

# 2025 CONTINUING EDUCATION FOR CALIFORNIA DENTISTS

# 25 Hours \$105

### **INSIDE THIS EDITION**

**California Dental Practice Act** 

**California Infection Control** 

### **Prescribing Schedule II Opioid Drugs**

(Approved by the Dental Board of California to Meet 2 Hours of Opioid CE)

### **Intercultural Competence**

Women's Health Botulinum and Dermal Fillers

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Dental Board of California #RP3841



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#### CONTINUING EDUCATION FOR CALIFORNIA DENTISTS 2025

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# The California Dental Practice Act

This course fulfills the California requirement for 2 hours of California Dental Practice Act education.

#### Audience

This course is designed for all California dentists, dental hygienists, and dental assistants in all practice settings.

#### **Course Objective**

The purpose of this course is to provide California dental professionals with a working knowledge of the contents of the California Dental Practice Act, ensuring that they practice legally and safely.

#### **Learning Objectives**

Upon completion of this course, you should be able to:

- 1. Define the scope of practice of dental professionals in California.
- 2. Describe the standards of licensure of and medication prescription by dental professionals in California.
- 3. Identify possible victims of violence or neglect and outline the appropriate response.

#### Faculty

Mark J. Szarejko, DDS, FAGD, received his dental degree from the State University of New York at Buffalo in 1985. He received fellowship from the Academy of General Dentistry in 1994.

#### **Faculty Disclosure**

Contributing faculty, Mark J. Szarejko, DDS, FAGD, has disclosed no relevant financial relationship with any product manufacturer or service provider mentioned.

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#### **Designations of Credit**

NetCE designates this activity for 2 continuing education credits.

AGD Subject Code 010.

This course meets the Dental Board of California's requirements for 2 units of continuing education.

Dental Board of California course #02-3841-00450.

#### Special Approval

This course fulfills the California requirement for 2 hours of Dental Practice Act education.

#### About the Sponsor

The purpose of NetCE is to provide challenging curricula to assist healthcare professionals to raise their levels of expertise while fulfilling their continuing education requirements, thereby improving the quality of healthcare.

Our contributing faculty members have taken care to ensure that the information and recommendations are accurate and compatible with the standards generally accepted at the time of publication. The publisher disclaims any liability, loss or damage incurred as a consequence, directly or indirectly, of the use and application of any of the contents. Participants are cautioned about the potential risk of using limited knowledge when integrating new techniques into practice.

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- Complete the test and evaluation.
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#### INTRODUCTION

The California Dental Practice Act is the body of laws in the California Business and Professions Code (CBPC) and the California Code of Regulations (CCR) governing all dental professionals, including dentists, oral and maxillofacial surgeons, orthodontists, unlicensed dental assistants, registered dental assistants, and dental hygienists. The Act is intended to serve as a legal guideline for both professionals and the public regarding all aspects of dental practice. As defined in Section 1016.(b)1 of the CCR, continuing education on the California Dental Practice Act is required and must include instruction on utilization, scope of practice, prescribing laws, violations, citations, fines, licensure, the identification of abuse, and mandatory abuse reporting [1]. Of course, the Act is a much larger volume, so much so that it is beyond the scope of this course to elucidate every section. The Dental Practice Act is not intended to replace professional oaths and codes of ethics but does define actions and omissions that may lead to legal action and revocation of a license to practice dentistry in the State of California, the laws of which are continually evolving.

The Dental Board of California (a division of the California Department of Consumer Affairs), which consists of eight practicing dentists, one registered dental hygienist, one registered dental assistant (each practicing for at least five years), and five public members, is responsible for licensure of qualified dental health professionals, enforcement of the California Dental Practice Act, and improving the education of consumers and licensees [19]. The Board's highest priority is to protect the health and safety of the public.

In addition, the practice of dental hygiene is regulated by the Dental Hygiene Board of California, the first of its kind in the United States [20].

#### DENTISTRY DEFINED: SCOPE OF PRACTICE

According to the American Dental Association, dentistry is defined as "the evaluation, diagnosis, prevention, and treatment of diseases, disorders, and conditions of the oral cavity, the craniomaxillofacial area and the adjacent structures and their impact on the human body. This care is provided by dentists within the scope of their education, training and experience in accordance with the ethics of the profession and applicable law" [2]. The CBPC and the CCR provide specific information regarding utilization and scope of practice for dentists, unlicensed dental assistants, registered dental assistants, and registered dental hygienists, as evidenced in the following sections [1].

#### DENTISTS

CBPC Section 1625. Dentistry is the diagnosis or treatment, by surgery or other method, of diseases and lesions and the correction of malpositions of the human teeth, alveolar process, gums, jaws, or associated structures; and such diagnosis or treatment may include all necessary related procedures as well as the use of drugs, anesthetic agents, and physical evaluation. Without limiting the foregoing, a person practices dentistry within the meaning of this chapter who does any one or more of the following [24]:

- (a) By card, circular, pamphlet, newspaper, Internet website, social media, or in any other way advertises themselves or represents themselves to be a dentist.
- (b) Performs, or offers to perform, an operation or diagnosis of any kind, or treats diseases or lesions of the human teeth, alveolar process, gums, jaws, or associated structures, or corrects malposed positions thereof.
- (c) In any way indicates that the person will perform by themselves or their agents or servants any operation upon the human teeth, alveolar process, gums, jaws, or associated structures, or in any way indicates that the person will construct, alter, repair, or sell any bridge, crown, denture or other prosthetic appliance or orthodontic appliance.
- (d) Makes, or offers to make, an examination of, with the intent to perform or cause to be performed any operation on the human teeth, alveolar process, gums, jaws, or associated structures.
- (e) Manages or conducts as manager, proprietor, conductor, lessor, or otherwise, a place where dental operations are performed.

The Board requires that dentists ensure that each patient of record receives a copy of the Dental Materials Fact Sheet (provided by the Board) prior to the placement of his or her first dental restoration [25]. The Dental Materials Fact Sheet details the comparative risks and benefits of available dental restorative materials. The patient must sign an acknowledgment of receipt of the fact sheet, and a copy of the acknowledgment must be placed in the patient's record.

#### DENTAL ASSISTANTS (UNLICENSED)

Although unlicensed dental assistants are not Board approved, their duties and actions are governed by the Act and they are required to complete coursework in the Dental Practice Act, infection control, and basic life support. Failure to follow the regulations set forth by California law can result in fines and/ or imprisonment. As defined in CBPC Section 1750.(a), "A dental assistant is an individual who, without a license, may perform basic supportive dental procedures, as authorized by Section 1750.1 and by regulations adopted by the board, under the supervision of a licensed dentist" [1]. Basic supportive dental procedures are those procedures that have technically elementary characteristics, are completely reversible, and are unlikely to precipitate potentially hazardous conditions for the patient being treated. A licensed dentist is responsible for assuring unlicensed dental assistants' competence and ensuring that they complete required coursework (e.g., two-hour Dental Practice Act, eight-hour infection control, basic life support) and maintain certification in basic life support (if employed for longer than 120 days). Specific duties pertaining to dental assistant practice can be found in CCR Section 1085 [28]. General information regarding regulations pertaining to dental assistants is located in CBPC Sections 1740–1777; although these sections are not discussed in this course, they should be periodically reviewed to ensure self-compliance with the act. The CBPC may include additional duties for various dental assistant professions.

CCR Section 1085. Dental Assistant Duties and Settings.

- (a) Unless specifically so provided by regulation, a dental assistant may not perform the following functions or any other activity which represents the practice of dentistry or requires the knowledge, skill and training of a licensed dentist:
  - 1. Diagnosis and treatment planning;
  - 2. Surgical or cutting procedures on hard or soft tissue;
  - 3. Fitting and adjusting of correctional and prosthodontic appliances;
  - 4. Prescription of medicines;
  - 5. Placement, condensation, carving or removal of permanent restorations, including final cementation procedures;
  - 6. Irrigation and medication of canals, try-in cones, reaming, filing or filling of root canals;
  - 7. Taking of impressions for prosthodontic appliances, bridges or any other structures which may be worn in the mouth;
  - 8. Administration of injectable and/or general anesthesia;
  - 9. Oral prophylaxis procedures.
- (b) A dental assistant may perform such basic supportive dental procedures as the following under the general supervision of a licensed dentist:
  - 1. Extra-oral duties or functions specified by the supervising dentist;
  - 2. Operation of dental radiographic equipment for the purpose of oral radiography if the dental assistant has complied with the requirements of section 1656 of the Code;
  - 3. Examine orthodontic appliances.
- (c) A dental assistant may perform such basic supportive dental procedures as the following under the direct supervision of a licensed dentist when done so pursuant to the order, control and full professional responsibility of the supervising dentist. Such procedures shall be checked and approved by the supervising dentist prior to dismissal of the patient from the office of said dentist.

- 1. Take impressions for diagnostic and opposing models, bleaching trays, temporary crowns and bridges, and sports guards;
- 2. Apply non-aerosol and non-caustic topical agents;
- 3. Remove post-extraction and periodontal dressings;
- 4. Placement of elastic orthodontic separators;
- 5. Remove orthodontic separators;
- 6. Assist in the administration of nitrous oxide analgesia or sedation; however, a dental assistant shall not start the administration of the gases and shall not adjust the flow of the gases unless instructed to do so by the dentist who shall be present at the patient's chairside at the implementation of these instructions. This regulation shall not be construed to prevent any person from taking appropriate action in the event of a medical emergency.
- 7. Hold anterior matrices;
- 8. Remove sutures;
- 9. Take intra-oral measurements for orthodontic procedures;
- 10. Seat adjusted retainers or headgears, including appropriate instructions;
- 11. Check for loose bands;
- 12. Remove arch wires;
- 13. Remove ligature ties;
- 14. Apply topical fluoride, after scaling and polishing by the supervising dentist or a registered dental hygienist;
- 15. Place and remove rubber dams;
- 16. Place, wedge and remove matrices;
- 17. Cure restorative or orthodontic materials in operative site with light-curing device.

For the purpose of this section, a supervising licensed dentist is defined as a dentist whose patient is receiving the services of a dental assistant in the treatment facility and is under the direct control of said licensed dentist [1]. Direct supervision is defined as supervision of dental procedures based on instructions given by a licensed dentist who must be physically present in the facility when the procedures are performed.

#### REGISTERED DENTAL ASSISTANTS

Registered dental assistants (RDAs) are Board-licensed professionals who may perform a greater range of duties than unlicensed dental assistants. Specific information pertaining to RDAs' scope of practice can be found in CCR Section 1086, and general information regarding regulations pertaining to RDAs is located in CBPC Sections 1740–1777, which should be reviewed periodically to ensure self-compliance with the act [28]. CCR Section 1086. RDA Duties and Settings.

- (a) Unless specifically so provided by regulation, the prohibitions contained in section 1085 of these regulations apply to registered dental assistants.
- (b) A registered dental assistant may perform all functions which may be performed by a dental assistant.
- (c) Under general supervision, a registered dental assistant may perform the following duties:
  - 1. Mouth-mirror inspection of the oral cavity, to include charting of obvious lesions, existing restorations and missing teeth;
  - 2. Placement and removal of temporary sedative dressings.
- (d) A registered dental assistant may perform the following procedures under the direct supervision of a licensed dentist when done so pursuant to the order, control and full professional responsibility of the supervising dentist. Such procedures shall be checked and approved by the supervising dentist prior to dismissal of the patient from the office of said dentist.
  - 1. Obtain endodontic cultures;
  - 2. Dry canals, previously opened by the supervising dentist, with absorbent points;
  - 3. Test pulp vitality;
  - 4. Place bases and liners on sound dentin;
  - 5. Remove excess cement from supragingival surfaces of teeth with a hand instrument or floss;
  - 6. Size stainless steel crowns, temporary crowns and bands;
  - 7. Fabrication of temporary crowns intra-orally;
  - 8. Temporary cementation and removal of temporary crowns and removal of orthodontic bands;
  - 9. Placement of orthodontic separators;
  - 10. Placement and ligation of arch wires;
  - 11. Placement of post-extraction and periodontal dressings;
  - 12. Apply bleaching agents;
  - 13. Activate bleaching agents with non-laser light-curing device;
  - 14. Take bite registrations for diagnostic models for case study only;
  - 15. Coronal polishing (Evidence of satisfactory completion of a board-approved course of instruction in this function must be submitted to the board prior to any performance thereof).

This procedure shall not be intended or interpreted as a complete oral prophylaxis (a procedure which can be performed only by a licensed dentist or registered dental hygienist). A licensed dentist or registered dental hygienist shall determine that the teeth to be polished are free of calculus or other extraneous material prior to coronal polishing.

- 16. Removal of excess cement from coronal surfaces of teeth under orthodontic treatment by means of an ultrasonic scaler. (Evidence of satisfactory completion of a board-approved course of instruction or equivalent instruction in an approved RDA program in this function must be submitted to the board prior to any performance thereof.)
- (e) Settings. Registered dental assistants may undertake the duties authorized by this section in a treatment facility under the jurisdiction and control of the supervising licensed dentist, or in an equivalent facility approved by the board.

#### Registered Dental Assistants in Extended Functions

Registered dental assistants in extended functions (RDAEFs) are Board-licensed dental professionals who have a greater breadth of permitted duties than RDAs. Specifics regarding these allowed duties can be found in CCR Section 1087 [28].

CCR Section 1087. RDAEF Duties and Settings.

- (a) Unless specifically so provided by regulation, the prohibitions contained in Section 1085 apply to RDAEFs.
- (b) An RDAEF may perform all duties assigned to dental assistants and registered dental assistants.
- (c) An RDAEF may perform the procedures set forth below under the direct supervision of a licensed dentist when done so pursuant to the order, control and full professional responsibility of the supervising dentist. Such procedures shall be checked and approved by the supervising dentist prior to dismissal of the patient from the office of said dentist.
  - 1. Cord retraction of gingivae for impression procedures;
  - 2. Take impressions for cast restorations;
  - 3. Take impressions for space maintainers, orthodontic appliances, and occlusal guards;
  - 4. Prepare enamel by etching for bonding;
  - 5. Formulate indirect patterns for endodontic post and core castings;
  - 6. Fit trial endodontic filling points;
  - 7. Apply pit and fissure sealants;
  - 8. Remove excess cement from subgingival tooth surfaces with a hand instrument;
  - 9. Apply etchant for bonding restorative materials.
- (d) Settings. Registered dental assistants in extended functions may undertake the duties authorized by this section in a treatment facility under the jurisdiction and control of the supervising licensed dentist, or in an equivalent facility approved by the board.

In addition to the duties outlined in CCR section 1087, section 1753.5 of the CBPC states that RDAEFs may conduct preliminary evaluation of the patient's oral health, including, but not limited to, charting, intraoral and extra-oral evaluation of soft tissue, classifying occlusion, and myofunctional evaluation, and perform oral health assessments in school-based, community health project settings under the direction of a dentist, registered dental hygienist, or registered dental hygienist in alternative practice [1]. RDAEFs may hold an orthodontic assistant permit, a dental sedation assistant permit, or both.

#### DENTAL HYGIENISTS

Registered dental hygienists (RDHs), registered dental hygienists in extended functions (RDHEFs), and registered dental hygienists in alternative practice (RDHAPs) are Board-licensed occupations administered by the Dental Hygiene Committee of California, and the California Dental Practice Act contains the main body of laws and regulations that govern their practice.

The Dental Hygiene Committee of California was created by the Board and consists of seven governor-appointed positions: two public members, four dental hygienists, and one practicing dentist; in addition, there are two public members appointed by the Senate Committee on Rules and the Speaker of the Assembly, respectively [20]. Responsibilities of the Dental Hygiene Committee include adopting regulations; issuing, reviewing, and revoking licenses; developing and administering examinations; determining fees; and updating continuing education requirements for all dental hygiene licensure categories. The Act contains specific information regarding the permitted duties and settings of RDH practice (CCR Section 1088), RDHEF practice (CCR Section 1089), and RDHAP practice (CCR Section 1090) [28]. Additional laws and regulations pertaining specifically to dental hygiene practice are located in CBPC Sections 1900-1966.6. These sections should be periodically reviewed to ensure self-compliance with the Act.

#### **Registered Dental Hygienists**

CCR Section 1088. RDH Duties and Settings.

- (a) Unless specifically so provided by regulation, the prohibition contained in Section 1085(a), subsections (1) through
  (8) of these regulations shall apply to duties performed by a registered dental hygienist.
- (b) A registered dental hygienist may perform all duties assigned to dental assistants and registered dental assistants, under the supervision of a licensed dentist as specified in these regulations.
- (c) Under general supervision, a registered dental hygienist may perform the following duties in addition to those provided by Section 1760(b) of the Code:
  - 1. Root planing;
  - 2. Polish and contour restorations;
  - 3. Oral exfoliative cytology;
  - 4. Apply pit and fissure sealants;

- 5. Preliminary examination, including but not limited to:
  - A. Periodontal charting;
  - B. Intra and extra-oral examination of soft tissue;
  - C. Charting of lesions, existing restorations and missing teeth;
  - D. Classifying occlusion;
  - E. Myofunctional evaluation.
- 6. Irrigate sub-gingivally with an antimicrobial and/or antibiotic liquid solution(s).
- 7. The following direct supervision duties of dental assistants and registered dental assistants:
  - A. Dental Assistant.
    - 1. Taking impressions for diagnostic and opposing models;
    - 2. Applying non-aerosol and non-caustic topical agents;
    - 3. Removing post-extraction and periodontal dressings;
    - 4. Removing sutures;
    - 5. Taking intra-oral measurements for orthodontic procedures;
    - 6. Checking for loose bands;
    - 7. Removing ligature ties;
    - 8. Applying topical fluoride;
    - 9. Placing elastic separators.
  - B. Registered Dental Assistant
    - 1. Test pulp vitality;
    - 2. Removing excess cement from supragingival surfaces of teeth;
    - 3. Sizing stainless steel crowns, temporary crowns and bands;
    - Temporary cementation and removal of temporary crowns and removal of orthodontic bands;
    - 5. Placing post-extraction and periodontal dressings.
- (d) A registered dental hygienist may perform the procedures set forth below under the direct supervision of a licensed dentist when done so pursuant to the order, control and full professional responsibility of the supervising dentist. Such procedures shall be checked and approved by the supervising dentist prior to dismissal of the patient from the office of said dentist.
  - 1. Placement of antimicrobial or antibiotic medicaments which do not later have to be removed;
  - 2. All duties so assigned to a dental assistant or a registered dental assistant, unless otherwise indicated;

- 3. Periodontal soft tissue curettage (Evidence of satisfactory completion of a board-approved course of instruction in this function must be submitted to the board prior to any performance thereof);
- 4. Administration of local anesthetic agents, infiltration and conductive, limited to the oral cavity (Evidence of satisfactory completion of a board-approved course of instruction in this function must be submitted to the board prior to any performance thereof);
- 5. Administration of nitrous oxide and oxygen when used as an analgesic, utilizing fail-safe type machines containing no other general anesthetic agents. (Evidence of satisfactory completion of a board-approved course of instruction in this function must be submitted to the board prior to any performance thereof.)
- (e) A registered dental hygienist may undertake the duties authorized by this section in the following settings, provided the appropriate supervision requirements are met:
  - 1. The treatment facility of a licensed dentist;
  - 2. Licensed health facilities as defined in Section 1250 of the Health and Safety Code,
  - 3. Licensed clinics as defined in Section 1203 of the Health and Safety Code,
  - 4. Licensed community care facilities as defined in Section 1502 of the Health and Safety Code,
  - 5. Schools of any grade level whether public or private,
  - 6. Public institutions, including but not limited to federal, state and local penal and correctional facilities.
  - 7. Mobile units operated by a public or governmental agency or a nonprofit and charitable organization approved by the board; provided, however, that the mobile unit meets the statutory and regulatory requirements for mobile units,
  - 8. Home of a non-ambulatory patient, provided there is a written note from a physician or registered nurse stating that the patient is unable to visit a dental office.
  - 9. Health fairs or similar non-profit community activities. Each such fair or activity shall be approved by the board.

Any other facility must be approved by the board.

#### Registered Dental Hygienists in Extended Functions

CCR Section 1089. RDHEF Duties and Settings.

- (a) Unless specifically provided by regulation, the prohibitions contained in Section 1085(a) (1) through (8) shall apply to RDHEFs.
- (b) An RDHEF may perform all duties assigned to dental assistants, registered dental assistants and registered dental hygienists.

- (c) An RDHEF may perform the procedures set forth below under the direct supervision of a licensed dentist when done so pursuant to the order, control and full professional responsibility of the supervising dentist. Such procedures shall be checked and approved by the supervising dentist prior to dismissal of the patient from the office of said dentist.
  - 1. Cord retraction of gingivae for impression procedures;
  - 2. Take impressions for cast restorations;
  - 3. Take impressions for space maintainers, orthodontic appliances and guards;
  - 4. Prepare enamel by etching for bonding;
  - 5. Formulate indirect patterns for endodontic post and core castings;
  - 6. Fit trial endodontic filling points;
  - 7. Apply etchant for bonding restorative materials.
- (d) Settings. Registered dental hygienists in extended functions may undertake the duties authorized by this section in a treatment facility under the jurisdiction and control of the supervising licensed dentist, or an equivalent facility approved by the Board.

