaders) typical of the disease, including anti-nuclear antibodies (ANA), anti-SSA and SSQ antibodies, or rheumatoid factor. Biopsies of saliva glands around the face or under the surface of the inner lip may also sometimes be used to establish a diagnosis.

How is Sjögren’s syndrome treated?
Treatment is designed to lessen the most bothersome symptoms. Dry eyes usually respond to the use of artificial tears applied regularly during the day or to gels applied at night. Other measures, such as plugging or blocking tear ducts, can be used in more severe cases. Eye drops that reduce inflammation in the glands around the eyes (cyclosporine-Restasis) may be used to increase tear production. Dry mouth can be relieved by drinking water, chewing gum or using saliva substitutes. Some patients benefit from using prescription medications that stimulate saliva flow, such as pilocarpine (Salagen) or cevimeline (Evoxac). If patients...
develop yeast infections, these can be relieved by anti-fungal therapies. The currently available treatments may help relieve some of the dryness, but usually some dryness persists.

All patients should receive regular dental care in order to prevent cavities and tooth loss that may occur as a complication of the disorder. Patients with dry eyes should see an ophthalmologist regularly for signs of damage to the cornea. Patients with excessive redness and pain in the eyes should be evaluated for infections.

Hydroxychloroquine (Plaquenil), an antimalarial drug used in lupus and rheumatoid arthritis, may be helpful in some patients with Sjögren’s syndrome by reducing joint pain and rash experienced by some patients. Patients with rare but serious systemic symptoms, such as fever, rashes, abdominal pain or lung or kidney problems, may require treatment with corticosteroids such as prednisone (Deltasone and others) and/or immunosuppressive agents, such as methotrexate (Rheumatrex), azathioprine (Imuran), mycophenolate (CellCept), cyclophosphamide (Cytoxan). In addition, rituximab (Rituxan) and other biological therapies (as used in rheumatoid arthritis) are undergoing evaluation for treating patients with severe systemic manifestations of disease.

Broader health impact of Sjögren’s syndrome
A vast majority of patients with Sjögren’s syndrome remain very healthy, without any serious complications. Patients should be aware that they do face an increased risk for infections in and around the eyes and an increased risk for dental problems – both of which are due to the long-term reduction in tears and saliva.

Rarely, patients may have complications related to inflammation in other body systems, including:
- Joint and muscle pain with fatigue.
- Lung problems that may mimic pneumonia.
- Abnormal liver and kidney function tests.
- Skin rashes related to inflammation of small blood vessels.
- Neurologic problems causing weakness and numbness.

In a small number of people, Sjögren’s syndrome may be associated with lymphoma, a cancer of the lymph glands.

Living with Sjögren’s syndrome
People with Sjögren’s syndrome are usually able to live normal lives with very few adjustments. When a diagnosis is made, many patients must focus a great deal of attention dealing with dry eyes and dry mouth, but these symptoms tend to subside with time. Any pain or redness in the eyes should be evaluated promptly, because this may signal an infection. To reduce risk for cavities and other dental problems, patients must pay close attention to proper oral hygiene and regular dental care.

Patients should see their physician regularly for general health screening and should pay close attention to any abnormal swelling in the glands around the face or neck, under the arms or in the groin areas because this may be a sign of lymphoma.

Sjögren’s syndrome is an autoimmune condition that can occur at any age, but is most common in older women. Many patients develop Sjögren’s syndrome as a complication of another autoimmune disease, such as rheumatoid arthritis or lupus.

Most of the treatment for Sjögren’s syndrome is aimed at relieving symptoms of dry eyes and mouth and preventing and treating long-term complications such as infection and dental disease. Currently available treatments often do not completely eliminate the symptoms of dryness in some patients.

Most patients with Sjögren’s syndrome remain healthy, but a number of rare complications have been described, including an increased risk for cancer of the lymph glands (lymphoma). Thus, regular medical care and follow-up is important for all patients.

Mouth problems with human immunodeficiency virus (HIV)
Human immunodeficiency virus is a lentivirus (a member of the retrovirus family) that causes acquired immunodeficiency syndrome (AIDS), a condition in humans in which the immune system begins to fail, leading to life-threatening opportunistic infections. Infection with HIV occurs by the transfer of blood, semen, vaginal fluid, pre-ejaculate or breast milk. Within these bodily fluids, HIV is present as both free virus particles and virus within infected immune cells.