#### Registered Dental Hygienists in Alternative Practice

CCR Section 1090. RDHAP Duties and Settings.

- (a) Unless specifically so provided by regulation, an RDHAP may not perform the following functions or any activity which represents the practice of dentistry or requires knowledge, skill and training of a licensed dentist:
  - 1. Diagnosing and treatment planning;
  - 2. Surgical or cutting procedures on hard or soft tissue;
  - 3. Fitting and adjusting of correctional and prosthodontic appliances;
  - 4. Prescribing medication;
  - 5. Placing, condensing, carving or removal of permanent restorations, including final cementation procedures;
  - 6. Irrigating and medicating canals, try-in cones, reaming, filing or filling of root canals;
  - 7. Taking of impressions for prosthodontic appliances, bridges, or any other devices which may be worn in the mouth;
  - 8. Administering local or general anesthesia, oral or parental conscious sedation.
- (b) Under the supervision of a licensed dentist, an RDHAP may perform the duties assigned to registered dental hygienists by Section 1088, under the same levels of supervision and in the same settings as specified in that section, in addition to those duties permitted by Section 1768(b)(3).

- (c) Independently and without the supervision of a licensed dentist, an RDHAP may, upon the prescription of a dentist or a physician and surgeon licensed in California, perform the duties assigned to a registered dental hygienist by Section 1088(c).
  - 1. All prescriptions shall contain the following information:
    - A. The pre-printed name, address, license number, and signature of the prescribing dentist or physician and surgeon.
    - B. The name, address and phone number of the patient.
    - C. The date the services are prescribed and the expiration date of the prescription. The prescription shall be for dental hygiene services and, if necessary, include special instructions for the care of that patient.

Prior to the establishment of an independent practice, an RDHAP shall provide to the board documentation of an existing relationship with at least one dentist for referral, consultation, and emergency services [1].

#### LICENSURE

All individuals practicing dentistry in California, with the exception of unlicensed dental assistants, must hold a current, valid license issued by the Board; California does not grant reciprocity with other states or nations. The Act requires that dental professionals meet certain education requirements, submit the correct applications and fees, pass the appropriate examinations, and submit a set of fingerprints. Fingerprinting is also required for license renewal if not previously conducted by the California Department of Justice (DOJ) or if records no longer exist [21]. Fingerprinting within California must be conducted using the DOJ Live Scan system; fingerprint records from other institutions (e.g., Department of Motor Vehicles) are not suitable, although ink-on-card fingerprints made at a law enforcement agency are acceptable if unable to travel to California. The required fingerprint cards must be requested from the Dental Board by phone or email [21]. The fingerprints will be used to conduct a criminal history record check and a state and federal level criminal offender record information search.

Issuance, review, and revocation of RDH/RDHEF/RDHAP licenses and the development and administration of license examinations for these auxiliaries are handled by the Dental Hygiene Board of California. All other licensure, including that for RDAs/RDAEFs, is handled by the Dental Board (despite the existence of the Dental Assisting Council, whose purpose is to consider matters related to dental assisting practice and make recommendations to the board). Complaints, investigations, and enforcement are handled by either the Dental Hygiene

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Board or the Dental Board, according to profession, but the governing regulations and laws set forth in the California Dental Practice Act pertain to all dental professionals. Information about application for licensure to practice as a dentist or dental auxiliary can be found in CCR Section 1028 and CCR Sections 1076–1079.3, respectively. Specific information about the licensure application requirements and process for dentists and dental assistants can be found at https://www.dbc.ca.gov/applicants and for hygienists at https://www.dhbc. ca.gov/applicants.

Effective July 2012, application for licensure may be denied based on delinquent state tax payments [1]. Similarly, current licenses/certifications/registrations may be revoked for failure to pay taxes.

#### LICENSE RENEWAL

Licenses for all dental professions must be renewed every two years before the last day of the professional's birth month. Practicing without renewing after this date is considered practicing without a license [1]. It is required that dentists have completed 50 hours of continuing education and dental auxiliaries (excluding RDHAPs) have completed 25 hours of continuing education (maximum of 25 hours and 12.5 hours of home study, respectively) upon renewal submission. The continuing education requirement is 35 hours for RDHAPs. Coursework regarding the Dental Practice Act, infection control, and basic life support is mandatory every two years for all licensees. To receive credit, all courses must be from Board-approved providers. In addition, the Board has identified topics that may only constitute a portion of the full continuing education requirement or that are not acceptable at all. A complete listing of allowable and non-allowable courses is available on the Board website.

Links to information regarding license renewal for dentists and dental assistants can be found at https://www.dbc.ca.gov/ licensees, and renewal information for hygienists can be found at https://www.dhbc.ca.gov/licensees/renewals.

#### ACTS LEADING TO SUSPENSION OF A LICENSE AND IN VIOLATION OF THE DENTAL PRACTICE ACT

Violations of the Act by Board licensees are grounds for suspension of a license/certification and are handled by the Board's Enforcement Program, which is composed of five sections: Complaint and Compliance Unit; Inspections/Probation Section; Investigation Unit: Sworn Investigators; Investigation Analysis Unit; and Discipline Coordination Unit [22]. Complaints originate from many sources, including dental professionals, healthcare providers, insurance companies, law enforcement agencies, and patients. Complaint intake specialists route these to the appropriate section; for example, an allegation of an unsafe or unsanitary office condition is routed to the inspection section, whereby Board enforcement inspectors may be sent out and are authorized to issue citations and fines. In addition to Board enforcement action, other law enforcement or regulatory agencies are involved when indicated [1]. Dental professionals placed on probation status by the Board for violations of the Act are monitored by the Enforcement Program's Probation Unit. The Board's Enforcement Unit may be contacted by phone at (916) 263-2300 or by e-mail at DentalBoardComplaints@dca.ca,gov. Violations of the Act by hygienists are handled by the Hygiene Board's Complaint Unit, which operates in a similar manner and can be contacted at (866) 810-9899 or by email at DHBCEnforcement@dca.ca.gov [20].

According to CBPC Section 1670.1, conviction of crimes committed by dental professionals outside of the workplace may also be grounds for Board discipline and can impact licensure status if the crime is "substantially related to the qualifications, functions, or duties of a dentist or dental assistant licensed under this chapter" [1]. These vary considerably on a case-by-case basis. Various lesser convictions, for example, driving under the influence (DUI), illicit drug possession, and prescription drug diversion, may not necessarily lead to license revocation provided the proper steps are taken toward remediation (e.g., entering the Board diversion program, submitting to periodic drug testing) [23]. In general, convictions for assaults, sex crimes, multiple misdemeanors (e.g., second DUI/controlled substance charge), and other egregious violations constitute a basis for denial or revocation of licenses or certifications. In addition to violations outside the workplace, unprofessional conduct, in its many forms, is grounds for Board Enforcement action. Acts and omissions that characterize unprofessional conduct are covered extensively in CBPC Sections 1680, 1681, and 1682 and CCR Section 1018.05.

CBPC Section 1680. Unprofessional conduct by a person licensed under this chapter is defined as, but is not limited to, any one of the following:

- (a) The obtaining of any fee by fraud or misrepresentation.
- (b) The employment directly or indirectly of any student or suspended or unlicensed dentist to practice dentistry as defined in this chapter.
- (c) The aiding or abetting of any unlicensed person to practice dentistry.
- (d) The aiding or abetting of a licensed person to practice dentistry unlawfully.
- (e) The committing of any act or acts of sexual abuse, misconduct, or relations with a patient that are substantially related to the practice of dentistry.
- (f) The use of any false, assumed, or fictitious name, either as an individual, firm, corporation, or otherwise, or any name other than the name under which the person is licensed to practice, in advertising or in any other manner indicating that the person is practicing or will practice dentistry, except that name as is specified in a valid permit issued pursuant to Section 1701.5.
- (g) The practice of accepting or receiving any commission or the rebating in any form or manner of fees for professional services, radiograms, prescriptions, or other services or articles supplied to patients.

- (h) The making use by the licensee or any agent of the licensee of any advertising statements of a character tending to deceive or mislead the public.
- (i) The advertising of either professional superiority or the advertising of performance of professional services in a superior manner. This subdivision shall not prohibit advertising permitted by subdivision (h) of Section 651.
- (j) The employing or the making use of solicitors.
- (k) The advertising in violation of Section 651.
- (l) The advertising to guarantee any dental service, or to perform any dental operation painlessly. This subdivision shall not prohibit advertising permitted by Section 651.
- (m) The violation of any of the provisions of law regulating the procurement, dispensing, or administration of dangerous drugs, as defined in Chapter 9 (commencing with Section 4000) or controlled substances, as defined in Division 10 (commencing with Section 11000) of the Health and Safety Code.
- (n) The violation of any of the provisions of this division.
- (o) The permitting of any person to operate dental radiographic equipment who has not met the requirements of Section 1656.
- (p) The clearly excessive prescribing or administering of drugs or treatment, or the clearly excessive use of diagnostic procedures, or the clearly excessive use of diagnostic or treatment facilities, as determined by the customary practice and standards of the dental profession. Any person who violates this subdivision is guilty of a misdemeanor and shall be punished by a fine of not less than one hundred dollars (\$100) or more than six hundred dollars (\$600), or by imprisonment for a term of not less than 60 days or more than 180 days, or by both a fine and imprisonment.
- (q) The use of threats or harassment against any patient or licensee for providing evidence in any possible or actual disciplinary action, or other legal action; or the discharge of an employee primarily based on the employee's attempt to comply with the provisions of this chapter or to aid in the compliance.
- (r) Suspension or revocation of a license issued, or discipline imposed, by another state or territory on grounds that would be the basis of discipline in this state.
- (s) The alteration of a patient's record with intent to deceive.
- (t) Unsanitary or unsafe office conditions, as determined by the customary practice and standards of the dental profession.
- (u) The abandonment of the patient by the licensee, without written notice to the patient that treatment is to be discontinued and before the patient has ample opportunity to secure the services of another dentist, registered dental hygienist, registered dental hygienist in alternative practice, or registered dental hygienist in extended functions and provided the health of the patient is not jeopardized.

- (v) The willful misrepresentation of facts relating to a disciplinary action to the patients of a disciplined licensee.
- (w) Use of fraud in the procurement of any license issued pursuant to this chapter.
- (x) Any action or conduct that would have warranted the denial of the license.
- (y) The aiding or abetting of a licensed dentist, dental assistant, registered dental assistant, registered dental assistant in extended functions, dental sedation assistant permitholder, orthodontic assistant permitholder, registered dental hygienist, registered dental hygienist in alternative practice, or registered dental hygienist in extended functions to practice dentistry in a negligent or incompetent manner.
- (z) 1. The failure to report to the board in writing within seven days any of the following: (A) the death of the licensee's patient during the performance of any dental or dental hygiene procedure; (B) the discovery of the death of a patient whose death is related to a dental or dental hygiene procedure performed by the licensee; or (C) except for a scheduled hospitalization, the removal to a hospital or emergency center for medical treatment of any patient to whom oral conscious sedation, conscious sedation, or general anesthesia was administered, or any patient as a result of dental or dental hygiene treatment. With the exception of patients to whom oral conscious sedation, conscious sedation, or general anesthesia was administered, removal to a hospital or emergency center that is the normal or expected treatment for the underlying dental condition is not required to be reported. Upon receipt of a report pursuant to this subdivision the board may conduct an inspection of the dental office if the board finds that it is necessary. A dentist shall report to the board all deaths occurring in the licensee's practice with a copy sent to the Dental Hygiene Board of California if the death was the result of treatment by a registered dental hygienist, registered dental hygienist in alternative practice, or registered dental hygienist in extended functions. A registered dental hygienist, registered dental hygienist in alternative practice, or registered dental hygienist in extended functions shall report to the Dental Hygiene Board of California all deaths occurring as the result of dental hygiene treatment, and a copy of the notification shall be sent to the board.
  - 2. The report required by this subdivision shall be on a form or forms approved by the board. The form or forms approved by the board shall require the licensee to include, but not be limited to, the following information for cases in which patients received anesthesia: the date of the procedure; the patient's age in years and months, weight, and sex; the patient's American Society of Anesthesiologists

(ASA) physical status; the patient's primary diagnosis; the patient's coexisting diagnoses; the procedures performed; the sedation setting; the medications used; the monitoring equipment used; the category of the provider responsible for sedation oversight; the category of the provider delivering sedation; the category of the provider monitoring the patient during sedation; whether the person supervising the sedation performed one or more of the procedures; the planned airway management; the planned depth of sedation; the complications that occurred; a description of what was unexpected about the airway management; whether there was transportation of the patient during sedation; the category of the provider conducting resuscitation measures; and the resuscitation equipment utilized. Disclosure of individually identifiable patient information shall be consistent with applicable law. A report required by this subdivision shall not be admissible in any action brought by a patient of the licensee providing the report.

- 3. For the purposes of paragraph (2), categories of provider are: General Dentist, Pediatric Dentist, Oral Surgeon, Dentist Anesthesiologist, Physician Anesthesiologist, Dental Assistant, Registered Dental Assistant, Dental Sedation Assistant, Registered Nurse, Certified Registered Nurse Anesthetist, or Other.
- 4. The form shall state that this information shall not be considered an admission of guilt, but is for educational, data, or investigative purposes.
- 5. The board may assess a penalty on any licensee who fails to report an instance of an adverse event as required by this subdivision. The licensee may dispute the failure to file within 10 days of receiving notice that the board had assessed a penalty against the licensee.
- (aa) Participating in or operating any group advertising and referral services that are in violation of Section 650.2.
- (ab) The failure to use a fail-safe machine with an appropriate exhaust system in the administration of nitrous oxide. The board shall, by regulation, define what constitutes a fail-safe machine.
- (ac) Engaging in the practice of dentistry with an expired license.
- (ad) Except for good cause, the knowing failure to protect patients by failing to follow infection control guidelines of the board, thereby risking transmission of bloodborne infectious diseases from dentist, dental assistant, registered dental assistant, registered dental assistant in extended functions, dental sedation assistant permitholder, orthodontic assistant permitholder, registered dental hygienist, registered dental hygienist in alternative practice, or registered dental hygienist in extended functions to patient, from patient to patient,

and from patient to dentist, dental assistant, registered dental assistant, registered dental assistant in extended functions, dental sedation assistant permitholder, orthodontic assistant permitholder, registered dental hygienist, registered dental hygienist in alternative practice, or registered dental hygienist in extended functions. In administering this subdivision, the board shall consider referencing the standards, regulations, and guidelines of the State Department of Public Health developed pursuant to Section 1250.11 of the Health and Safety Code and the standards, guidelines, and regulations pursuant to the California Occupational Safety and Health Act of 1973 (Part 1 (commencing with Section 6300) of Division 5 of the Labor Code) for preventing the transmission of HIV, hepatitis B, and other bloodborne pathogens in health care settings. The board shall review infection control guidelines, if necessary, on an annual basis and proposed changes shall be reviewed by the Dental Hygiene Board of California to establish a consensus. The Board shall submit any recommended changes to the infection control guidelines for review to establish a consensus. As necessary, the board shall consult with the Medical Board of California, the California Board of Podiatric Medicine, the Board of Registered Nursing, and the Board of Vocational Nursing and Psychiatric Technicians, to encourage appropriate consistency in the implementation of this subdivision.

The board shall seek to ensure that all appropriate dental personnel are informed of the responsibility to follow infection control guidelines, and of the most recent scientifically recognized safeguards for minimizing the risk of transmission of bloodborne infectious diseases.

- (ae) The utilization by a licensed dentist of any person to perform the functions of any registered dental assistant, registered dental assistant in extended functions, dental sedation assistant permitholder, orthodontic assistant permitholder, registered dental hygienist, registered dental hygienist in alternative practice, or registered dental hygienist in extended functions who, at the time of initial employment, does not possess a current, valid license or permit to perform those functions.
- (af) The prescribing, dispensing, or furnishing of dangerous drugs or devices, as defined in Section 4022, in violation of Section 2242.1.
- (ag) Using water, or other methods used for irrigation, that are not sterile or that do not contain recognized disinfecting or antibacterial properties when performing dental procedures on exposed dental pulp.
- (ah) The failure by the treating dentist, prior to the initial diagnosis and correction of malpositions of human teeth or initial use of orthodontic appliances, to perform an examination pursuant to subdivision (b) of Section 1684.5, including the review of the patient's most recent diagnostic digital or conventional radiographs or other equivalent bone imaging suitable for orthodontia. New

radiographs or other equivalent bone imaging shall be ordered if deemed appropriate by the treating dentist.

Section 1681. In addition to other acts constituting unprofessional conduct within the meaning of this chapter, it is unprofessional conduct for a person licensed under this chapter to do any of the following:

- (a) Obtain or possess in violation of law, or except as directed by a licensed physician and surgeon, dentist, or podiatrist, administer to himself, any controlled substance, as defined in Division 10 (commencing with Section 11000) of the Health and Safety Code, or any dangerous drug as defined in Article 8 (commencing with Section 4211) of Chapter 9.
- (b) Use any controlled substance, as defined in Division 10 (commencing with Section 11000) of the Health and Safety Code, or any dangerous drug as defined in Article 8 (commencing with Section 4211) of Chapter 9, or alcoholic beverages or other intoxicating substances, to an extent or in a manner dangerous or injurious to himself, to any person, or the public to the extent that such use impairs his ability to conduct with safety to the public the practice authorized by his license.
- (c) The conviction of a charge of violating any federal statute or rules, or any statute or rule of this state, regulating controlled substances, as defined in Division 10 (commencing with Section 11000) of the Health and Safety Code, or any dangerous drug, as defined in Article 8 (commencing with Section 4211) of Chapter 9, or the conviction of more than one misdemeanor, or any felony, involving the use or consumption of alcohol or drugs, if the conviction is substantially related to the practice authorized by his license. The record of conviction or certified copy thereof, certified by the clerk of the court or by the judge in whose court the conviction is had, shall be conclusive evidence of a violation of this section; a plea or verdict of guilty or a conviction following a plea of nolo contendere is deemed to be a conviction within the meaning of this section; the board may order the license suspended or revoked, or may decline to issue a license, when the time for appeal has elapsed or the judgment of conviction has been affirmed on appeal, or when an order granting probation is made suspending imposition of sentence, irrespective of a subsequent order under any provision of the Penal Code, including, but not limited to, Section 1203.4 of the Penal Code, allowing such person to withdraw his plea of guilty and to enter a plea of not guilty, or setting aside the verdict of guilty, or dismissing the accusation, information or indictment.

Section 1682. In addition to other acts constituting unprofessional conduct under this chapter, it is unprofessional conduct for:

(a) Any dentist performing dental procedures to have more than one patient undergoing moderate sedation, deep sedation, or general anesthesia on an outpatient basis at any given time unless each patient is being continuously monitored on a one-to-one ratio while sedated by either the dentist or another licensed health professional authorized by law to administer moderate sedation, deep sedation, or general anesthesia.

- (b) Any dentist with patients recovering from moderate sedation, deep sedation, or general anesthesia to fail to have the patients closely monitored by licensed health professionals experienced in the care and resuscitation of patients recovering from moderate sedation, deep sedation, or general anesthesia. If one licensed professional is responsible for the recovery care of more than one patient at a time, all of the patients shall be physically in the same room to allow continuous visual contact with all patients and the patient to recovery staff ratio should not exceed three to one.
- (c) Any dentist with patients who are undergoing deep sedation, general anesthesia, or moderate sedation to fail to have these patients continuously monitored during the dental procedure with a pulse oximeter or similar or superior monitoring equipment and ventilation continuously monitored using at least two of the three following methods:
  - 1. Auscultation of breath sounds using a precordial stethoscope.
  - 2. Monitoring for the presence of exhaled carbon dioxide with capnography.
  - 3. Verbal communication with a patient under moderate sedation. This method shall not be used for a patient under deep sedation or general anesthesia.
- (d) Any dentist with patients who are undergoing moderate sedation to have dental office personnel directly involved with the care of those patients who are not certified in basic cardiac life support (CPR) and recertified biennially.
- (e) 1. Any dentist to fail to obtain the written informed consent of a patient prior to administering moderate sedation, deep sedation, general anesthesia. In the case of a minor, the consent shall be obtained from the child's parent or guardian.
  - 2. The written informed consent for general anesthesia, in the case of a minor, shall include, but not be limited to, the following information:

"The administration and monitoring of deep sedation or general anesthesia may vary depending on the type of procedure, the type of practitioner, the age and health of the patient, and the setting in which anesthesia is provided. Risks may vary with each specific situation. You are encouraged to explore all the options available for your child's anesthesia for their dental treatment, and consult with your dentist, family physician, or pediatrician as needed."

3. Nothing in this subdivision shall be construed to establish the reasonable standard of care for administering or monitoring oral moderate sedation, moderate sedation, deep sedation, or general anesthesia.

Section 1683. (a) Every dentist, dental health professional, or other licensed health professional who performs a service on a patient in a dental office shall identify himself or herself in the patient record by signing his or her name, or an identification number and initials, next to the service performed and shall date those treatment entries in the record. Any person licensed under this chapter who owns, operates, or manages a dental office shall ensure compliance with this requirement.

(b) Repeated violations of this section constitute unprofessional conduct.

Section 1683.1 (a) Any individual, partnership, corporation, or other entity that provides dental services through telehealth shall make available the name, telephone number, practice address, and California state license number of any dentist who will be involved in the provision of services to a patient prior to the rendering of services and when requested by a patient.

(b) A violation of this section shall constitute unprofessional conduct.

Section 1684. In addition to other acts constituting unprofessional conduct under this chapter, it is unprofessional conduct for a person licensed under this chapter to perform, or hold himself or herself out as able to perform, professional services beyond the scope of his or her license and field or fields of competence as established by his or her education, experience, training, or any combination thereof. This includes, but is not limited to, the use of any instrument or device in a manner that is not in accordance with the customary standards and practices of the dental profession. This section shall not apply to research conducted by accredited dental schools or colleges, or to research conducted pursuant to an investigational device exemption issued by the United States Food and Drug Administration.

1. (a) (1) A licensee who fails or refuses to comply with a request for the dental records of a patient, that is accompanied by written authorization of the patient or the patient's representative, as defined in subdivision (e) of Section 123105 of the Health and Safety Code, for release of record to the board, within 15 days of receiving the request and authorization, shall pay to the board a civil penalty of two hundred fifty dollars (\$250) per day for each day that the documents have not been produced after the 15th day, up to a maximum of five thousand dollars (\$5,000) unless the licensee is unable to provide the documents within this time period for good cause.

(2) A health care facility shall comply with a request for the dental records of a patient that is accompanied by that patient's written authorization for release of records to the board together with a notice citing this section and describing the penalties for failure to comply with this section. Failure to provide the patient's dental records to the board within 30 days of receiving this request, authorization, and notice shall subject the health care facility to a civil penalty, payable to the board, of up to two hundred fifty dollars (\$250) per day for each day that the documents have not been produced after the 30th day, up to a maximum of five thousand dollars (\$5,000), unless the health care facility is unable to provide the documents within this time period for good cause. This paragraph shall not require health care facilities to assist the board in obtaining the patient's authorization. The board shall pay the reasonable cost of copying the dental records.

- (b) (1) A licensee who fails or refuses to comply with a court order, issued in the enforcement of a subpoena, mandating the release of records to the board shall pay to the board a civil penalty of one thousand dollars (\$1,000) per day for each day that the documents have not been produced after the date by which the court order requires the documents to be produced, unless it is determined that the order is unlawful or invalid. Any statute of limitations applicable to the filing of an accusation by the board shall be tolled during the period the licensee is out of compliance with the court order and during any related appeals.
  - (2) Any licensee who fails or refuses to comply with a court order, issued in the enforcement of a subpoena, mandating the release of records to the board is guilty of a misdemeanor punishable by a fine payable to the board not to exceed five thousand dollars (\$5,000). The fine shall be added to the licensee's renewal fee if it is not paid by the next succeeding renewal date. Any statute of limitations applicable to the filing of an accusation by the board shall be tolled during the period the licensee is out of compliance with the court order and during any related appeals.
  - (3) A health care facility that fails or refuses to comply with a court order, issued in the enforcement of a subpoena, mandating the release of patient records to the board, that is accompanied by a notice citing this section and describing the penalties for failure to comply with this section, shall pay to the board a civil penalty of up to one thousand dollars (\$1,000) per day for each day that the documents have not been produced, up to ten thousand dollars (\$10,000), after the date by which the court order requires the documents to be produced, unless it is determined that the order is unlawful or invalid. Any statute of limitations applicable to the filing of an accusation by the board against a licensee shall be tolled during the period the health care facility is out of compliance with the court order and during any related appeals.
  - (4) Any health care facility that fails or refuses to comply with a court order, issued in the enforcement of a subpoena, mandating the release of records to the board is guilty of a misdemeanor punishable by a fine payable to the board not to exceed five thousand dollars (\$5,000). Any statute of limitations

applicable to the filing of an accusation by the board against a licensee shall be tolled during the period the health care facility is out of compliance with the court order and during any related appeals.

- (c) Multiple acts by a licensee in violation of subdivision (b) shall be punishable by a fine not to exceed five thousand dollars (\$5,000) or by imprisonment in a county jail not exceeding six months, or by both that fine and imprisonment. Multiple acts by a health care facility in violation of subdivision (b) shall be punishable by a fine not to exceed five thousand dollars (\$5,000) and shall be reported to the State Department of Health Care Services and shall be considered as grounds for disciplinary action with respect to licensure, including suspension or revocation of the license or certificate.
- (d) A failure or refusal to comply with a court order, issued in the enforcement of a subpoena, mandating the release of records to the board constitutes unprofessional conduct and is grounds for suspension or revocation of the licensee's license.
- (e) Imposition of the civil penalties authorized by this section shall be in accordance with the Administrative Procedure Act (Chapter 5 (commencing with Section 11500) of Division 3 of Title 2 of the Government Code).
- (f) For the purposes of this section, a "health care facility" means a clinic or health care facility licensed or exempt from licensure pursuant to Division 2 (commencing with Section 1200) of the Health and Safety Code.

1684.5. (a) In addition to other acts constituting unprofessional conduct under this chapter, it is unprofessional conduct for any dentist to perform or allow to be performed any treatment on a patient who is not a patient of record of that dentist. A dentist may, however, after conducting a preliminary oral examination, require or permit any dental auxiliary to perform procedures necessary for diagnostic purposes, provided that the procedures are permitted under the auxiliary's authorized scope of practice. Additionally, a dentist may require or permit a dental auxiliary to perform all of the following duties prior to any examination of the patient by the dentist, provided that the duties are authorized for the particular classification of dental auxiliary pursuant to Article 7 (commencing with Section 1740):

- 1. Expose emergency radiographs upon direction of the dentist.
- 2. If the dental auxiliary is a registered dental assistant in extended functions, a registered dental hygienist, or a registered dental hygienist in alternative practice, determine and perform radiographs for the specific purpose of aiding a dentist in completing a comprehensive diagnosis and treatment plan for a patient using telehealth, as defined by Section 2290.5, for the purpose of communication with the supervising dentist pursuant to Sections 1753.55, 1910.5, and 1926.05. A dentist is not required to review patient records or make a diagnosis using telehealth.

- 3. Perform extra-oral duties or functions specified by the dentist.
- 4. Perform mouth-mirror inspections of the oral cavity, to include charting of obvious lesions, malocclusions, existing restorations, and missing teeth.
- (b) For purposes of this section, "patient of record" refers to a patient who has been examined, has had a medical and dental history completed and evaluated, and has had oral conditions diagnosed and a written plan developed by the licensed dentist.
- (c) For purposes of this section, if dental treatment is provided to a patient by a registered dental assistant in extended functions, a registered dental hygienist, or a registered dental hygienist in alternative practice pursuant to the diagnosis and treatment plan authorized by a supervising dentist, at a location other than the dentist's practice location, it is the responsibility of the authorizing dentist that the patient or the patient's representative receive written notification that the care was provided at the direction of the authorizing dentist and that the notification include the authorizing dentist's name, practice location address, and telephone number. This provision shall not require patient notification for dental hygiene preventive services provided in public health programs as specified and authorized in Section 1911, or for dental hygiene care when provided as specified and authorized in Section 1926.
- (d) A dentist shall not concurrently supervise more than a total of five registered dental assistants in extended functions, registered dental hygienists, or registered dental hygienists in alternative practice providing services pursuant to Sections 1753.55, 1910.5, and 1926.05.
- (e) This section shall not apply to dentists providing examinations on a temporary basis outside of a dental office in settings including, but not limited to, health fairs and school screenings.
- (f) This section shall not apply to fluoride mouth rinse or supplement programs administered in a school or preschool setting.

Section 1685. In addition to other acts constituting unprofessional conduct under this chapter, it is unprofessional conduct for a person licensed under this chapter to require, either directly or through an office policy, or knowingly permit the delivery of dental care that discourages necessary treatment or permits clearly excessive treatment, incompetent treatment, grossly negligent treatment, repeated negligent acts, or unnecessary treatment, as determined by the standard of practice in the community.

CCR Section 1018.05 Unprofessional Conduct Defined. In addition to those acts detailed in Business and Professions Code Sections 1670, 1680, 1681 and 1682, the following shall also constitute unprofessional conduct:

- (a) Failure to provide records requested by the Board within 15 days of the date of receipt of the request or within the time specified in the request, whichever is later, unless the licensee is unable to provide the documents within this time period for good cause. For the purposes of this section, "good cause" includes physical inability to access the records in the time allowed due to illness or travel.
- (b) Failure to report to the Board, within 30 days, any of the following:
  - 1. The bringing of an indictment or information charging a felony against the licensee.
  - 2. The conviction of the licensee, including any verdict of guilty, or pleas of guilty or no contest, of any felony or misdemeanor.
  - 3. Any disciplinary action taken by another professional licensing entity or authority of this state or of another state or an agency of the federal government or the United States military.
  - 4. For the purposes of this section, "conviction" means a plea or verdict of guilty or a conviction following a plea of nolo contendere or "no contest" and any conviction that has been set aside or deferred pursuant to Sections 1000 or 1203.4 of the Penal Code, including infractions, misdemeanors, and felonies. "Conviction" does not include traffic infractions with a fine of less than one thousand dollars (\$1,000) unless the infraction involved alcohol or controlled substances.

#### VIOLATIONS AND PENALTIES

As discussed, various acts or omissions can be cause for revocation or suspension of a license. Violation of any section of the Dental Practice Act can also lead to civil and criminal prosecution, including [1]:

Section 1700. Any person, company, or association is guilty of a misdemeanor, and upon conviction thereof shall be punished by imprisonment in the county jail not less than 10 days nor more than one year, or by a fine of not less than one hundred dollars (\$100) nor more than one thousand five hundred dollars (\$1,500), or by both fine and imprisonment, who:

- (a) Assumes the degree of "doctor of dental surgery," "doctor of dental science," or "doctor of dental medicine" or appends the letters "DDS," or "DDSc" or "DMD" to his or her name without having had the right to assume the title conferred upon him or her by diploma from a recognized dental college or school legally empowered to confer the same.
- (b) Assumes any title, or appends any letters to his or her name, with the intent to represent falsely that he or she has received a dental degree or license.
- (c) Engages in the practice of dentistry without causing to be displayed in an area that is likely to be seen by all patients who use the facility, the original or copy of the current

license, permit, or registration of each person employed at the facility to practice dentistry.

- (d) Within 10 days after demand is made by the executive officer of the board, fails to furnish to the board the name and address of all persons practicing or assisting in the practice of dentistry in the office of the person, company, or association, at any time within 60 days prior to the demand, together with a sworn statement showing under and by what license or authority this person, company, or association and any employees are or have been practicing dentistry. This sworn statement shall not be used in any prosecution under this section.
- (e) Is under the influence of alcohol or a controlled substance while engaged in the practice of dentistry in actual attendance on patients to an extent that impairs his or her ability to conduct the practice of dentistry with safety to patients and the public.

Section 1700.5. Notwithstanding Section 1700, any person who holds a valid, unrevoked, and unsuspended certificate as a dentist under this chapter may append the letters "DDS" to his or her name, regardless of the degree conferred upon him or her by the dental college from which the licensee graduated.

Section 1701. (a) Any person is for the first offense guilty of a misdemeanor and shall be punishable by a fine of not less than two hundred dollars (\$200) or more than three thousand dollars (\$3,000), or by imprisonment in a county jail for not to exceed six months, or both, and for the second or a subsequent offense is guilty of a felony and upon conviction thereof shall be punished by a fine of not less than two thousand dollars (\$2,000) nor more than six thousand dollars (\$6,000), or by imprisonment pursuant to subdivision (h) of Section 1170 of the Penal Code, or by both such fine and imprisonment, who:

- (1) Sells or barters or offers to sell or barter any dental degree or any license or transcript made or purporting to be made pursuant to the laws regulating the license and registration of dentists.
- (2) Purchases or procures by barter any such diploma, license or transcript with intent that the same shall be used in evidence of the holder's qualification to practice dentistry, or in fraud of the laws regulating such practice.
- (3) With fraudulent intent, makes or attempts to make, counterfeits or alters in a material regard any such diploma, certificate or transcript.
- (4) Uses, attempts or causes to be used, any such diploma, certificate or transcript which has been purchased, fraudulently issued, counterfeited or materially altered, either as a license to practice dentistry, or in order to procure registration as a dentist.
- (5) In an affidavit, required of an applicant for examination, license or registration under this chapter, willfully makes a false statement in a material regard.

- (6) Practices dentistry or offers to practice dentistry as it is defined in this chapter, either without a license, or when his license has been revoked or suspended.
- (7) Under any false, assumed or fictitious name, either as an individual, firm, corporation or otherwise, or any name other than the name under which he is licensed, practices, advertises or in any other manner indicates that he is practicing or will practice dentistry, except such name as is specified in a valid permit issued pursuant to Section 1701.5.
- (b) The board may post an administrative citation issued pursuant to Section 148 on the board's internet website for an offense described in subdivision (a).

Section 1701.1. (a) Notwithstanding Sections 1700 and 1701, a person who willfully, under circumstances or conditions that cause or create risk of bodily harm, serious physical or mental illness, or death, practices or attempts to practice, or advertises or holds himself or herself out as practicing dentistry without having at the time of so doing a valid, unrevoked, and unsuspended certificate, license, registration, or permit as provided in this chapter, or without being authorized to perform that act pursuant to a certificate, license, registration, or permit obtained in accordance with some other provision of law, is guilty of a public offense, punishable by a fine not exceeding ten thousand dollars (\$10,000), by imprisonment pursuant to subdivision (h) of Section 1170 of the Penal Code, by imprisonment in a county jail not exceeding one year, or by both the fine and either imprisonment.

- (b) A person who conspires with or aids and abets another to commit any act described in subdivision (a) is guilty of a public offense and subject to the punishment described in subdivision (a).
- (c) The board may post an administrative citation issued pursuant to Section 148 on the board's internet website for an offense described in subdivisions (a) and (b).
- (d) The remedy provided in this section shall not preclude any other remedy provided by law.

## LAWS GOVERNING THE PRESCRIPTION OF DRUGS

The California Dental Practice Act states that only doctors of dentistry are permitted to prescribe drugs, including analgesics, sedatives, and antibiotics, although prescription of oral conscious sedation to children younger than 13 years of age requires a permit. Dental assistants and dental hygienists are not permitted to write prescriptions [1]. There are many federal and state laws and regulations pertaining to prescribing. It is the responsibility of each Drug Enforcement Administration (DEA)-registered prescriber (or those exempted) to be familiar with and maintain knowledge of all applicable laws and regulations. Pertinent citations of federal laws governing the prescription of controlled substances are included in the DEA Practitioner's Manual, available at https://www.deadiversion. usdoj.gov/GDP/(DEA-DC-071)(EO-DEA226)\_Practitioner's\_Manual\_(final).pdf. The California Uniform Controlled Substances Act (part of the California Health and Safety Code) can be found at https://leginfo.legislature.ca.gov/faces/ codes\_displayexpandedbranch.xhtml?tocCode=HSC&divisio n=10.&title=&part=&chapter=&article. The Substances Act begins at Section 11000, and information regarding prescriptions begins in Section 11150.

There must be careful consideration when prescribing to addicts or suspected addicts, particularly when patients are requesting specific drugs. As of 2016, California legislation requires that all prescribers of controlled substances register to access CURES, the state prescription drug monitoring program database intended to aid prescribers and dispensers in identifying fraudulent activity, thereby reducing prescription drug abuse and diversion without affecting legitimate medical practice or patient care. As of October 2018, all licensees authorized to prescribe, order, administer, furnish or dispense controlled substances in California must, with some exceptions, check a patient's prescription history in CURES 2.0 before prescribing a Schedule II, III, or IV substance [27].

The following section of the California Business and Professional Code addresses unprofessional conduct related to furnishing prescription drugs and excessive prescribing.

Section 725. (a) Repeated acts of clearly excessive prescribing, furnishing, dispensing, or administering of drugs or treatment, repeated acts of clearly excessive use of diagnostic procedures, or repeated acts of clearly excessive use of diagnostic or treatment facilities as determined by the standard of the community of licensees is unprofessional conduct for a physician and surgeon, dentist, podiatrist, psychologist, physical therapist, chiropractor, optometrist, speech-language pathologist, or audiologist.

- (b) Any person who engages in repeated acts of clearly excessive prescribing or administering of drugs or treatment is guilty of a misdemeanor and shall be punished by a fine of not less than one hundred dollars (\$100) nor more than six hundred dollars (\$600), or by imprisonment for a term of not less than 60 days nor more than 180 days, or by both that fine and imprisonment.
- (c) A practitioner who has a medical basis for prescribing, furnishing, dispensing, or administering dangerous drugs or prescription controlled substances shall not be subject to disciplinary action or prosecution under this section.
- (d) No physician and surgeon shall be subject to disciplinary action pursuant to this section for treating intractable pain in compliance with Section 2241.5.

The following sections of the Uniform Controlled Substances Act addresses the facilitation of abuse by prescribing practices, including the new CURES reporting requirements.

Section 11150.2. (a) Notwithstanding any other law, if cannabinoids are excluded from Schedule I of the federal Controlled Substances Act and placed on a schedule of the act other than Schedule I, or if a product composed of cannabinoids is

approved by the federal Food and Drug Administration and either placed on a schedule of the act other than Schedule I, or exempted from one or more provisions of the act, so as to permit a physician, pharmacist, or other authorized healing arts licensee acting within their scope of practice, to prescribe, furnish, or dispense that product, the physician, pharmacist, or other authorized healing arts licensee who prescribes, furnishes, or dispenses that product in accordance with federal law shall be deemed to be in compliance with state law governing those acts.

- (b) For purposes of this chapter, upon the effective date of one of the changes in federal law described in subdivision (a), notwithstanding any other state law, a product composed of cannabinoids may be prescribed, furnished, dispensed, transferred, transported, possessed, or used in accordance with federal law and is authorized pursuant to state law.
- (c) This section does not apply to any product containing cannabinoids that is made or derived from industrial hemp, as defined in Section 11018.5 and regulated pursuant to that section.

Section 11153. (a) A prescription for a controlled substance shall only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. Except as authorized by this division, the following are not legal prescriptions: (1) an order purporting to be a prescription which is issued not in the usual course of professional treatment or in legitimate and authorized research; or (2) an order for an addict or habitual user of controlled substances, which is issued not in the course of professional treatment or as part of an authorized narcotic treatment program, for the purpose of providing the user with controlled substances, sufficient to keep him or her comfortable by maintaining customary use.

- (b) Any person who knowingly violates this section shall be punished by imprisonment pursuant to subdivision (h) of Section 1170 of the Penal Code, or in a county jail not exceeding one year, or by a fine not exceeding twenty thousand dollars (\$20,000), or by both that fine and imprisonment.
- (c) No provision of the amendments to this section enacted during the second year of the 1981–82 Regular Session shall be construed as expanding the scope of practice of a pharmacist.

Section 11164.1. (a) 1. Notwithstanding any other law, a prescription for a controlled substance issued by a prescriber in another state for delivery to a patient in another state may be dispensed by a California pharmacy, if the prescription conforms with the requirements for controlled substance prescriptions in the state in which the controlled substance was prescribed.

- 2. A prescription for Schedule II, Schedule III, Schedule IV, or Schedule V controlled substances dispensed pursuant to this subdivision shall be reported by the dispensing pharmacy to the Department of Justice in the manner prescribed by subdivision (d) of Section 11165.
- (b) A pharmacy may dispense a prescription for a Schedule III, Schedule IV, or Schedule V controlled substance from an out-of-state prescriber pursuant to Section 4005 of the Business and Professions Code and Section 1717 of Title 16 of the California Code of Regulations.
- (c) This section shall become operative on January 1, 2021.

Section 11165. (a) To assist health care practitioners in their efforts to ensure appropriate prescribing, ordering, administering, furnishing, and dispensing of controlled substances, law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II, Schedule III, Schedule IV, and Schedule V controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds in the CURES Fund, maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of, and Internet access to information regarding, the prescribing and dispensing of Schedule II, Schedule III, Schedule IV, and Schedule V controlled substances by all practitioners authorized to prescribe, order, administer, furnish, or dispense these controlled substances.