HIV infection in humans is considered pandemic by the World Health Organization (WHO). Nevertheless, complacency about HIV may play a key role in HIV risk. From its discovery in 1981 to 2006, AIDS killed more than 25 million people. HIV infects about 0.6 percent of the world’s population. In 2005 alone, AIDS claimed an estimated 2.4 million to 3.3 million lives, of which more than 570,000 were children.

Oral problems are very common in people with HIV. More than a third of people living with HIV have oral conditions that arise because of their weakened immune system. And even though combination antiretroviral therapy has made some oral problems less common, others are occurring more often with this type of treatment. These problems can be very painful, annoying and lead to other problems. Oral problems can also lead to trouble with eating, as well as cause discomfort and embarrassment. If the mouth is in pain and has tenderness, it becomes difficult to chew and swallow, and the patient may not eat enough, causing weight loss and other complications. The body may not have enough energy to deal with HIV.

Some of the most common oral problems linked with HIV can be treated; they include:
- **Aphthous ulcers (canker sores):** Red sores that might also have a yellow-gray film on top. They are usually on the movable parts of the mouth, such as the tongue or inside of the cheeks and lips.
- **Herpes:** A viral infection, red sores usually on the roof of the mouth. They are sometimes on the outside of the lips, where they are called fever blisters.
- **Hairy leukoplakia:** This is caused by the Epstein-Barr virus. They are white patches that do not wipe away and are sometimes very thick and hairlike. They usually appear on the side of the tongue or sometimes on the cheeks and lower lip.
- **Candidiasis:** This is a fungal yeast infection that produces white or yellowish patches (sometimes red). If wiped away, there will be redness or bleeding underneath. They can appear anywhere in the mouth.
- **Warts:** Small, white, gray or pinkish rough bumps that look like cauliflower. They can appear inside the lips and on other parts of the mouth.
- **Dry mouth xerostomia/salivary gland dysfunction:** This happens when the patient does not have enough saliva to keep the mouth wet. Without enough saliva, the patient could develop tooth decay or other infections and might have trouble chewing and swallowing. This can cause the mouth to be very dry, with a burning feeling, cracked and chapped lips. (See the section below on xerostomia.)

Treatment for these include:
- **Infection control.**
  - Brush and floss regularly with a soft bristle toothbrush.
- **Aphthous ulcers or canker sores:** An over-the-counter cream or prescription mouthwash that contains corticosteroids; for more severe cases, use corticosteroids pills.
- **Herpes:** Antiviral medications can reduce the healing time and frequency of outbreaks.
- **Hairy leukoplakia:** Antivirals for the more severe cases may reduce symptoms. In some cases, a pain reliever may be required.
- **Candidiasis:** A mild prescription for an antifungal lozenge or mouthwash. An antifungal pill might be necessary for the more severe cases.
- **Warts in the mouth:** These can be removed surgically or by cryosurgery. A prescription cream may be used for treatment. The warts may return after treatment.

Oral complications with xerostomia/ salivary gland dysfunction or dry mouth
Dry mouth is a complication of many of these diseases, but it is also a symptom of a gland dysfunction.

Dry mouth is the feeling that there is not enough saliva in the mouth. Everyone has dry mouth occasionally, often when they are nervous, upset, under stress or taking certain medications. Many older adults have dry mouth, but it is not a normal part of aging.

Saliva does more than keep the mouth wet. It protects teeth from decay, it helps heal sores in
the mouth and prevents infection by controlling bacteria, viruses and fungi in the mouth.

Saliva helps digest food and helps us chew and swallow. Saliva is involved in taste perception as well. Each of these functions of saliva is hampered when a person has dry mouth. It can be very uncomfortable. Some people notice a sticky, dry feeling in the mouth. Others notice a burning feeling or difficulty while eating. It may cause the throat to feel dry, making swallowing difficult and choking common. People with dry mouth may get sores, cracked lips and a dry, rough tongue.

People get dry mouth when the glands in the mouth that make saliva are not working properly and do not produce enough saliva to keep the mouth healthy. There are several reasons why salivary glands might not work right.

More than 400 medicines, including some over-the-counter medications, can cause the salivary glands to make less saliva, or to change the composition of the saliva so that it can’t perform the functions it should. As an example, medicines for urinary incontinence, allergies, high blood pressure and depression often cause dry mouth.

Some diseases can affect the salivary glands. Dry mouth can occur in patients with diabetes and Parkinson’s disease. Dry mouth is the hallmark symptom of the fairly common autoimmune disease Sjögren’s syndrome.