- (b) The Department of Justice may seek and use grant funds to pay the costs incurred by the operation and maintenance of CURES. The department shall annually report to the Legislature and make available to the public the amount and source of funds it receives for support of CURES.
- (c) 1. The operation of CURES shall comply with all applicable federal and state privacy and security laws and regulations.
  - 2. A. CURES shall operate under existing provisions of law to safeguard the privacy and confidentiality of patients. Data obtained from CURES shall only be provided to appropriate state, local, and federal public agencies for disciplinary, civil, or criminal purposes and to other agencies or entities, as determined by the department, for the purpose of educating practitioners and others in lieu of disciplinary, civil, or criminal actions. Data may be provided to public or private entities, as approved by the department, for educational, peer review, statistical, or research purposes, if patient information, including information that may identify the patient, is not compromised. The University of California shall be provided access to identifiable data for research purposes if the requirements of subdivision (t) of Section 1798.24 of the Civil Code are

satisfied. Further, data disclosed to an individual or agency as described in this subdivision shall not be disclosed, sold, or transferred to a third party, unless authorized by, or pursuant to, state and federal privacy and security laws and regulations. The department shall establish policies, procedures, and regulations regarding the use, access, evaluation, management, implementation, operation, storage, disclosure, and security of the information within CURES, consistent with this subdivision.

- B. Notwithstanding subparagraph (A), a regulatory board whose licensees do not prescribe, order, administer, furnish, or dispense controlled substances shall not be provided data obtained from CURES.
- 3. The department shall, no later than January 1, 2021, adopt regulations regarding the access and use of the information within CURES. The department shall consult with all stakeholders identified by the department during the rulemaking process. The regulations shall, at a minimum, address all of the following in a manner consistent with this chapter:
  - A. The process for approving, denying, and disapproving individuals or entities seeking access to information in CURES.
  - B. The purposes for which a health care practitioner may access information in CURES.
  - C. The conditions under which a warrant, subpoena, or court order is required for a law enforcement agency to obtain information from CURES as part of a criminal investigation.
  - D. The process by which information in CURES may be provided for educational, peer review, statistical, or research purposes.
- 4. In accordance with federal and state privacy laws and regulations, a health care practitioner may provide a patient with a copy of the patient's CURES patient activity report as long as no additional CURES data are provided and the health care practitioner keeps a copy of the report in the patient's medical record in compliance with subdivision (d) of Section 11165.1.
- (d) For each prescription for a Schedule II, Schedule III, Schedule IV, or Schedule V controlled substance, as defined in the controlled substances schedules in federal law and regulations, specifically Sections 1308.12, 1308.13, 1308.14, and 1308.15, respectively, of Title 21 of the Code of Federal Regulations, the dispensing pharmacy, clinic, or other dispenser shall report the following information to the department or contracted prescription data processing vendor as soon as reasonably possible, but not more than one working day after the date a controlled substance is released to the patient or patient's representative, in a format specified by the department:

- Full name, address, and, if available, telephone number of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services, and the gender, and date of birth of the ultimate user.
- 2. The prescriber's category of licensure, license number, national provider identifier (NPI) number, if applicable, the federal controlled substance registration number, and the state medical license number of a prescriber using the federal controlled substance registration number of a government-exempt facility.
- 3. Pharmacy prescription number, license number, NPI number, and federal controlled substance registration number.
- 4. National Drug Code (NDC) number of the controlled substance dispensed.
- 5. Quantity of the controlled substance dispensed.
- 6. The International Statistical Classification of Diseases (ICD) Code contained in the most current ICD revision, or any revision deemed sufficient by the State Board of Pharmacy, if available.
- 7. Number of refills ordered.
- 8. Whether the drug was dispensed as a refill of a prescription or as a first-time request.
- 9. Prescribing date of the prescription.
- 10. Date of dispensing of the prescription.
- 11. The serial number for the corresponding prescription form, if applicable.
- (e) The department may invite stakeholders to assist, advise, and make recommendations on the establishment of rules and regulations necessary to ensure the proper administration and enforcement of the CURES database. A prescriber or dispenser invitee shall be licensed by one of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, in active practice in California, and a regular user of CURES.
- (f) The department shall, prior to upgrading CURES, consult with prescribers licensed by one of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, one or more of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, and any other stakeholder identified by the department, for the purpose of identifying desirable capabilities and upgrades to the CURES Prescription Drug Monitoring Program (PDMP).
- (g) The department may establish a process to educate authorized subscribers of the CURES PDMP on how to access and use the CURES PDMP.

- (h) 1. The department may enter into an agreement with an entity operating an interstate data sharing hub, or an agency operating a prescription drug monitoring program in another state, for purposes of interstate data sharing of prescription drug monitoring program information.
  - 2. Data obtained from CURES may be provided to authorized users of another state's prescription drug monitoring program, as determined by the department pursuant to subdivision (c), if the entity operating the interstate data sharing hub, and the prescription drug monitoring program of that state, as applicable, have entered into an agreement with the department for interstate data sharing of prescription drug monitoring program information.
  - 3. An agreement entered into by the department for purposes of interstate data sharing of prescription drug monitoring program information shall ensure that all access to data obtained from CURES and the handling of data contained within CURES comply with California law, including regulations, and meet the same patient privacy, audit, and data security standards employed and required for direct access to CURES.
  - 4. For purposes of interstate data sharing of CURES information pursuant to this subdivision, an authorized user of another state's prescription drug monitoring program shall not be required to register with CURES, if the authorized user is registered and in good standing with that state's prescription drug monitoring program.
  - 5. The department shall not enter into an agreement pursuant to this subdivision until the department has issued final regulations regarding the access and use of the information within CURES as required by paragraph (3) of subdivision (c).
- If the dispensing pharmacy, clinic, or other dispenser (i) experiences a temporary technological or electrical failure, it shall, without undue delay, seek to correct any cause of the temporary technological or electrical failure that is reasonably within its control. The deadline for transmitting prescription information to the department or contracted prescription data processing vendor pursuant to subdivision (d) shall be extended until the failure is corrected. If the dispensing pharmacy, clinic, or other dispenser experiences technological limitations that are not reasonably within its control, or is impacted by a natural or manmade disaster, the deadline for transmitting prescription information to the department or contracted prescription data processing vendor shall be extended until normal operations have resumed.

Section 11165.1. (a) 1. A. (i) A health care practitioner authorized to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, Schedule IV, or Schedule V controlled substances pursuant to Section 11150 shall, upon receipt of a federal Drug Enforcement Administration (DEA) registration, submit an application developed by the department to obtain approval to electronically access information regarding the controlled substance history of a patient that is maintained by the department. Upon approval, the department shall release to that practitioner or their delegate the electronic history of controlled substances dispensed to an individual under the practitioner's care based on data contained in the CURES Prescription Drug Monitoring Program (PDMP).

- (ii) A pharmacist shall, upon licensure, submit an application developed by the department to obtain approval to electronically access information regarding the controlled substance history of a patient that is maintained by the department. Upon approval, the department shall release to the pharmacist or their delegate the electronic history of controlled substances dispensed to an individual under the pharmacist's care based on data contained in the CURES PDMP.
- (iii) A licensed physician and surgeon who does not hold a DEA registration may submit an application developed by the department to obtain approval to electronically access information regarding the controlled substance history of the patient that is maintained by the department. Upon approval, the department shall release to the physician and surgeon or their delegate the electronic history of controlled substances dispensed to a patient under their care based on data contained in the CURES PDMP.
- (iv) The department shall implement its duties described in clauses (i), (ii), and (iii) upon completion of any technological changes to the CURES database necessary to support clauses (i), (ii), and (iii), or by October 1, 2022, whichever is sooner.
- B. The department may deny an application or suspend a subscriber, for reasons that include, but are not limited to, the following:
  - (i) Materially falsifying an application to access information contained in the CURES database.
  - (ii) Failing to maintain effective controls for access to the patient activity report.
  - (iii) Having their federal DEA registration suspended or revoked.
  - (iv) Violating a law governing controlled substances or another law for which the possession or use of a controlled substance is an element of the crime.

- (v) Accessing information for a reason other than to diagnose or treat a patient, or to document compliance with the law.
- C. An authorized subscriber shall notify the department within 30 days of a change to the subscriber account.
- D. An approved health care practitioner, pharmacist, or a person acting on behalf of a health care practitioner or pharmacist pursuant to subdivision (b) of Section 209 of the Business and Professions Code may use the department's online portal or a health information technology system that meets the criteria required in subparagraph (E) to access information in the CURES database pursuant to this section. A subscriber who uses a health information technology system that meets the criteria required in subparagraph (E) to access the CURES database may submit automated queries to the CURES database that are triggered by predetermined criteria.
- E. An approved health care practitioner or pharmacist may submit queries to the CURES database through a health information technology system if the entity that operates the health information technology system certifies all of the following:
  - (i) The entity will not use or disclose data received from the CURES database for any purpose other than delivering the data to an approved health care practitioner or pharmacist or performing data processing activities that may be necessary to enable the delivery unless authorized by, and pursuant to, state and federal privacy and security laws and regulations.
  - (ii) The health information technology system will authenticate the identity of an authorized health care practitioner or pharmacist initiating queries to the CURES database and, at the time of the query to the CURES database, the health information technology system submits the following data regarding the query to CURES:
    - (I) The date of the query.
    - (II) The time of the query.
    - (III) The first and last name of the patient queried.
    - (IV) The date of birth of the patient queried.
    - (V) The identification of the CURES user for whom the system is making the query.

- (iii) The health information technology system meets applicable patient privacy and information security requirements of state and federal law.
- The entity has entered into a memoran-(iv)dum of understanding with the department that solely addresses the technical specifications of the health information technology system to ensure the security of the data in the CURES database and the secure transfer of data from the CURES database. The technical specifications shall be universal for all health information technology systems that establish a method of system integration to retrieve information from the CURES database. The memorandum of understanding shall not govern, or in any way impact or restrict, the use of data received from the CURES database or impose any additional burdens on covered entities in compliance with the regulations promulgated pursuant to the federal Health Insurance Portability and Accountability Act of 1996 found in Parts 160 and 164 of Title 45 of the Code of Federal Regulations.
- F. No later than October 1, 2018, the department shall develop a programming interface or other method of system integration to allow health information technology systems that meet the requirements in subparagraph (E) to retrieve information in the CURES database on behalf of an authorized health care practitioner or pharmacist.
- G. The department shall not access patientidentifiable information in an entity's health information technology system.
- H. An entity that operates a health information technology system that is requesting to establish an integration with the CURES database shall pay a reasonable fee to cover the cost of establishing and maintaining integration with the CURES database.
- I. The department may prohibit integration or terminate a health information technology system's ability to retrieve information in the CURES database if the health information technology system fails to meet the requirements of subparagraph (E), or the entity operating the health information technology system does not fulfill its obligation under subparagraph (H).

- 2. A health care practitioner authorized to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, Schedule IV, or Schedule V controlled substances pursuant to Section 11150 or a pharmacist shall be deemed to have complied with paragraph (1) if the licensed health care practitioner or pharmacist has been approved to access the CURES database through the process developed pursuant to subdivision (a) of Section 209 of the Business and Professions Code.
- (b) A request for, or release of, a controlled substance history pursuant to this section shall be made in accordance with guidelines developed by the department.
- (c) In order to prevent the inappropriate, improper, or illegal use of Schedule II, Schedule III, Schedule IV, or Schedule V controlled substances, the department may initiate the referral of the history of controlled substances dispensed to an individual based on data contained in CURES to licensed health care practitioners, pharmacists, or both, providing care or services to the individual.
- (d) The history of controlled substances dispensed to an individual based on data contained in CURES that is received by a practitioner or pharmacist from the department pursuant to this section is medical information subject to the provisions of the Confidentiality of Medical Information Act contained in Part 2.6 (commencing with Section 56) of Division 1 of the Civil Code.
- (e) Information concerning a patient's controlled substance history provided to a practitioner or pharmacist pursuant to this section shall include prescriptions for controlled substances listed in Sections 1308.12, 1308.13, 1308.14, and 1308.15 of Title 21 of the Code of Federal Regulations.
- (f) A health care practitioner, pharmacist, or a person acting on behalf of a health care practitioner or pharmacist, when acting with reasonable care and in good faith, is not subject to civil or administrative liability arising from false, incomplete, inaccurate, or misattributed information submitted to, reported by, or relied upon in the CURES database or for a resulting failure of the CURES database to accurately or timely report that information.
- (g) For purposes of this section, the following terms have the following meanings:
  - 1. "Automated basis" means using predefined criteria to trigger an automated query to the CURES database, which can be attributed to a specific health care practitioner or pharmacist.
  - 2. "Department" means the Department of Justice.
  - 3. "Entity" means an organization that operates, or provides or makes available, a health information technology system to a health care practitioner or pharmacist.
  - 4. "Health information technology system" means an information processing application using hardware

and software for the storage, retrieval, sharing of or use of patient data for communication, decisionmaking, coordination of care, or the quality, safety, or efficiency of the practice of medicine or delivery of health care services, including, but not limited to, electronic medical record applications, health information exchange systems, or other interoperable clinical or health care information system.

(h) This section shall become operative on July 1, 2021, or upon the date the department promulgates regulations to implement this section and posts those regulations on its Internet website, whichever date is earlier.

Section 11165.2. (a) The Department of Justice may conduct audits of the CURES Prescription Drug Monitoring Program system and its users.

- (b) The Department of Justice may establish, by regulation, a system for the issuance to a CURES Prescription Drug Monitoring Program subscriber of a citation which may contain an order of abatement, or an order to pay an administrative fine assessed by the Department of Justice if the subscriber is in violation of any provision of this chapter or any regulation adopted by the Department of Justice pursuant to this chapter.
- (c) The system shall contain the following provisions:
  - 1. Citations shall be in writing and shall describe with particularity the nature of the violation, including specific reference to the provision of law or regulation of the department determined to have been violated.
  - 2. Whenever appropriate, the citation shall contain an order of abatement establishing a reasonable time for abatement of the violation.
  - 3. In no event shall the administrative fine assessed by the department exceed two thousand five hundred dollars (\$2,500) for each violation. In assessing a fine, due consideration shall be given to the appropriateness of the amount of the fine with respect to such factors as the gravity of the violation, the good faith of the subscribers, and the history of previous violations.
  - 4. An order of abatement or a fine assessment issued pursuant to a citation shall inform the subscriber that if the subscriber desires a hearing to contest the finding of a violation, a hearing shall be requested by written notice to the CURES Prescription Drug Monitoring Program within 30 days of the date of issuance of the citation or assessment. Hearings shall be held pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code.
  - 5. In addition to requesting a hearing, the subscriber may, within 10 days after service of the citation, request in writing an opportunity for an informal conference with the department regarding the citation. At the conclusion of the informal conference,

the department may affirm, modify, or dismiss the citation, including any fine levied or order of abatement issued. The decision shall be deemed to be a final order with regard to the citation issued, including the fine levied or the order of abatement which could include permanent suspension to the system, a monetary fine, or both, depending on the gravity of the violation. However, the subscriber does not waive its right to request a hearing to contest a citation by requesting an informal conference. If the citation is affirmed, a formal hearing may be requested within 30 days of the date the citation was affirmed. If the citation is dismissed after the informal conference, the request for a hearing on the matter of the citation shall be deemed to be withdrawn. If the citation, including any fine levied or order of abatement, is modified, the citation originally issued shall be considered withdrawn and a new citation issued. If a hearing is requested for a subsequent citation, it shall be requested within 30 days of service of that subsequent citation.

- 6. Failure of a subscriber to pay a fine within 30 days of the date of assessment or comply with an order of abatement within the fixed time, unless the citation is being appealed, may result in disciplinary action taken by the department. If a citation is not contested and a fine is not paid, the subscriber account will be terminated:
  - A. A citation may be issued without the assessment of an administrative fine.
  - B. Assessment of administrative fines may be limited to only particular violations of law or department regulations.
- (d) Notwithstanding any other provision of law, if a fine is paid to satisfy an assessment based on the finding of a violation, payment of the fine shall be represented as a satisfactory resolution of the matter for purposes of public disclosure.
- (e) Administrative fines collected pursuant to this section shall be deposited in the CURES Program Special Fund, available upon appropriation by the Legislature. These special funds shall provide support for costs associated with informal and formal hearings, maintenance, and updates to the CURES Prescription Drug Monitoring Program.
- (f) The sanctions authorized under this section shall be separate from, and in addition to, any other administrative, civil, or criminal remedies; however, a criminal action may not be initiated for a specific offense if a citation has been issued pursuant to this section for that offense, and a citation may not be issued pursuant to this section for a specific offense if a criminal action for that offense has been filed.

(g) Nothing in this section shall be deemed to prevent the department from serving and prosecuting an accusation to suspend or revoke a subscriber if grounds for that suspension or revocation exist.

Section 11165.4. (a) 1. A. (i) A health care practitioner authorized to prescribe, order, administer, or furnish a controlled substance shall consult the patient activity report or information from the patient activity report obtained from the CURES database to review a patient's controlled substance history for the past 12 months before prescribing a Schedule II, Schedule III, or Schedule IV controlled substance to the patient for the first time and at least once every six months thereafter if the prescriber renews the prescription and the substance remains part of the treatment of the patient.

- (ii) If a health care practitioner authorized to prescribe, order, administer, or furnish a controlled substance is not required, pursuant to an exemption described in subdivision (c), to consult the patient activity report from the CURES database the first time the health care practitioner prescribes, orders, administers, or furnishes a controlled substance to a patient, the health care practitioner shall consult the patient activity report from the CURES database to review the patient's controlled substance history before subsequently prescribing a Schedule II, Schedule III, or Schedule IV controlled substance to the patient and at least once every six months thereafter if the prescriber renews the prescription and the substance remains part of the treatment of the patient.
- (iii) A health care practitioner who did not directly access the CURES database to perform the required review of the controlled substance use report shall document in the patient's medical record that they reviewed the CURES database generated report within 24 hours of the controlled substance prescription that was provided to them by another authorized user of the CURES database.
- B. For purposes of this paragraph, "first time" means the initial occurrence in which a health care practitioner, in their role as a health care practitioner, intends to prescribe, order, administer, or furnish a Schedule II, Schedule III, or Schedule IV controlled substance to a patient and has not previously prescribed a controlled substance to the patient.

- 2. A health care practitioner shall review a patient's controlled substance history that has been obtained from the CURES database no earlier than 24 hours, or the previous business day, before the health care practitioner prescribes, orders, administers, or furnishes a Schedule II, Schedule III, or Schedule IV controlled substance to the patient.
- (b) The duty to consult the CURES database, as described in subdivision (a), does not apply to veterinarians or pharmacists.
- (c) The duty to consult the CURES database, as described in subdivision (a), does not apply to a health care practitioner in any of the following circumstances:
  - 1. If a health care practitioner prescribes, orders, or furnishes a controlled substance to be administered to a patient while the patient in any of the following facilities or during an emergency transfer between any of the following facilities, or for use while on facility premises:
    - A licensed clinic, as described in Chapter 1 (commencing with Section 1200) of Division 2.
    - B. An outpatient setting, as described in Chapter
       1.3 (commencing with Section 1248) of Division 2.
    - C. A health facility, as described in Chapter 2 (commencing with Section 1250) of Division 2.
    - D. A county medical facility, as described in Chapter 2.5 (commencing with Section 1440) of Division 2.
    - E. Another medical facility, including, but not limited to, an office of a health care practitioner and an imaging center.
    - F. A correctional clinic, as described in Section 4187 of the Business and Professions Code, or a correctional pharmacy, as described in Section 4021.5 of the Business and Professions Code.
  - 2. If a health care practitioner prescribes, orders, administers, or furnishes a controlled substance in the emergency department of a general acute care hospital and the quantity of the controlled substance does not exceed a nonrefillable seven-day supply of the controlled substance to be used in accordance with the directions for use.
  - 3. If a health care practitioner prescribes, orders, administers, or furnishes buprenorphine or other controlled substance containing buprenorphine in the emergency department of a general acute care hospital.
  - 4. If a health care practitioner prescribes, orders, administers, or furnishes a controlled substance to a patient as part of the patient's treatment for a

surgical, radiotherapeutic, or diagnostic procedure and the quantity of the controlled substance does not exceed a nonrefillable seven-day supply of the controlled substance to be used in accordance with the directions for use, in any of the following facilities:

- A. A licensed clinic, as described in Chapter 1 (commencing with Section 1200) of Division 2.
- An outpatient setting, as described in Chapter
   1.3 (commencing with Section 1248) of Division 2.
- C. A health facility, as described in Chapter 2 (commencing with Section 1250) of Division 2.
- D. A county medical facility, as described in Chapter 2.5 (commencing with Section 1440) of Division 2.
- E. A place of practice, as defined in Section 1658 of the Business and Professions Code.
- F. Another medical facility where surgical procedures are permitted to take place, including, but not limited to, the office of a health care practitioner.
- 5. If a health care practitioner prescribes, orders, administers, or furnishes a controlled substance to a patient who is terminally ill, as defined in subdivision (c) of Section 11159.2.
- 6. A. If all of the following circumstances are satisfied:
  - (i) It is not reasonably possible for a health care practitioner to access the information in the CURES database in a timely manner.
  - (ii) Another health care practitioner or designee authorized to access the CURES database is not reasonably available.
  - (iii) The quantity of controlled substance prescribed, ordered, administered, or furnished does not exceed a nonrefillable seven-day supply of the controlled substance to be used in accordance with the directions for use and no refill of the controlled substance is allowed.
  - B. A health care practitioner who does not consult the CURES database under subparagraph (A) shall document the reason they did not consult the database in the patient's medical record.
- 7. If the CURES database is not operational, as determined by the department, or cannot be accessed by a health care practitioner because of a temporary technological or electrical failure. A health care practitioner shall, without undue delay, seek to correct the cause of the temporary technological or electrical failure that is reasonably within the health care practitioner's control.

- 8. If the CURES database cannot be accessed because of technological limitations that are not reasonably within the control of a health care practitioner.
- 9. If consultation of the CURES database would, as determined by the health care practitioner, result in a patient's inability to obtain a prescription in a timely manner and thereby adversely impact the patient's medical condition, provided that the quantity of the controlled substance does not exceed a nonrefillable seven-day supply if the controlled substance were used in accordance with the directions for use.
- (d) 1. A health care practitioner who fails to consult the CURES database, as described in subdivision (a), shall be referred to the appropriate state professional licensing board solely for administrative sanctions, as deemed appropriate by that board.
  - 2. This section does not create a private cause of action against a health care practitioner. This section does not limit a health care practitioner's liability for the negligent failure to diagnose or treat a patient.
- (e) All applicable state and federal privacy laws govern the duties required by this section.
- (f) The provisions of this section are severable. If any provision of this section or its application is held invalid, that invalidity shall not affect other provisions or applications that can be given effect without the invalid provision or application.
- (g) This section shall become operative on July 1, 2021, or upon the date the department promulgates regulations to implement this section and posts those regulations on its internet website, whichever date is earlier.

#### **REPORTING OF ABUSE AND NEGLECT**

In accordance with California Penal Code Section 11165.7, dentists, dental assistants, and dental hygienists are mandated reporters of child abuse and neglect [3]. Reporting suspected abuse is not only an ethical duty but is also a legal obligation.

#### CHILD ABUSE AND NEGLECT REPORTING LAW

Section 11164. (a) This article shall be known and may be cited as the Child Abuse and Neglect Reporting Act.

(b) The intent and purpose of this article is to protect children from abuse and neglect. In any investigation of suspected child abuse or neglect, all persons participating in the investigation of the case shall consider the needs of the child victim and shall do whatever is necessary to prevent psychological harm to the child victim.

Section 11166. (a) Except as provided in subdivision (d), and in Section 11166.05, a mandated reporter shall make a report to an agency specified in Section 11165.9 whenever the mandated reporter, in the mandated reporter's professional capacity or within the scope of the mandated reporter's employment, has knowledge of or observes a child whom the mandated reporter knows or reasonably suspects has been the victim of child abuse or neglect. The mandated reporter shall make an initial report by telephone to the agency immediately or as soon as is practicably possible, and shall prepare and send, fax, or electronically transmit a written follow-up report within 36 hours of receiving the information concerning the incident. The mandated reporter may include with the report any nonprivileged documentary evidence the mandated reporter possesses relating to the incident.

Section 11165.9. Reports of suspected child abuse or neglect shall be made by mandated reporters, or in the case of reports pursuant to Section 11166.05, may be made, to any police department or sheriff's department, not including a school district police or security department, county probation department, if designated by the county to receive mandated reports, or the county welfare department. Any of those agencies shall accept a report of suspected child abuse or neglect whether offered by a mandated reporter or another person, or referred by another agency, even if the agency to whom the report is being made lacks subject matter or geographical jurisdiction to investigate the reported case, unless the agency can immediately electronically transfer the call to an agency with proper jurisdiction. When an agency takes a report about a case of suspected child abuse or neglect in which that agency lacks jurisdiction, the agency shall immediately refer the case by telephone, fax, or electronic transmission to an agency with proper jurisdiction. Agencies that are required to receive reports of suspected child abuse or neglect may not refuse to accept a report of suspected child abuse or neglect from a mandated reporter or another person unless otherwise authorized pursuant to this section, and shall maintain a record of all reports received.

#### IDENTIFYING, DOCUMENTING, AND REPORTING ABUSE AND NEGLECT

Preventing serious morbidity and mortality involves intervening at the first suspicion or indication of abuse and/or neglect. Dentists and dental hygienists are often the healthcare professionals who have the most frequent interactions with children and should be attentive to any signs of neglect and physical abuse—as abusive injuries commonly involve the face, jaw, mouth, teeth, and tongue [4]. One study found that orofacial trauma was concurrent with 49% of documented cases of child physical abuse [5]. Other studies show that craniofacial and neck injuries occur in 50% to 65% of child abuse victims and that the lips are a site for abusive injury in 54% of cases [6; 7].

#### Clinical Signs of Abuse

The American Academy of Pediatrics (AAP) Committee on Child Abuse and Neglect and the California Dental Association have published useful articles regarding the identification of the orofacial signs of abuse and particular injuries of concern. According to these sources, possible signs of abuse include [6; 7; 12]:

- Forced feeding injuries caused by eating utensils, bottles, hands, fingers, and other objects; scalding liquids; or caustic substances. These may be responsible for burns, contusions, or lacerations of the lips, tongue, buccal mucosa, gingival alveolar mucosa, frenum, or palate (soft and hard). Objects forced into the face/mouth may also cause facial bone and jaw fractures and avulsed, displaced, or fractured teeth.
- Mouth gagging injuries resulting in bruises, lichenification, or scarring at the corners of the mouth
- Strangulation injuries resulting in bruising, a hoarse or raspy voice, and difficulty breathing
- Discolored teeth from previous trauma
- Serious trauma (e.g., retropharyngeal abscesses, posterior pharyngeal injuries) resulting from caregivers with factitious disorder (i.e., Münchausen syndrome) by proxy
- Injury to the petechiae of the palate (particularly at the junction of soft and hard palate) resulting from forced oral sex
- Sexually transmitted oral/perioral infections (e.g., gonorrhea, human papillomavirus warts), although these can be transmitted by other means as well
- Bite marks or bruises on the head or face, strangulation marks, or black eyes
- Missing hair from hair pulling
- Welts in the shape of objects (e.g., belt buckle, clothes iron)
- Other suspicious trauma/bruises indicative of abuse (e.g., rope marks)

During examination, excessive caries, gingivitis, and oral infections/diseases should be noted as possible signs of neglect. (Parents or caretakers with an ignorance of proper oral care, who have no perceived value of oral health, with limited access to health care or insurance, and/or geographic isolation should be differentiated from those with a willful disregard for the child's health [6].) Perioral and intraoral injuries and infections in various stages of healing, especially those that seem inappropriate for the child's developmental age, should be documented. Additionally, abuse and neglect are more prevalent (up to four times more common) in individuals with developmental or physical disability [12].

Although accidental injuries are common in pediatric patients, the history of trauma, including mechanism and timing, must be weighed against the injury features. Characteristics of the injury that do not seem to match the reported history should spur suspicion of abuse. The acronym RADAR is commonly used to assist in the routine abuse screening of patients [29]:

• Routinely screen for signs and symptoms of abuse/neglect

- Ask direct, non-judgmental questions with compassion
- Document your findings
- Assess patient safety before the patient leaves the medical setting
- Review, refer, report

A parent or primary caretaker may be genuinely unaware of the abuse or injuries and may not be able to offer information relevant to the history. It is important not to make judgments of family members (either innocent or guilty), apportion blame, or attempt to personally undertake a criminal investigation. The scope of dental practice does not include these actions, and they may interfere with a law enforcement investigation. The AAP notes that the dental professional's role in a criminal investigation is to interpret medical information for nonmedical professionals in an understandable manner that accurately reflects the medical evidence [8]. Identify the medical problem, document the suspected abuse (e.g., names, photos, body map, preserve evidence), treat the injuries, and offer honest, factual medical information to parents, families, law enforcement, and justice officials.

#### **Reporting Abuse**

As noted in the California Dental Practice Act, dental healthcare professionals have a legal and ethical responsibility to report suspected child abuse to the proper authorities, not to punish perpetrators of abuse but to protect the abuse victims. One author writes, "The dentist must view himself as a child advocate. Simply treating dental and facial injuries of abused children while ignoring the social needs of the child and family is unacceptable" [9].

Nonetheless, the decision of whether or not to report suspected abuse is ethically challenging. Although healthcare professionals are obligated to report suspected abuse, suspicion of abuse is somewhat of a judgment call and certain biases may influence the decision to report. It has been noted that well-intentioned professionals in all fields are swayed by both negative and positive social biases (e.g., sex, race, socioeconomic status, physical appearance, job status), and it is advisable to challenge personal biases and weigh only the facts of the case. A 2008 prospective, observational AAP study found that, "clinicians did not report 27% of injuries considered likely or very likely caused by child abuse and 76% of injuries considered possibly caused by child abuse" because of various biases and experiences [10]. However, patients who had an injury that was not a laceration, who had more than one family risk factor, who had a serious injury, who had a child risk factor other than an inconsistent injury, who had a parental history of substance abuse, or who were unfamiliar to the clinician were more likely to be reported.

Professionally mandated reporters are protected from civil or criminal prosecution in consequence of a good-faith report of abuse, and no clinician in the aforementioned AAP study was sued for malpractice as a result of reporting abuse [7; 10]. However, it is possible for dental professionals to be sued, and a state petition for up to \$50,000 in recompensatory legal fees is available for dentists having to defend themselves in court [7]. On the other hand, civil or criminal penalties for willfully not reporting abuse or impeding a report when abuse has been found to have occurred include 6 months in jail and/or a fine of \$1,000 or, in cases of serious injury/death following a failure to report, 12 months in jail, and/or a fine of \$5,000.

#### ELDER AND DEPENDENT ADULT ABUSE AND NEGLECT

Abusive injuries to the mouth and oral cavity of elder or dependent (e.g., developmentally or physically disabled) adults are similar in type and causation to those sustained by pediatric patients, including trauma from forced feeding, object insertion, mouth gagging, and being slapped, hit, or strangled, but also include damage to and from prostheses. The number of new elder and dependent adult abuse cases is usually about 18,000 per month in California alone, with family members constituting two-thirds of perpetrators [11; 26]. However, researchers estimate that for each incident of reported abuse there are at least five (and perhaps up to 14) unreported incidents [11]. Studies have shown that dental professionals are reluctant to report elder or dependent abuse/neglect and that they have a low index of suspicion of this category of abuse [13].

The national frequency of elder abuse is estimated at up to 10%, with some research indicating that the number may be as high as 1 in 6 [14]. The overwhelming majority of abuse and neglect occurs in domestic, rather than institutional (e.g., residential care) settings, largely due to the shift in care in the 20th century from state institutions to the home (particularly for younger disabled individuals) [12; 14]. However, with an increasing aging population and longer life expectancies, it is projected that by 2030 there will be a 50% increase in the number of older adults who require nursing home care [14]. Women are the victims of elder abuse two-thirds of the time.

Elder and dependent adults are also at risk for poor oral health due to caretaker neglect. In fact, neglect is one of the most common causes of elder injury reporting [14]. These populations are also at a high risk for self-neglect, accounting for more than 500,000 additional reported cases in the United States per year. A 2010 study revealed that 40% of individuals 65 years of age or older suffer from some form of neglect [15].

#### Elder and Dependent Adult Abuse Laws

Laws pertaining to mandatory elder and dependent adult abuse reporting are found in the California Welfare and Institutions Code Sections 15600 to 15632 [16].

Section 15600. (a) The Legislature recognizes that elders and dependent adults may be subjected to abuse, neglect, or abandonment and that this state has a responsibility to protect these persons. (i) Therefore, it is the intent of the Legislature in enacting this chapter to provide that adult protective services agencies, local long-term care ombudsman programs, and local law enforcement agencies shall receive referrals or complaints from public or private agencies, from any mandated reporter submitting reports pursuant to Section 15630, or from any other source having reasonable cause to know that the welfare of an elder or dependent adult is endangered, and shall take any actions considered necessary to protect the elder or dependent adult and correct the situation and ensure the individual's safety.

Section 15630. (a) Any person who has assumed full or intermittent responsibility for the care or custody of an elder or dependent adult, whether or not he or she receives compensation, including administrators, supervisors, and any licensed staff of a public or private facility that provides care or services for elder or dependent adults, or any elder or dependent adult care custodian, health practitioner, clergy member, or employee of a county adult protective services agency or a local law enforcement agency, is a mandated reporter.

(b) (1) Any mandated reporter who, in his or her professional capacity, or within the scope of his or her employment, has observed or has knowledge of an incident that reasonably appears to be physical abuse, abandonment, abduction, isolation, financial abuse, or neglect, or is told by an elder or dependent adult that he or she has experienced behavior, including an act or omission, constituting physical abuse, abandonment, abduction, isolation, financial abuse, or neglect, or reasonably suspects that abuse, shall report the known or suspected instance of abuse by telephone or through a confidential Internet reporting tool, as authorized by Section 15658, immediately or as soon as practicably possible. If reported by telephone, a written report shall be sent, or an Internet report shall be made through the confidential Internet reporting tool established in Section 15658, within two working days.

#### INTIMATE PARTNER VIOLENCE

Intimate partner violence is defined as violence directed at a "spouse, former spouse, cohabitant, former cohabitant, or person with whom the suspect has had a child or is having or has had a dating or engagement relationship" [7]. According to a 2016 to 2017 survey by the Centers for Disease Control and Prevention, severe physical violence by an intimate partner (including acts such as being hit with something hard, being kicked or beaten, or being burned on purpose) has been experienced by an estimated 32.5% of women and 24.6% of men during their lifetimes [17].

Dental professionals should be vigilant in recognizing signs of abuse among adolescent and adult patients. Up to 50% of abusive injuries occur to the head (particularly areas covered with hair) and neck, and facial injuries occur in 94% of intimate partner violence cases and are similar to those already discussed [7; 18]. Again, dental visits may be a patient's only contact with healthcare professionals, making identification of abuse an important part of dental visits [7]. A history of

intimidation, fear, isolation, and dependency is often present in victims of abuse, so it is especially important to determine the origin of orofacial or craniofacial injuries through the use of nonjudgmental questions. The Stanford School of Medicine recommends the following lines of indirect questioning for most age groups [31]:

- How are things going at home?
- What about stress levels? How are things going at work? At home?
- How do you feel about the relationships in your life?
- How does your partner treat you?
- Are you having any problems with your partner?

Alternately, lines of direct questioning may be used [31]:

- Are you afraid of your partner? Do you feel you are in danger?
- You mentioned your partner's problem with temper/ stress/drinking. When that happens, has he ever threatened or hurt you?
- Every couple fights at times what are your fights like at home? Do the fights ever become physical?
- Have you been hit or scared since the last time I saw you?
- Has anyone at home hit you or tried to injure you in any way?
- What kinds of experiences with violence have you had in your life?
- Do you feel controlled or isolated by your partner?
- Does your partner ever try to control you by threatening to hurt you or your family?
- Has anyone close to you ever threatened or hurt you?
- Does your partner ever hit, kick, hurt or threaten you?
- Have you ever been slapped, pushed or shoved by your partner?
- Have you ever been touched in a way that made you feel uncomfortable?
- Has anyone ever made you to do something sexual when you did not want to?
- Has your partner ever refused to practice safe sex?

It is up to the practitioner's judgment which line of questioning to employ. Remember that the objectives are to advocate for and protect the patient. The questions can be framed in a way that does not cause a patient to feel singled out [31]:

- Because unfortunately violence is so common in our society, I have started asking all of my patients about it.
- Because domestic violence has so many effects on health, I now ask all my patients about it.
- From past experience with other patients, I'm concerned that some of your medical problems may be the result of someone hurting you. Is that happening?
- I don't know if this is a problem for you, but many of my patients are dealing with abusive relationships. Some are too afraid or uncomfortable to bring it up themselves, so I've started asking about it routinely.
- Violence affects many families. Violence in the home may result in physical and emotional problems for you and your child. We are offering services to anyone who may be concerned about violence in their home.

When working cross-culturally, it is helpful to learn the colloquialisms used to describe abuse. For example, in some Latino cultures "disrespected me" refers to intimate partner violence or sexual assault [30]. If abuse is suspected and there is a cultural disconnect, consider the assistance of a knowledgeable co-worker, who may be able to act as a cultural broker.

#### CONCLUSION

Although its primary objective is to safeguard the public, the California Dental Practice Act is an excellent resource for dental professionals to ensure compliance with state law. Dental professionals with a good knowledge of the Dental Practice Act and its effects on dental care will practice legally and safely.

#### RESOURCES

**California Dental Practice Act** https://www.dbc.ca.gov/about\_us/lawsregs/ laws.shtml

California Dental Association https://www.cda.org

Dental Hygiene Board of California https://dhbc.ca.gov

Be sure to transfer your answers to the Answer Sheet located on the envelope insert located between pages 68–69. DO NOT send these test pages to NetCE. Retain them for your records. **PLEASE NOTE: Your postmark or facsimile date will be used as your test completion date.** 

#### COURSE TEST - #51294 THE CALIFORNIA DENTAL PRACTICE ACT

This is an open book test. Please record your responses on the Answer Sheet. A passing grade of at least 70% must be achieved in order to receive credit for this course.

#### This 2 CE Credit Hour activity must be completed by January 31, 2028.

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**DESIGNATIONS OF CREDIT:** NETCE DESIGNATES THIS ACTIVITY FOR 2 CONTINUING EDUCATION CREDITS.

AGD SUBJECT CODE: 010.

This course meets the Dental Board of California's requirements for 2 units of continuing education. Dental Board of California course #02-3841-00450.

- 1. When employed continuously for 120 days or more, an unlicensed dental assistant's employer is responsible for ensuring that they have completed which of the following courses?
  - A) Infection control
  - B) Basic life support
  - C) The California Dental Practice Act
  - D) All of the above
- 2. A dental hygienist may perform all of the following procedures under general supervision, EXCEPT:
  - A) Root planing
  - B) Periodontal charting
  - C) Oral exfoliative cytology
  - D) Periodontal soft tissue curettage
- 3. Of the following, who may legally provide dental care in California?
  - A) An unlicensed dental assistant
  - B) A dentist with an expired license
  - C) A dental hygienist with a valid license in another state
  - D) A dentist who has not recorded his or her fingerprints through the Department of Justice Live Scan system
- 4. All of the following are grounds for having a license suspended, EXCEPT:
  - A) Employing an unlicensed dentist
  - B) Unsanitary or unsafe office conditions
  - C) Practicing dentistry with an expired license
  - D) Alteration of a patient record without an intent to deceive
- 5. What is the maximum fine and term of imprisonment for a first offense misdemeanor violation of the Dental Practice Act?
  - A) \$200 and 3 months
  - B) \$200 and 6 months
  - C) \$3,000 and 6 months
  - D) \$30,000 and 12 months

## 6. Which of the following dental professionals are permitted to prescribe drugs?

- A) Dental assistants
- B) Dental hygienists
- C) Doctors of dentistry
- D) All of the above

## 7. Which of the following are mandated reporters of child abuse?

- A) Dental assistants
- B) Dental hygienists
- C) Doctors of dentistry
- D) All of the above

## 8. What percentage of child abuse injuries involve the lips?

- A) 14%
- B) 34%
- C) 54%
- D) 74%
- 9. All of the following are clinical signs of physical child abuse, EXCEPT:
  - A) Excessive caries
  - B) Welts in the shape of household objects
  - C) A hoarse or raspy voice with evidence of strangulation injury
  - D) Lacerations of the lips, tongue, buccal mucosa, gingival alveolar mucosa, frenum, or palate
- 10. What percentage of individuals 65 years of age or older suffer from some form of neglect?
  - A) 20%
  - B) 40%
  - C) 60%
  - D) 80%

# Infection Control for Dental Professionals: The California Requirement

This course fulfills the California requirement for 2 hours of Infection Control education.

#### Audience

This course is designed for all dentists, dental hygienists, and dental assistants in all practice settings, particularly those practicing in California.

#### **Course Objective**

The purpose of this course is to familiarize dental professionals with infection control techniques in order to minimize the risks of microbial transmission in the dental healthcare setting.