Sjögren’s syndrome can occur either by itself or with another autoimmune disease like rheumatoid arthritis or lupus. Salivary and tear glands are the major targets of the syndrome, and the result is a decrease in production of saliva and tears. The disorder can occur at any age, but the average person with the disorder at the Sjögren’s Syndrome Clinic of the National Institute of Dental and Craniofacial Research (NIDCR) is in his or her late 50s. Women with the disorder outnumber men 9 to 1.

Certain cancer treatments can affect the salivary glands. Head and neck radiation therapy can cause the glands to produce little or no saliva. Chemotherapy may cause the salivary glands to produce thicker saliva, which makes the mouth feel dry and sticky.

Injury to the head or neck can damage the nerves that tell salivary glands to make saliva.

How is dry mouth treated?

- First try to determine the cause.
- Change the patient’s medication or dosage if this is the cause.
- Prescribe a medicine for the salivary glands, if this is the cause.
- Suggest the use of artificial saliva to keep the mouth wet.
- Suggest the patient drink lots of water and sugarless drinks.
- Instruct patients to avoid caffeine drinks such as coffee, tea and some sodas. (Caffeine can dry out the mouth.)
- Tell patients to avoid tobacco or alcohol, which will dry out the mouth.
- Suggest that the patient chew sugarless gum or suck on sugarless hard candy to stimulate saliva flow.
- Tell the patient to stay away from spicy or salty foods because they will cause pain in a dry mouth.
- Suggest using a humidifier at night to promote moisture in the air while the patient is sleeping.

Scientists are exploring the potential use of gene therapy – replacing, manipulating or supplementing nonfunctional genes with healthy genes – to treat salivary gland dysfunction. The idea is to transfer additional or replacement genes into the salivary glands of people with Sjögren’s syndrome and cancer patients whose salivary glands are damaged by radiation treatment. The hope is that these genes will increase the production of saliva and eliminate the chronic parched sensation that bothers people with dry mouth conditions.

Research efforts are also under way to develop an artificial salivary gland for patients who have lost all salivary gland function. The first-generation artificial gland will be a tiny tube lined with cells that have been engineered to produce saliva-like fluid. Made of biodegradable material, the tube would be inserted into the inside of the cheek. All the components for the artificial gland have been developed with the goal of producing a prototype within a few years.

Advise patients to take these steps to prevent xerostomia/salivary gland dysfunction or dry mouth:

- Brush teeth several times a day with an extra-soft toothbrush, at least after every meal and at bedtime. If brushing hurts, soften the bristles in warm water.
- Floss teeth gently every day. If gums bleed, avoid the areas that are bleeding and sore.
- Always use toothpaste with fluoride.
- Avoid sticky, sugary foods. Brush immediately eating.
- Do not use mouthwashes with alcohol in them. Alcohol can dry out the mouth.
- If necessary, prescribe a fluoride gel to help prevent dental decay.

Conclusion

There are many causes for oral complications, and the best way to help your patients is to stay informed about the types of diseases, treatments and ways to reduce the risk and impact of these often painful side effects that diminish their quality of life. Good oral health not only makes them feel better, it also makes them look better and elevates their self-esteem, a very important factor.

But the most important fact to remember is that good health begins in the mouth, and that saliva carries germs through the bloodstream, which can cause complications. Patients with these diseases have been through so much that they tend to ignore or “let go” their dental care. As a dental professional, you can help to prevent these complications with a health care strategy and advice on necessary home-care treatment, thus removing at least one problem for people facing such serious diseases.

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**ORAL COMPLICATIONS WITH DISEASES**

**Final Examination Questions**

Choose True or False for questions 1 through 5 and mark your answers online at www.onlinedentalCE.com.

1. People with diabetes are not at risk for mouth infections such as thrush or dry mouth.
   - True
   - False

2. After hematopoietic stem cell transplantation, you should monitor patients carefully for second malignancies in the oral region.
   - True
   - False

3. Infective endocarditis prevention includes avoiding body piercing or tattoos that can allow germs to enter the bloodstream.
   - True
   - False

4. Most people with Sjögren’s syndrome suffer from lymphoma and have serious complications.
   - True
   - False

5. Saliva protects teeth from decay, heals sores in the mouth and prevents infection by controlling bacteria, viruses and fungi in the mouth.
   - True
   - False

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