#### Learning Objectives

Upon completion of this course, you should be able to:

- 1. Outline OSHA and Cal/OSHA regulations that impact the provision of dental care.
- 2. Analyze potential modes of transmission and pathogens that can result in infection in dental facilities.
- 3. Discuss potential prevention strategies for infection control, including hand hygiene, and personal protective equipment.
- 4. Describe effective environmental control measures that should be applied in dental care.
- 5. Identify steps that should be taken to protect dental healthcare personnel, including vaccination, education, and exposure responses.

#### Faculty

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Mark J. Szarejko, DDS, FAGD, received his dental degree from the State University of New York at Buffalo in 1985. He received fellowship from the Academy of General Dentistry in 1994.

#### Faculty Disclosure

Contributing faculty, Mark J. Szarejko, DDS, FAGD, has disclosed no relevant financial relationship with any product manufacturer or service provider mentioned. Senior Director of Development and Academic Affairs Sarah Campbell

#### **Division Planner/Director Disclosure**

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This course meets the Dental Board of California's requirements for 2 units of continuing education.

Dental Board of California course #02-3841-00452.

#### Special Approval

This course fulfills the California requirement for 2 hours of infection control education.

#### About the Sponsor

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#### INTRODUCTION

In 2023, there were more than 751,000 jobs in dental occupations in the United States [1]. In California alone there are approximately 104,000 dental healthcare professionals, including dentists, dental hygienists, and dental assistants [29]. Most of these dental workers come in daily contact with a variety of infectious diseases in their workplace and are at risk for both transmitting and contracting these diseases.

Universal Precautions were originally developed and recommended by the Centers for Disease Control and Prevention (CDC) in the 1980s as an infection control approach to protect healthcare professionals from bloodborne pathogens. Under Universal Precaution recommendations, all human blood and certain bodily fluids are treated as if they are infectious, regardless of patient or setting. In 1996, the CDC expanded these recommendations and introduced Standard Precautions, not only to protect healthcare workers from pathogens in human blood and body fluids but also from pathogens present in bodily fluids that are not covered under Universal Precautions, including saliva during dental procedures. Standard Precautions are the minimum standard of care applied to all patients, and include hand hygiene, use of specific types of personal protective equipment (PPE) based on anticipated exposure, safe injection practices, and management of contaminated environmental items. In addition to Standard Precautions, Transmission-Based Precautions (i.e., Contact Precautions, Droplet Precautions, and Airborne Precautions) are used to prevent transmission of an infectious agent that is not interrupted by Standard Precautions alone. The type of Transmission-Based Precaution used is based on what is known or suspected about a patient's infection.

In California, to address the issue of infection control and reduce the potential for harm, the Dental Board of California (DBC) established a requirement that licensed dental healthcare professionals in California complete a course on infection control and prevention, further expanding the requirement to all dental health personnel (DHCP), defined as [9]:

...all paid and non-paid personnel in the dental healthcare setting who might be occupationally exposed to infectious materials, including body substances and contaminated supplies, equipment, environmental surfaces, water, or air. DHCP includes dentists, dental hygienists, dental assistants, dental laboratory technicians (in-office and commercial), students and trainees, contractual personnel, and other persons not directly involved in patient care but potentially exposed to infectious agents (e.g., administrative, clerical, housekeeping, maintenance, or volunteer personnel).

#### #58584 Infection Control for Dental Professionals: The California Requirement

The DBC Infection Control standards require that DHCP comply with and enforce the minimum precautions to minimize the transmission of pathogens in healthcare settings, as set forth by Cal/OSHA. These standards are reviewed by the DBC and Dental Hygiene Committee of California to obtain a consensus on infection control standards. A written protocol should be developed for proper instrument processing, operatory cleanliness, and management of injuries, and a copy of infection control regulations should be conspicuously posted in each dental office [9].

#### INFECTION CONTROL REGULATIONS

Legal issues first began to impact infection control practices at the beginning of the acquired immunodeficiency syndrome (AIDS) epidemic in the early 1980s. The need to protect healthcare workers from bloodborne exposures resulted in the publication of the Bloodborne Pathogens Standard by OSHA in 1991 [3].

#### BLOODBORNE PATHOGENS STANDARD

The OSHA Standard requires employers whose employees have exposure to blood or other potentially infectious material (OPIM) to implement safe work practices, education, and barriers to exposure. OPIM includes saliva in dental procedures and all bodily fluid in situations where it is difficult or impossible to differentiate between bodily fluids; any unfixed tissue or organ (other than intact skin) from a human (living or dead); human immunodeficiency virus (HIV)-containing cell or tissue cultures, organ culture and blood, or other tissues from experimental animals [9]

The OSHA Bloodborne Pathogens Standard requires that all DHCP who may have contact on the job with blood or other bodily fluids must receive specific annual education, which includes instruction in the basics of infection control and prevention. Training must also cover bloodborne pathogens, modes of transmission, the proper use of needles, and Transmission-Based Precautions [2; 3].

#### CALIFORNIA AEROSOL TRANSMISSIBLE DISEASE STANDARD

In 2009, Cal/OSHA adopted the nation's first aerosol transmissible disease (ATD) standard, which remains in effect today. The standard is designed to protect healthcare workers from diseases spread by an airborne or droplet route. The ATD standard requires employers in health care to develop exposure control procedures and train employees to follow those procedures [4]. Basic exposure precautions, such as source screening, infection control, hand hygiene, and cleaning and decontamination procedures, are a fundamental part of the standard. Employees must be included in the periodic review and assessment of these procedures. According to the California ATD Standard, California dental offices whose patients have suspected or confirmed illnesses that require Airborne or Droplet Precautions, such as tuberculosis (TB) or other respiratory illnesses, must comply with the ATD standards [4]. Key points include:

- Dental employees must be trained to screen patients for ATDs.
- The screening process must be described in a written office procedure.
- Screening must be consistently implemented.
- Elective dental treatment should be deferred until the patient is non-infectious for TB or other diseases requiring Airborne or Droplet Precautions.

A simple screening procedure can be done by the first person who comes in contact with a patient. For example, the patient may be asked "How are you feeling today?" or "Do you have any coughs, fever, or flu-like symptoms?" If the patient is not feeling well or gives a positive answer to any part of the second question, the dental treatment should be rescheduled.

Outpatient dental clinics or offices are not required to comply with this standard if they meet all of the following conditions [4; 21]:

- Dental procedures are not performed on patients identified as ATD cases or suspected ATD cases (e.g., persons with TB or other respiratory illnesses).
- The clinic's injury and illness prevention program includes a written procedure for screening patients for ATDs that is consistent with the CDC guidelines for infection control in dental settings. This procedure must be followed before performing any dental work on a patient.
- Employees have been trained in the screening procedure in accordance with state law.
- Aerosol-generating dental procedures are not performed on a patient identified through the screening procedure as presenting a possible ATD exposure risk unless a licensed physician determines that the patient does not currently have an ATD.

As of 2024, California remains the only state with such a permanent standard; however, the coronavirus disease (COVID) pandemic of 2019–2022 highlighted the need for a standard addressing infectious pathogens spread by aerosols or droplets. During the pandemic, OSHA did issue interim guidance for safe workplaces, and some states issued emergency temporary standards. Experts have called for these requirements to be codified in order to ensure the safety of professions and patients, but this has not yet been accomplished [15]. Full guidance on aerosol-transmissible diseases can be found in the 2023 California Workplace Guide to Aerosol Transmissible Diseases at https://www.dir.ca.gov/dosh/dosh\_publications/ ATD-Guide.pdf [4].

COMMON MODES OF INFECTION TRANSMISSION	
Category	Definition
Direct contact	Person-to-person transmission of pathogens (e.g., through skin, blood, or body fluid contact)
Indirect contact	An intermediate person or item acts as a transport between the portal of exit in one person and the portal of entry to the next person (e.g., via unwashed hands, shared equipment, needlesticks)
Droplets <sup>a</sup>	Large respiratory droplets propelled by an infected person coughing, sneezing, talking, or breathing heavily. Droplets settle rapidly within 6 feet of the individual on surfaces and in the upper airway of individuals exposed via the eyes, nose, or mouth.
Airborne (aerosols) <sup>a</sup>	Small particles or micro-droplets are released into the air by an infected person coughing, sneezing, talking, or breathing heavily. Airborne pathogens can linger for long periods of time and travel longer distances, landing on surfaces and being breathed in by other individuals into the lower airway.
Fomites	Contact with a contaminated inanimate object (e.g., used gloves, pens, used tissues, soiled laundry, keyboards, furniture).
Water	Water may be contaminated by micro-organisms in dental water unit lines, causing patient contamination as well as dispersing infected airborne particles and droplets.
<sup>a</sup> In 2024, a global consensus was reached to replace the terms droplet, airborne, and aerosol with a general umbrella term of "through the air transmission," regardless of infected respiratory particle size and/or distance traveled.	
Source: [5; 6; 8]	Table 1

#### MODES OF TRANSMISSION

Almost all pathogens are transmitted by being carried from one place to another. The mode or means of transmission is the weakest link in the chain of infection, and it is the only link that can be eliminated entirely. Most infection control efforts are aimed at preventing transmission of pathogens from a reservoir to a susceptible host. Both Standard and Transmission-Based Precautions are designed to interrupt the mode of transmission. *Table 1* details the most common modes of infection transmission in dentistry [5; 6; 8].

#### DIRECT AND INDIRECT CONTACT

The most common modes of transmission in the healthcare setting are through contact, both direct and indirect. Because it addresses the weakest link in the chain of transmission, hand hygiene is the single most important procedure for preventing the spread of infection. Items moving between patients should be cleaned and sterilized after each use to avoid indirect transmission of pathogens. Standard Precautions in conjunction with identified Contact Precautions are often used in the dental setting.

#### **Bloodborne Pathogens**

Healthcare employees can be exposed to blood through needlestick and other sharps injuries, damaged mucous membranes, and broken skin exposures. The pathogens of primary concern to dental professions are HIV, hepatitis B virus, and hepatitis C virus.

#### Hepatitis B Virus

Healthcare personnel who have received the hepatitis B vaccine and developed immunity to the virus are at virtually no risk for infection. For a susceptible person, the risk from a single needlestick or cut exposure to hepatitis B-infected blood ranges from 6% to 30%, depending on the hepatitis B antigen status of the source individual. While there is a risk for hepatitis B infection from exposures of mucous membranes or nonintact skin, there is no known risk for infection from exposure to intact skin [5; 10].

#### Hepatitis C Virus

Hepatitis C is transmitted primarily through percutaneous exposure to infected blood. The average risk for infection after a needlestick or cut exposure to hepatitis C virus-infected blood is approximately 1.8%. The risk following a blood exposure to the eye, nose, or mouth is unknown but is believed to be very small; however, hepatitis C virus infection from blood splashes to the eye has been reported. There also has been a report of hepatitis C virus transmission that may have resulted from exposure to intact skin, but there is no known risk from exposure to intact skin. Documented transmission of hepatitis C or hepatitis B virus has resulted from using the same syringe or vial to administer medication to more than one patient, even if the needle was changed [5; 10].

The prevalence of hepatitis C virus infection among dentists and surgeons is similar to that among the general population, approximately 1% to 2% [5]. No studies of transmission from hepatitis C virus-infected DHCP to patients have been reported, and the risk for such transmission appears limited [10].

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#### HIV/AIDS

The average risk of HIV infection after a needlestick or cut exposure to HIV-infected blood is 0.3%; 99.7% of needlestick or cut exposures do not lead to infection. The risk after exposure of the eye, nose, or mouth to HIV-infected blood is estimated to be 0.1%. There have been no documented cases of HIV transmission due to an exposure involving a small amount of blood on intact skin (i.e., a few drops of blood on skin for a short period of time) [5; 10].

In the United States, the risk of HIV transmission in dental settings is extremely low. According to surveillance data from 1981 to 2013, a total of 58 cases of HIV seroconversion had been documented among healthcare personnel after occupational exposure to a known HIV-infected source, but none were among dental care personnel [12].

Certain factors affect the risk of HIV transmission after an occupational exposure. Laboratory studies have determined if needles that pass through latex gloves are solid rather than hollow-bore or are of small gauge (e.g., anesthetic needles), less blood is transferred. In a retrospective, case-control study of healthcare personnel, an increased risk for HIV infection was associated with exposure to a relatively large volume of blood, as with a deep injury with a device that was visibly contaminated with the patient's blood or a procedure that involved a needle placed in a vein or artery [12]. The risk was also increased if the exposure was to blood from patients with terminal illnesses, possibly reflecting the higher titer of HIV in patients with late-stage AIDS.

#### AEROSOLS, DROPLETS, AND SPLATTER

Aerosols, droplets (produced by the respiratory tract), and splatter contaminated with blood and bacteria are produced during many dental procedures. Devices such as dental handpieces, ultrasonic and sonic scalers, air polishers, air-water syringes, and air abrasion units produce visible aerosol clouds and possible airborne contamination. Splatter generated by dental procedures such as drilling is a primary risk for transmission of bloodborne pathogens. In general, because of their smaller size, aerosols pose the greatest risk for airborne infection [9].

Several studies have shown that airborne or droplet nuclei may extend up to 6 feet away from the source and can remain airborne for up to 30 minutes after a procedure. Tuberculosis (TB) is of special concern because it is a large particle that can remain airborne or can dry on a surface and become airborne again as part of a dust particle.

In 2024, the World Health Organization (WHO) and the Centers for Disease Control and Prevention from the United States, China, Europe, and Africa, published a global consensus of the terminology for pathogens that transmit through the air. Key changes include [8]:

• Any infected particles that are expelled from an individual through nose or mouth are referred to as "infectious respiratory particles" (IRPs).

- IRPs exist on a spectrum of sizes and should no longer be distinguished as "small" (aerosol) or "large" (droplet).
- The descriptor "through the air transmission" should be used to characterize any transmission that involves a pathogen moving through the air or being suspended in the air. Two further descriptors can be used:
- Airborne transmission or inhalation: IRPs are expelled into the air and inhaled by another person. This can occur at short or long distances, dependent on various factors (e.g., airflow, humidity, temperature, ventilation).
- Direct deposition: IRPs are expelled into the air and directly deposited on the exposed mouth, nose, or eyes of another person.

Due to the existing research and recommendations primarily using the terms and definitions of "aerosol" and "droplet," these terms will continue to be used throughout this course, unless otherwise noted.

The American Dental Association recommends that in addition to using Universal and Standard Precautions, such as masks, gloves, and eye protection, Transmission-Based Precautions, including the proper sterilization of instruments and treatment of dental unit waterlines is necessary to reduce or eliminate this source of potentially contaminated dental aerosols. Preprocedural rinsing with an antimicrobial mouthwash such as chlorhexidine is also recommended, although it is only effective for oral bacteria found in saliva and those adhering to mucous membranes. It does not penetrate subgingivally and likely has no effect on bacteria in the nasopharynx [5; 6].

Diseases known to spread by aerosols or droplet include:

- TB
- Pneumonic Yersinia pestis infection (plague)
- Influenza
- Legionellosis (Legionnaires disease)
- Measles
- Chickenpox
- Disseminated shingles
- Severe acute respiratory syndrome and coronavirus (SARS and COVID)

Procedures or equipment aimed at eliminating the means of transmission include [5; 6]:

- Universal preprocedural rinses
- Dental dams for certain procedures
- High-volume evacuator (HVE) at the treatment site (An HVE can only remove airborne contamination if it removes a large volume of air. A saliva ejector does not remove enough air to be classified as an HVE.)
- High-efficiency particulate arresting and ultraviolet filters in the ventilation system

- Disposable PPE discarded after each patient (e.g., gloves, masks, gowns)
- Cleaning, disinfection, and sterilization of equipment used by more than one patient
- Environmental cleaning and disinfection, especially of high-touch surfaces

#### FOMITE TRANSMISSION

Devices can transmit pathogens if they are contaminated with blood or bodily fluids or are shared without cleaning, disinfecting, and sterilizing between patients; these are classified as fomites. Surgical instruments that are inadequately cleaned between patients or that have manufacturing defects that interfere with the effectiveness of reprocessing may transmit bacterial, fungal, and viral pathogens. Clothing, uniforms, laboratory coats, or gowns used as PPE may become contaminated with potential pathogens after care of a patient colonized or infected with an infectious agent [5; 6; 10].

#### WATER TRANSMISSION

Dental water units and dental unit waterlines are both potential sources of transmission and potential reservoirs. Routine cleaning and sterilization and adherence to the CDC's recommended procedures for treating dental unit waterlines have been shown to be effective in eliminating transmission of infectious organisms via these devices. Infections known to be caused by dental-related water transmission include *Pseudomonas aeruginosa*, *Mycobacterium avium*, and *Legionella pneumophila* [5; 7].

#### STANDARD PRECAUTIONS

In 1986, California became the first state to pass a comprehensive bloodborne pathogen standard. The California standard provided a model for federal legislation, and in 1991, OSHA published its Bloodborne Pathogens Standard [3; 30]. Since then, regulatory and legislative activity has focused on implementing a hierarchy of prevention and control measures to improve infection control in healthcare settings.

The gradual acceptance of various infection prevention standards has changed the way we work in the provision of dental care. The DBC defines Standard Precautions as "a group of infection prevention practices that apply to all patients, regardless of suspected or confirmed infection status, in any setting in which healthcare is delivered" [9]. The DBC mandates that Standard Precautions must be practiced in the care of all patients, and all body fluids, except sweat, are considered potentially infectious [9]. The use of Standard Precautions reduces the risk of infection to staff and patients and ensures that the right precautions are used with both known and unknown carriers of diseases due to bloodborne pathogens. Standard Precautions apply to contact with blood, intact or nonintact skin, mucous membranes, and all bodily fluids, secretions, and excretions (except sweat), regardless of whether they contain blood. A central tenet of Standard Precautions is to consider

all patients to be potentially infected with a bloodborne pathogen. Saliva has always been considered a potentially infectious material in dental infection control; thus, no operational difference exists in clinical dental practice between Universal Precautions and Standard Precautions. For organisms other than bloodborne pathogens, early identification and prompt isolation are critical.

As noted, Standard Precautions are the minimum infection prevention practices that apply to all patient care, regardless of health or dental care setting, and include [5]:

- Utilization of effective hand hygiene
- Use of PPE (e.g., gloves, masks, eyewear)
- Respiratory hygiene, including cough/sneeze etiquette
- Sharps safety (engineering and work practice controls)
- Safe injection practices (aseptic technique)
- Cleaning, sterilization, and disinfection of instruments and devices
- Cleaning and disinfection of environmental surfaces

#### HAND HYGIENE

Despite the simplicity and effectiveness of hand hygiene in preventing the spread of infectious disease, adherence to hand hygiene practice remains low. Adherence varies among professional categories of healthcare workers but is usually estimated at less than 50%. Healthcare providers may be required to clean their hands as many as 100 times in a 12-hour shift, depending on the number of patients and intensity of care [14; 17]. For dental healthcare workers, strict adherence to proper hand hygiene is the most important prevention strategy to protect both the patient and the worker. In one study, adherence rates to hand hygiene among postgraduate-year dentists found that overall handwashing compliance rate was 34.7%, with higher rates of compliance noted in oral surgery services (92.8%) than during work in general clinical practice (34.2%) [13]. The World Health Organization has designed the guidelines 5 Moments for Hand Hygiene as a reminder of when proper hand hygiene should be completed [11]:

- 1. Before touching a patient
- 2. Before a procedure
- 3. After a procedure or exposure to body fluids
- 4. After touching a patient
- 5. After touching a patient's surroundings

In general, perform hand hygiene [14]:

- After contact with any bodily fluids, including your own
- Before any non-invasive or invasive procedure
- Each time you remove your gloves
- When your hands feel or look dirty
- After contact with contaminated things or environments, such as charts
- After handling used equipment or linen

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- After using the bathroom
- Before contact with any portal of entry, your patient's or your own
- Before and after eating

A number of conditions restrict DHCP from participating in direct patient care. These include weeping dermatitis, exudative lesions, or any hand condition that increases the risk of disease transmission [9].

Good handwashing is difficult to practice, is rarely known or taught, and is one of the single most effective ways to prevent transmission of many diseases, including influenza. Everyone knows to wash their hands before eating and after using the restroom. However, few do little more than remove obvious dirt. Good handwashing involves removing the skin oils where organisms can remain even when the hands look clean. A quick pass under the water faucet and fast dry with a towel may remove visible dirt, but the oils and organisms remain.

To effectively remove the oils and organisms, the process should take at least 20 seconds, or the amount of time it takes to sing "Twinkle, Twinkle Little Star." The hands should be soaped and rubbed vigorously for 15 seconds to create a good lather and to assure that all parts of each hand are soaped and rubbed well. Then, the hands should be rinsed thoroughly and dried, preferably with a paper towel. The towel should be used to turn off the water faucet and then properly thrown away. However, 20 seconds is a long time in the busy life of a healthcare provider, and this 20 seconds has been identified as a major barrier to handwashing, particularly among those who consider themselves "too busy" to wash their hands. If there is no visible dirt or contamination, a waterless hand sanitizer with at least 60% alcohol can be used between patients. However, nothing is as good as washing well with soap and water. Further, some organisms are not eliminated through the use of hand sanitizers alone (e.g., Clostridioides difficile spores). Hands should be thoroughly dried before donning gloves and washed again immediately after glove removal [9].

Some mistakenly think that hot water must be used to kill the organisms. Water hot enough to kill organisms would be too hot to touch. Warm water softens oils but mainly adds to comfort and encourages better washing technique (i.e., longer duration). Careful attention to handwashing and cleansing may result in chapped skin, so the dental professional must find effective lotions to care for his/her hands [14; 17].

Certain soaps contain stronger antiseptic compounds, such as chlorhexidine, and these soaps may be considered in cases in which exposure to potentially infectious material is likely. Antiseptic soaps or surgical preparation liquids have been found more effective than plain soap in removing bacteria from healthcare workers hands both pre- and postprocedure. In addition, antiseptics may be added to alcohol-based handrubs in order to achieve persistent germicidal activity. Possible side effects associated with frequent use of antiseptic hand scrubs include skin irritation, dermatitis, allergic reactions, and potential development of microbial resistances. Chlorhexidine products are considered safe for regular use in dental practice; however, if associated side effects are bothersome, they may result in decreased hand hygiene compliance [10; 14].

In summary, start and end each work day using an antibacterial soap. Gloves provide a breeding ground for microbial growth, and washing before and after use is encouraged. If hands are not visibly soiled, a waterless hand sanitizer (at least 60% alcohol) may be used. For surgical procedures, wash hands with antimicrobial soap prior to gowning and gloving [5].

#### PERSONAL PROTECTIVE EQUIPMENT

PPE is defined as special coverings designed to protect healthcare personnel from exposure to or contact with infectious agents [18]. Cal/OSHA regulations require use of PPE in dental care settings to protect personnel from exposure to bloodborne pathogens and other OPIM [9]. Under OSHA's General Duty Clause, PPE is also required for any potential infectious disease exposure. Employers must provide their employees with appropriate PPE and ensure its proper disposal. If reusable, it must be properly cleaned or laundered, repaired, and stored after use [19]. PPE must fit the individual user, and it is up to the employer to ensure that PPE is available in sizes appropriate for all their workers. Employees are prohibited from taking PPE home to launder.

In addition to the familiar gloves, masks, and gowns, PPE includes a variety of barriers and respirators used alone or in combination to protect skin, mucous membranes, and airways from contact with infectious agents. The selection of PPE is based on the nature of the patient/provider interaction and the likely mode of transmission. Primary PPE used in oral healthcare settings includes gloves, surgical masks, respiratory devices, protective eyewear, face shields, and protective shoes and clothing.

Procedures that can generate splashes or sprays of blood, bodily fluids, secretions, excretions, or chemical agents require either a face shield (disposable or reusable) or mask and goggles. The wearing of masks, eye protection, and face shields in specified circumstances (when blood or OPIM exposures are likely to occur) is mandated by the OSHA Bloodborne Pathogens Standard. Sterile barriers for invasive procedures and masks or respirators for the prevention of droplet contamination are also required [2].

The use of PPE is not a substitute for safe work practices. Avoid contaminating yourself by keeping your hands away from your face and not touching or adjusting equipment. PPE is a potential means of transmission if not changed between patients. All PPE should be removed when leaving patient care areas.

#### Gloves

DHCP should wear medical exam gloves to prevent contamination of their hands when touching mucous membranes, blood, saliva, or OPIM [9]. Gloves reduce the likelihood that micro-organisms present on the hands will be transmitted to patients during surgical or other patient-care procedures. Gloves used in the healthcare setting are subject to U.S. Food
and Drug Administration (FDA) evaluation and clearance. Nonsterile, disposable medical gloves made of latex or nitrile should be available for routine patient care. Dental personnel should always use gloves when [18]:

- Anticipating direct contact with blood or bodily fluids, mucous membranes, nonintact skin, and OPIM
- Engaging in direct contact with patients who are colonized or infected with pathogens transmitted by the contact route, such as vancomycin-resistant enterococci or methicillin-resistant *Staphylococcus aureus* (MRSA)
- Handling or touching visibly or potentially contaminated patient care equipment and environmental surfaces

Studies have repeatedly shown that vinyl gloves have higher failure rates than latex or nitrile gloves. For this reason, either latex or nitrile gloves are preferable for clinical procedures that require manual dexterity or those involving more than brief patient contact. Heavier, reusable utility gloves should be used for non-patient-care activities, such as handling or cleaning contaminated equipment or surfaces, handling chemicals, or disinfecting contaminated tools [9; 18].

During dental procedures, patient examination gloves commonly contact multiple types of chemicals and materials, such as disinfectants and antiseptics, composite resins, and bonding agents, and these materials can compromise the integrity of latex, nitrile, and other synthetic glove materials. In addition, latex gloves can interfere with the setting of vinyl polysiloxane impression materials. Given the diverse selection of dental materials on the market, dental practitioners should consult glove manufacturers regarding the chemical compatibility of glove materials [5; 18].

Wearing sterile surgeon's gloves during surgical procedures has a strong theoretical rationale. Sterile gloves minimize transmission of micro-organisms from the hands of surgical personnel to patients and prevent contamination of the hands of surgical personnel with the patient's blood and bodily fluids. In addition, sterile surgeon's gloves are more rigorously regulated by the FDA and may provide an increased level of protection for the provider if exposure to blood is likely [10; 18].

Gloves should be removed and replaced if torn or punctured and discarded between patients to prevent transmission of infectious material. They should never be washed and reused, as micro-organisms cannot be removed reliably from glove surfaces. Glove reuse has been associated with transmission of MRSA and gram-negative bacilli [9; 10].

When gloves are worn in combination with other PPE, they should be put on last. Gloves that fit snugly around the wrist are preferred for use with a gown because they will cover the gown cuff and provide a more reliable continuous barrier for the arms, wrists, and hands. Removing gloves properly also prevents hand contamination. Hand hygiene following glove removal ensures that the hands will not carry potentially infectious material that might have penetrated through unrecognized tears or contaminated the hands during glove removal. When processing contaminated sharp instruments, needles, and devices, heavy utility gloves should be used to prevent puncture injuries [10; 18].

When adhering to Standard Precautions, always [5]:

- Use good hand hygiene.
- Use gloves for contact with blood, bodily fluids, nonintact skin (including rashes), mucous membranes, used equipment, linens, and trash.
- Change gloves if they become heavily soiled when working on a patient or if you must go from a potentially more infective area to a lesser one.

In addition, never:

- Wear artificial fingernails.
- Touch a second patient with the same pair of gloves used on the first patient.
- Contaminate the environment with dirty gloves.
- Wear gloves outside the treatment area unless you can say why you are wearing them.

# Protective Clothing

Gowns are intended to protect the arms and exposed body areas and prevent contamination of clothing with blood, bodily fluids, and OPIM. The type of gown selected is based on the nature of the patient/provider interaction, including the anticipated degree of contact with infectious material and potential for blood and bodily fluid penetration of the barrier. General work clothes (e.g., uniforms, scrubs, laboratory coats, jackets) are not considered PPE. Dental personnel should change protective clothing when it becomes visibly soiled or as soon as possible if penetrated by blood or other possibly infectious fluid [18].

California regulations require that all DHCP wear reusable or disposable protective attire when their clothing or skin is likely to be exposed to aerosol spray or splashing or spattering of blood, OPIM, or chemicals and germicidal agents. Gowns must be changed daily or between patients if they become moist or visibly soiled. All PPE used during patient care shall be removed when leaving laboratories or areas of patient care activities. Reusable gowns should be laundered in accordance with Cal/OSHA Bloodborne Pathogens Standards. In addition, gowns should be worn for disinfection, sterilization, and housekeeping procedures involving the use of germicides or handling contaminated items [9].

# Masks, Protective Eyewear, and Face Shields

In California, DHCP are required to wear surgical masks that cover both the nose and mouth, in combination with either chin-length plastic face shields or protective eyewear when there is potential for splashing or spattering of blood, droplets, chemical, or germicidal agents, or OPIM. After each patient, masks should be changed and disposed of properly. After each

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patient treatment, face shields and protective eyewear shall be disposed or cleaned and disinfected [9; 18].

Masks should fit snugly and fully cover the nose and mouth to prevent fluid penetration. For this reason, masks that have a flexible nose piece and can be secured to the head with string ties or elastic are preferable. Surgical masks protect against micro-organisms generated by the wearer and also protect dental personnel from large-particle droplet spatter that might contain bloodborne pathogens or OPIM. If the mask becomes wet or contaminated, it should be changed between patients or even during patient treatment. For employees at increased risk of exposure to ATDs, such as those working in endemic areas (e.g., Southeast Asia) or in areas designated for isolation or quarantine, the employer must provide a respirator at least as effective as an N95 respirator.

Most surgical masks are not National Institute for Occupational Safety and Health (NIOSH)-certified as respirators, do not protect the user adequately from exposure to TB, and do not satisfy OSHA requirements for respiratory protection. However, certain surgical masks (i.e., N95 respirators) do meet the requirements and are certified by NIOSH. The level of protection a respirator provides is determined by the efficiency of the filter material for incoming air (e.g., 95% for N95) and how well the face piece fits or seals to the face. N95 respirators are required to be labeled as such on the device.

Respirators are used when treating patients with diseases requiring Airborne Precautions and should be used in the context of a complete respiratory protection program. This program should include training and fit testing to ensure an adequate seal between the edges of the respirator and the wearer's face.

Goggles with side shields provide barrier protection for the eyes and should fit snugly over and around the eyes or personal prescription lenses. Personal prescription lenses do not provide optimal eye protection and should not be used as a substitute for goggles. If goggles or face shields are reusable, they must be placed in a designated receptacle for subsequent reprocessing. If they are not reusable, they may be discarded in a designated waste receptacle.

Face shields extending from chin to crown provide better face and eye protection from splashes and sprays than goggles. Shields that wrap around the sides may reduce splashes around the edge. Removal of a face shield, goggles, and mask can be performed safely after gloves have been removed and hand hygiene performed. The ties, earpieces, or headband used to secure the equipment to the head are considered clean and therefore safe to touch with bare hands. The front of the face shield is considered contaminated [10; 18].

# **RESPIRATORY HYGIENE**

If dental clinics and offices comply with state regulations for screening of patients with ATDs, they are not required to comply with the new standards for prevention of transmission of ATDs [4]. However, because no screening process is universally effective, dental personnel should be aware of the potential dangers associated with transmission of pathogens via the airborne and droplet routes.

Respiratory droplets can transmit infection when they travel directly from the respiratory tract of the infected individual to the mucosal surfaces of the recipient, generally over short distances (i.e., 6 feet or less). Airborne transmission occurs with only a few organisms that can survive the drying of respiratory droplets. When the droplets evaporate, they leave behind droplet nuclei, which are so small they remain suspended in the air and can travel over longer distances. Respiratory droplets and droplet nuclei are generated when an infected person coughs, sneezes, or talks during procedures. Facial masks or shields generally provide direct protection from droplet transmission. Some pathogens transmitted via the airborne route (e.g., TB) require the use of an N95 respirator or better (e.g., N99, N100) due to the small particle size [5].

Measures to contain respiratory secretions in symptomatic patients and accompanying adults may include [5; 18]:

- Post signs to instruct patients with known or suspected respiratory infection to cover mouth and nose when sneezing or coughing, use and properly dispose of tissues, and wash hands after sneezing or coughing.
- Provide tissues and no-touch receptacles.
- Have handwashing stations or hand sanitizer available in waiting areas.
- Offer masks to patients and accompanying adults.
- Provide ample space in waiting areas, or consider placing symptomatic patients in a separate waiting area.

# ENGINEERING AND WORK PRACTICE CONTROLS (SHARPS SAFETY)

Most percutaneous injuries among DHCP involve scalers, burs, needles, wires, and sharp instruments. In 2000, the Federal Needlestick Safety and Prevention Act authorized OSHA to revise its Bloodborne Pathogens Standard to require the use of safety-engineered sharp devices in healthcare settings [2; 3; 16]. Guidelines on the design, implementation, and evaluation of a sharps injury prevention program have been developed by the CDC, and outline engineering controls and work practice controls as primary methods to prevent such occurrences. Engineering controls, such as sharps disposal containers, selfsheathing needles, and safer medical devices (e.g., sharps with engineered sharps injury protections and needleless systems) isolate or remove the bloodborne pathogens hazard from the workplace. On the other hand, work practice controls reduce the likelihood of exposure by specifying the manner in which a task is performed (e.g., prohibiting recapping of needles by a two-handed technique).

Engineering and work practice controls are intended to work synergistically to eliminate or minimize employee exposure. These controls must be examined and maintained or replaced on a regular basis to ensure their effectiveness. To maintain a safe workplace, employers must provide handwashing facilities that are readily accessible to employees.

Contaminated needles and other contaminated sharps should not be bent, recapped, or removed unless the employer can demonstrate that there is no alternative or that such action is required by a specific procedure. Necessary bending, recapping, or needle removal must be accomplished through the use of a mechanical device or a one-handed scoop technique. Shearing or breaking of contaminated needles is prohibited. Immediately, or as soon as possible after use, contaminated reusable sharps (e.g., scalpels, dental knives) must be placed in appropriate containers until properly reprocessed. These containers must be [9; 10]:

- Puncture resistant
- Labeled or color-coded
- Leak-proof on the sides and bottom
- Maintained in accordance with OSHA requirements for reusable sharps
- Designed so personnel are not required to reach by hand into the container
- Located as close as possible to the point of use

# SAFE INJECTION PRACTICES (ASEPTIC TECHNIQUE)

Safe injection practices are designed to prevent disease transmission within the healthcare setting. The absence of visible blood or other signs of contamination in a used syringe does not mean the item is free from potentially infectious agents. Bacteria and other microbes can be present without any visible evidence of contamination. All used injection supplies and materials should be considered potentially contaminated and should be discarded.

To ensure safe injection practices, use aseptic technique throughout all aspects of injection preparation and administration. Aseptic technique involves the handling, preparation, and storage of medications in a manner that prevents microbial contamination. It also applies to the handling of all supplies used for injections and infusions. To avoid contamination, medications should be drawn in a clean medication preparation area. Any item that may have come in contact with blood or OPIM should be kept separate from medications. In addition, eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses are prohibited in work areas where there is a reasonable likelihood of occupational exposure. Food and drink should not be kept in refrigerators, freezers, shelves, or cabinets or on countertops where blood or OPIM is present.

A new, sterile syringe and needle should be used to draw up medications while preventing contact between the injection materials and the nonsterile environment. Practice proper hand hygiene before handling medications, and discard medication vials upon expiration or any time there are concerns regarding the sterility of the medication [5]. Never leave a needle or other device inserted into a vial or bottle for multiple uses. This provides a direct route for micro-organisms to enter the vial and contaminate the fluid. Medications should never be combined between vials or administered from the same syringe to more than one patient, even if the needle is changed. Multidose vials should be used on a single patient whenever possible and should never enter the immediate patient treatment area [5].

Dental personnel should follow proper technique when using and handling needles, cannulae, and syringes. Whenever possible, use sharps with engineered sharps injury protections (e.g., non-needle or needle devices with built-in safety features or mechanisms that effectively reduce the risk of an exposure incident). Do not disable or circumvent the safety feature on devices [5].

Cases of bloodborne pathogen transmission as a result of improper injection practices have common themes. Often, aseptic technique and Standard Precautions were not carefully followed. Infection control programs may be lacking or responsibilities unclear. In several instances, failure to recognize an infection control breach has led to prolonged transmission and a growing number of infected patients. In all cases, investigations were time-consuming and costly and required the notification, testing, and counseling of hundreds and sometimes thousands of patients [5; 16].

# STERILIZATION AND DISINFECTION OF PATIENT-CARE ITEMS AND DEVICES

Application of accepted infection control principles helps maintain a safe environment for both patients and dental care workers. This includes proper use of Standard Precautions and application of approved techniques for cleaning, disinfection, sterilization, and reprocessing of dental equipment. Healthcare policies must identify—primarily on the basis of an item's intended use—whether cleaning and disinfection or sterilization is indicated (*Table 2*) [9; 10; 21].

Cleaning is defined as the removal of visible soil (organic and inorganic material) debris and OPIM from objects and surfaces; normally, it is accomplished manually or mechanically using water with detergents or enzymatic products [9]. Cleaning must precede any disinfection or sterilization process.

Decontamination reduces the number of pathogenic microorganisms on objects, usually with a 0.5% chlorine solution [21]. Thorough cleaning and decontamination are essential before high-level disinfection and sterilization because inorganic and organic materials that remain on the surfaces of instruments interfere with the effectiveness of these processes.

Disinfection is a process that eliminates many or all pathogenic micro-organisms, except bacterial spores, on inanimate objects. In healthcare settings, objects are usually disinfected using liquid chemicals or wet pasteurization (i.e., the use of hot water to destroy micro-organisms). There are three levels of disinfection [9; 10]:

Process Result	Method			METHODS FOR STERILIZING AND DISINFECTING PATIENT-CARE ITEMS AND ENVIRONMENTAL SURFACES				
		Examples	Patient Care Items	Environmental Surfaces				
Sterilization Destroys all forms of viable micro-organism	Heat-automated, high temperature s,	Steam, dry heat, unsaturated chemical vapor	Heat-tolerant critical and semicritical	NA				
including bacte spores.	rial Heat-automated, low temperature	Ethylene oxide gas, plasma sterilization	Heat-sensitive critical and semicritical					
	Liquid immersion <sup>a</sup>	Glutaraldehyde, glutaraldehydes with phenols, hydrogen peroxide, hydrogen peroxide with peracetic acid, peracetic acid						
High-level Destroys all mi	cro- Heat-automated	Washer disinfector	Heat-sensitive semicritical	NA				
disinfection organisms, but not necessarily high numbers of bacterial spores	Liquid immersion <sup>a</sup> of	Glutaraldehyde, glutaraldehydes with phenols, hydrogen peroxide, hydrogen peroxide with peracetic acid, ortho-phthalaldehyde						
Intermediate- level Destroys vegeta disinfection most fungi and viruses. Inactive Mycobacterium bovis <sup>b</sup> . Not necessarily capable of killin bacterial spores	tive Liquid contact ntes ng	EPA-registered hospital disinfectant with label claim of tuberculocidal activity (e.g., chlorine-containing products, quaternary ammonium compounds with alcohol, phenolics, bromides, iodophors, EPA-registered chlorine-based product)	Noncritical with visible blood	Clinical contact surfaces, blood spills on housekeeping surfaces				
Low-level Destroys most disinfection vegetative bacte and certain fun and viruses. Do not inactivate Mycobacterium b	ria gi jes ovis.	EPA-registered hospital disinfectant with no label claim regarding tuberculocidal activity. OSHA also requires label claim of HIV and HBV potency for use of low-level disinfectant for use on clinical contact surfaces (e.g., quaternary ammonium compounds, some phenolics, some iodophors)	Noncritical without visible blood	Clinical contact surfaces, housekeeping surfaces				
<sup>a</sup> Contact time is the single critica with FDA-cleared liquid chemical	l variable distinguishing th sterilants. High-level disin	e sterilization process from high-lev fection uses shorter submersion ti	vel disinfection mes.					
<sup>o</sup> Inactivation of the more resistan	t Mycobacterium bovis is use	d as a benchmark to measure germ	iicidal potency.	T11.2				

Table 2

- High-level disinfection: Used to disinfect patientcare equipment that touches mucous membranes or blood.
- Intermediate-level disinfection: Used mainly to disinfect items that have contact with intact skin, but is appropriate for certain semicritical items (e.g., chair arms).
- Low-level disinfection: Used to disinfect the healthcare environment or items that touch intact skin.

Surface disinfection is an important part of environmental cleaning. Most bacteria and mycobacteria (e.g., TB) survive for several months on dry surfaces [20]. Respiratory viruses, such as coxsackie or influenza, can persist on surfaces for a few days. Hepatitis viruses and HIV can persist for more than one week, and herpes viruses have been shown to persist from only a few hours up to seven days [20]. All surfaces in patient care areas should be cleaned then disinfected according to the manufacturer's instructions and allowed to dry completely.

Sterilization is a process that destroys or eliminates all forms of microbial life and is carried out in healthcare facilities by physical or chemical methods. Sterile and nonsterile are absolute concepts. If a sterile item is touched by anything nonsterile, the formerly sterile item is contaminated.

The sterilization area should be separate from any patient care or staff break areas. The sterilization section of the processing area should include the sterilizers and related supplies, with adequate space for loading, unloading, and cool down [10]. The area can also include incubators for analyzing spore tests and enclosed storage for sterile items and single-use items. Manufacturer and local building code specifications will determine placement and room ventilation requirements.

According to the CDC guideline, heat-tolerant dental instruments usually are sterilized by steam under pressure (autoclaving), dry heat, or unsaturated chemical vapor [10]. All sterilization should be performed by using medical sterilization equipment cleared by the FDA. The sterilization times, temperatures, and other operating parameters recommended by the manufacturer of the equipment used, as well as instructions for correct use of containers, wraps, and chemical or biological indicators, should always be followed [10]. Sterilization most often fails due to overloading.

Devices being sterilized should first be cleaned, as debris interferes with the sterilization process. If an ultrasonic unit is utilized, it should be covered while actively in use. Instruments should be fully dry prior to packaging and storage.

Storage practices for wrapped sterilized instruments can be either date- or event-related. Packages containing sterile supplies should be inspected before use to verify barrier integrity and dryness. Although some facilities continue to date every sterilized package and use shelf-life practices, other facilities have switched to event-related practices [10]. This approach recognizes that the product should remain sterile indefinitely, unless an event causes it to become contaminated (e.g., torn or wet packaging). Even for event-related packaging, the date of sterilization should be placed on the package, and if multiple sterilizers are used in the facility, the sterilizer used should be indicated on the outside of the packaging material to facilitate the retrieval of processed items in the event of a sterilization failure [10]. If packaging is compromised, the instruments should be re-cleaned, sterilized again, and packaged in new wrap.

# **Categorizing Patient-Care Items**

Patient-care items (e.g., dental instruments, devices, and equipment) are categorized using the Spaulding classification system as critical, semicritical, or noncritical, depending on the potential risk for infection associated with their intended use.

Critical items are those items that enter sterile spaces, such as soft tissue or bone, or items that come into contact with the bloodstream. These items pose the greatest risk of transmitting infection and require sterilization. Examples of critical dental instruments include surgical instruments, periodontal scalers, scalpel blades, and surgical dental burs [9; 10]. Critical instruments, items, and devices should be discarded or pre-cleaned, packaged or wrapped, and sterilized after each use. Methods of sterilization include steam under pressure (autoclaving), chemical vapor, and dry heat. If a critical item is heat-sensitive, it should, at minimum, be processed with high-level disinfection and packaged or wrapped after disinfection. These instruments, items, and devices shall remain sealed and stored in a manner so as to prevent contamination and shall be labeled with the date of sterilization and the specific sterilizer used if more than one sterilizer is utilized in the facility [9].

Semicritical items touch intact mucous membranes or nonintact skin and have a lower risk of transmission. Examples of semicritical dental instruments include mouth mirrors, amalgam condensers, reusable dental impression trays, and dental handpieces. Because the majority of semicritical items in dentistry are heat-tolerant, they should be sterilized using heat. If a semicritical item is heat-sensitive, it should, at a minimum, be processed with high-level disinfection, which kills all microbial life except spores [9; 10; 21]. Semi-critical instruments, items, and devices should be pre-cleaned, packaged or wrapped, and sterilized after each use. Methods of sterilization include autoclaving, chemical vapor, and dry heat. If a semi-critical item is heat sensitive, it should, at minimum, be processed with high-level disinfection and packaged or wrapped upon completion of the disinfection process. These packages or containers shall remain sealed, shall be stored in a manner so as to prevent contamination, and shall be labeled with the date of sterilization and the specific sterilizer used if more than one sterilizer is utilized in the facility [9].

Noncritical items pose the least risk of transmission of infection and include devices, equipment, and surfaces that come in contact with soil, debris, saliva, blood, OPIM, and intact skin, but not mucous membranes [9]. Noncritical items include radiograph heads/cones, blood pressure cuffs, facebows, and pulse oximeters. In the majority of cases, cleaning and disinfection with a California Environmental Protection Agency (CalEPA)-registered hospital low-level disinfectant labeled effective against HBV and HIV is adequate. When the item is visibly contaminated with blood or OPIM, a CalEPA-registered hospital intermediate-level disinfectant with a tuberculocidal claim (i.e., intermediate-level disinfectant) should be used [9; 10].

High-speed dental hand pieces, low-speed hand pieces, rotary components and dental unit attachments (e.g., reusable air or water syringe tips and ultrasonic scaler tips) shall be packaged and heat-sterilized in a manner consistent with the same sterilization practices as a semi-critical instrument or item [9]. Single-use disposable items such as prophylaxis angles, cups, brushes, tips for high-speed evacuators, saliva ejectors, air and water syringe tips, and gloves must be used for one patient only and discarded. California requires proper functioning of the sterilization cycle of all sterilization devices be verified at least weekly through the use of a biologic indicator (such as a spore testing monitor). Test results should be documented and maintained for 12 months [9]. Studies have demonstrated variability among dental practices in meeting sterilization

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standards. In one study, 49% of respondents did not challenge autoclaves with biological indicators. Other studies using biologic indicators found a high proportion (15% to 65%) of positive spore tests after assessing the efficacy of sterilizers used in dental offices [21].

# Laboratory Areas

According to California regulations, splash shields and equipment guards should be used on dental laboratory lathes. Fresh pumice and a sterilized or new ragwheel should be used for each patient. Devices used to polish, trim, or adjust contaminated intraoral devices must be disinfected or sterilized and stored in a manner so as to prevent contamination [9].

All intraoral items, such as impressions, bite registrations, and prosthetic or orthodontic appliances, must be cleaned and disinfected with an intermediate-level disinfectant before manipulation in the laboratory and before placement in the patient's mouth. Such items should be thoroughly rinsed prior to placement in the patient's mouth [9].

# Reprocessing Reusable Medical Equipment

Reusable instruments, medical devices, and equipment should be managed and reprocessed according to recommended and appropriate methods. Industry guidelines as well as equipment and chemical manufacturer recommendations should be used to develop and update reprocessing policies and procedures. Written instructions should be available for each instrument, medical device, and equipment reprocessed. The FDA has issued guidance on ensuring the safety of reusable medical devices [23].

All procedures involving blood or OPIM must be performed in such a manner as to minimize splashing, spraying, spattering, and generation of droplets of these substances. Splatter shields should be used on medical equipment associated with risk-prone procedures.

Equipment that may become contaminated with blood or OPIM must be examined before servicing or shipping and should be decontaminated as necessary, unless the employer can demonstrate that decontamination of such equipment or portions of such equipment is not feasible. A readily observable label should be attached to the equipment stating which portions remain contaminated. The employer must ensure that this information is conveyed to all affected employees, the servicing representative, and the manufacturer before handling, servicing, or shipping, so appropriate precautions may be taken.

# Single-Use Devices

A single-use device is a device that is intended for use on a single patient during a single procedure. An unused single-use device is referred to as an original device. A reprocessed single-use device is an original device that has previously been used on a patient and has been subjected to additional processing and manufacturing for the purpose of an additional single use on a patient [22].

# Dental Unit Waterlines, Biofilm, and Water Quality

Studies have shown that dental unit waterlines, such as narrow-bore plastic tubing that carries water to high-speed handpieces, air/water syringes, and ultrasonic scalers, can become colonized with micro-organisms, including bacteria, fungi, and protozoa. Protected by a polysaccharide layer known as a glycocalyx, these micro-organisms colonize and replicate on the interior surfaces of the tubing and form a biofilm. This biofilm serves as a reservoir that can increase the number of micro-organisms in the water used during dental treatment [10].

California regulations require that dental unit water lines be anti-retractive, to prevent patient material, such as oral microorganisms, blood, and saliva, from entering a dental water system during treatment. These dental unit lines and devices should be purged with air or flushed with water at the beginning of the clinic day for at least two minutes prior to attaching handpieces, scalers, air water syringe tips, or other devices [9]. The dental unit lines and devices should be flushed between each patient for a minimum of 20 seconds [9]. Commercial devices and procedures shown to improve the quality of water used in dental treatment include self-contained water systems with chemical treatment, in-line microfilters, and combinations of these treatments. Simply using tap, distilled, or sterile water will not eliminate bacterial contamination in treatment water if biofilms in the system are not controlled. Microbial load should be less than or equal to 500 colony-forming units of heterotrophic bacteria per milliliter (≤500 CFU/mL) of water, the standard set for drinking water by the EPA [7]. Removal or inactivation of dental waterline biofilms requires use of chemical germicides. California law defines "germicide" as a chemical agent that can be used to disinfect items and surfaces based on the level of contamination. All germicides must be used in accordance with intended use and label instructions [9].

Regarding irrigation, if a surgical procedure involves soft tissue or bone, California regulations require the use of sterile coolants or irrigants, delivered using a sterile delivery system [9]. In addition, a new infection control standard that took effect in 2019, requires that water or other methods for irrigation must be sterile or contain recognized disinfecting or antibacterial properties when performing procedures on exposed dental pulp. Appropriate oral irrigants include chlorhexidine, BioPure MTAD, and sodium hypochlorite [33]. This requirement was in response to a 2016 outbreak of mycobacterial infection from a Southern California dental clinic that led to the hospitalization of more than 60 children. The cause was determined to be bacteria introduced through water during pulpotomies [33].

### CLEANING AND DISINFECTION OF ENVIRONMENTAL SURFACES

As discussed, contaminated surfaces and objects can serve as the means of transmission for potential pathogens. The transfer of a micro-organism from an environmental surface to a patient is largely via hand contact with the surface. Although hand hygiene is important to minimize the impact of this transfer, cleaning and disinfecting environmental surfaces is fundamental in reducing their potential contribution to the incidence of infections [10].

All work areas, including contact surfaces and barriers, must be maintained in a clean and sanitary condition. Employers are required to determine and implement a written schedule for cleaning and disinfection based on the location, type of surface to be cleaned, type of soil present, and tasks or procedures being performed. All equipment and environmental and working surfaces must be properly cleaned and disinfected after contact with blood or OPIM.

If non-critical items or surfaces likely to be contaminated are manufactured in a manner preventing cleaning and disinfection, they should be protected with disposable impervious barriers. Disposable barriers should be changed when visibly soiled or damaged and between patients. Products used to clean items or surfaces prior to disinfection procedures shall be clearly labeled and follow all material safety data sheet (MSDS) handling and storage instructions. Clean and disinfect all clinical contact surfaces that are not protected by impervious barriers using a CalEPA-registered, hospital grade low- to intermediate-level disinfectant after each patient. The low-level disinfectants used must be labeled effective against hepatitis B virus and HIV. Use disinfectants in accordance with the manufacturer's instructions. Clean all housekeeping surfaces (e.g., floors, walls, sinks) with a detergent and water or a CalEPA-registered, hospital-grade disinfectant. Chemicalresistant utility gloves should be worn when handling hazardous chemicals [9].

#### Medical Waste Management

Federal, state, and local guidelines and regulations specify the categories of medical waste subject to regulation and outline the requirements associated with treatment and disposal [9]. Regulated medical waste is defined as [10]:

- Liquid or semi-liquid blood or OPIM
- Contaminated items that would release blood or OPIM in a liquid or semi-liquid state if compressed
- Items that are caked with dried blood or OPIM capable of releasing these materials during handling
- Contaminated sharps (e.g., needles, burs, scalpel blades, endodontic files)
- Pathologic and microbiologic wastes containing blood or OPIM

Regulated medical waste accounts for only 9% to 15% of total waste in hospitals and 1% to 2% of total waste in dental offices [10]. Examples of regulated waste found in dental practice settings are solid waste soaked or saturated with blood or saliva (e.g., gauze saturated with blood after surgery), extracted teeth, surgically removed hard and soft tissues, and contaminated sharp items, such as needles, scalpel blades, and wires [10]. General medical waste, including used gloves, masks, gowns, and lightly soiled gauze or cotton rolls, may be disposed of with ordinary waste.

Regulated medical waste requires careful disposal and containment before collection and consolidation for treatment. A single, leak-resistant biohazard bag is usually adequate for containment of regulated medical wastes, provided the bag is sturdy and the waste can be discarded without contaminating the bag's exterior. Contamination or puncturing of the bag requires placement into a second biohazard bag. All bags should be securely closed for disposal.

Medical waste requiring storage should be kept in labeled, leak-proof, puncture-resistant containers under conditions that minimize or prevent foul odors. The storage area should be well-ventilated and inaccessible to pests. Any facility that generates regulated medical waste should have a regulated medical waste management plan to ensure health and environmental safety in accordance with federal, state, and local regulations [10; 21].

# TRANSMISSION-BASED PRECAUTIONS

As discussed, Transmission-Based Precautions are used in addition to Standard Precautions for patients that require additional precautions to prevent infection transmission. The three categories of Transmission-Based Precautions are Contact, Droplet, and Airborne Precautions; these categories may overlap, and more than one category may be used at a time [25].

### CONTACT PRECAUTIONS

Contact Precautions are utilized for patients with known or suspected infections that represent an increased risk for contact transmission. Contact Precautions require that practitioners [24]:

- Ensure appropriate patient placement to lessen risk for other patients or employees.
- Use PPE appropriately, including gloves and a gown. Donning PPE upon room entry and properly discarding before exiting the patient room is recommended to contain pathogens.
- Use disposable or dedicated patient-care equipment such as blood pressure cuffs. If common equipment must be used for multiple patients, thoroughly clean and disinfect.
- Prioritize cleaning and disinfection of patient rooms and contact surfaces, focusing on frequently touched surfaces and equipment and objects in the immediate vicinity of the patient.

#### DROPLET PRECAUTIONS

Use Droplet Precautions for patients that are known or suspected to be infected with pathogens transmitted by respiratory droplets. Droplet Precautions requires that one [24]:

• Source control by putting a mask on the patient to prevent respiratory droplets from spreading.

- Ensure appropriate patient placement to lessen risk for other patients or employees.
- Use PPE appropriately, including gloves and a gown. Donning PPE upon rom entry and properly discarding before exiting the patient room is recommended to contain pathogens.
- Limit transport and movement of patients outside of the room, and if movement is necessary, instruct patient to wear a mask and follow Respiratory Hygiene/Cough Etiquette.

# AIRBORNE PRECAUTIONS

Airborne Precautions are used when patients are known or suspected to be infected with pathogens transmitted by airborne or aerosol route. Airborne pathogens include TB, measles, chickenpox, and herpes zoster. Airborne Precautions require [24]:

- Source control by putting a mask on the patient to prevent respiratory droplets from spreading.
- Ensure appropriate patient placement in an airborne infection isolation room (AIIR) constructed according to the CDC's Guideline for Isolation Precautions. In settings where Airborne Precautions cannot be implemented due to limited engineering resources, masking the patient and placing the patient in a private room with the door closed will reduce the likelihood of airborne transmission until the patient is either transferred to a facility with an AIIR or returned home.
- Restrict susceptible healthcare personnel from entering the room of patients known or suspected to have measles, chickenpox, disseminated zoster, or smallpox if other immune healthcare personnel are available.
- Use PPE appropriately, including a fit-tested NIOSHapproved N95 or higher level respirator for healthcare personnel.
- Limit transport and movement of patients outside of the room, and if movement is necessary, instruct patient to wear a surgical mask and observe Respiratory Hygiene/Cough Etiquette. Healthcare personnel transporting patients who are on Airborne Precautions do not need to wear a mask or respirator during transport if the patient is wearing a mask and infectious skin lesions are covered.
- Immunize susceptible persons as soon as possible following unprotected contact with vaccine-preventable infections (e.g., measles, varicella or smallpox).

# PROTECTING DENTAL HEALTHCARE WORKERS

Protecting DHCP is an integral part of every dental organization's general program for infection prevention and control. The objectives usually include [5]:

- Educating personnel about the principles of infection control and emphasizing individual responsibility
- Providing care to personnel for work-related illnesses or exposures
- Identifying work-related infection risks and implementing appropriate preventive measures
- Containing costs by preventing infectious diseases that result in absenteeism and disability

# OCCUPATIONAL EXPOSURES

An occupational exposure is defined as a percutaneous injury or contact of mucous membrane or nonintact skin with blood, tissue, or OPIM, most commonly a needlestick injury. The risk of infection depends on several factors, including [27]:

- Whether the exposure was from a hollow-bore needle or other sharp instrument
- Whether the exposure was to non-intact skin or mucous membranes
- The amount of blood involved
- The amount of contagion present in the source person's blood

If a sharps injury occurs, wash the exposed area with soap and water. Do not "milk" or squeeze the wound. There is no evidence that using antiseptics will reduce the risk of transmission for any bloodborne pathogens; however, the use of antiseptics is not contraindicated. In the event that the wound needs suturing, emergency treatment should be obtained. The risk of contracting HIV from this type of exposure is extremely rare. There are no documented cases of a dental healthcare professional contracting HIV from an occupational exposure.

OSHA requires dental employers of an individual with an occupational exposure to a bloodborne pathogen to arrange a confidential medical evaluation and follow-up for any employee reporting an exposure incident [3]. An exposure incident is any eye, mouth, mucous membrane, nonintact skin, or other parenteral contact with blood or OPIM. Saliva in dental procedures is treated as potentially infectious material.

Following an exposure, the dental employer must refer the exposed employee to a licensed healthcare professional who can provide information and counseling and discuss how to prevent further spread of a potential infection. The exposed employee is entitled to appropriate follow-up and evaluation of any reported illness to determine if the symptoms may be related to HIV or hepatitis B or C infection [27].

Prompt response is necessary whenever an occupational exposure occurs. If possible, the patient should be interviewed to determine if any risk factors or bloodborne pathogens not previously disclosed are present. The patient may be tested along with the employee, if he or she agrees, in order to obtain the most information possible. Testing and postexposure prophylaxis may be conducted at an occupational injury clinic. All events leading up to and after the exposure should be documented in a written report [27].

### Postexposure Prophylaxis

Postexposure prophylaxis (PEP) involves the provision of medications to someone who has had a substantial exposure, usually to blood, in order to reduce the likelihood of infection. PEP is available for HIV and hepatitis B virus. Although there is no PEP recommended for hepatitis C virus, limited data indicate that antiviral therapy might be beneficial when started early in the course of infection [28]. For employees who have not received the hepatitis B vaccine series, the vaccine (and in some circumstances hepatitis B immunoglobulin) should be offered as soon as possible (within seven days) after the exposure incident. The effectiveness of hepatitis B immunoglobulin administered more than seven days after exposure is unknown. PEP has been the standard of care for healthcare providers with substantial occupational exposures since 1996 and must be provided in accordance with the recommendations of the U.S. Public Health Service [28].

# TUBERCULOSIS PREVENTION

California has one of the highest incidence rates of TB in the country, primarily because of its large population of persons born outside of the United States [31]. In 2023, the TB infection rate in California was 13 times higher among non-U.S.-born individuals than among those born in the United States. The rates of TB among Asian and Black individuals born outside the United States were 43 and 28 times higher, respectively, than that of U.S.-born White persons [31].

To prevent the transmission of Mycobacterium tuberculosis in dental care settings, infection-control policies should be developed based on the community TB risk assessment and reviewed annually. The policies should include appropriate screening for latent or active TB disease in dental care providers, education about the risk for TB transmission, and provisions for detection and management of patients who have suspected or confirmed TB disease.

The CDC recommends that all dental care providers be screened for TB upon hire, using either a tuberculin skin test or blood test [10]. The California Department of Public Health recommends an initial skin or blood test; positive reactions or results should be followed up by chest x-ray. Annual testing thereafter is recommended for dental personnel, although local and/or employer policies and methods of testing (e.g., questionnaire or skin or blood test) may differ [32]. Patients with symptoms of TB should be identified by screening; dental treatment should be deferred until active TB has been ruled out or the patient is no longer infectious following treatment. The potentially active TB patient should be promptly referred to an appropriate medical setting for evaluation of possible infectiousness and should be kept in the dental care setting only long enough to arrange for referral. Standard Precautions are not sufficient to prevent transmission of active TB [24].

A diagnosis of active respiratory TB should be considered for any patient with the following symptoms:

- Coughing for more than three weeks
- Loss of appetite
- Unexplained weight loss
- Night sweats
- Bloody sputum or hemoptysis
- Hoarseness
- Fever
- Fatigue
- Chest pain

A person with latent TB (positive skin test and no symptoms) can be treated in a dental office using standard infection control precautions [26]. This person has no symptoms and cannot transmit TB to others as there are no spores in his or her sputum.

The American Dental Association recommends that all patients be asked about any history of TB or exposure to TB, including signs and symptoms and medical conditions that increase their risk for TB disease. The Health History Form, developed by the U.S. Department of Health and Human Services, can be used to ask these questions.

If a patient with suspected or confirmed infectious TB disease requires urgent dental care, that care should be provided in a setting that meets the requirements for California ATD standards and airborne infection isolation. Respiratory protection (with a fitted N95 disposable respirator) should be used while performing procedures on such patients. Standard surgical masks are not designed to protect against TB transmission [4; 26].

# VACCINATION

Due to increased risk of occupational exposure, the CDC strongly recommends that all healthcare workers, including dental care providers, receive immunizations as a preventive measure. While these are the recommendations from the CDC, state and local legislation and workplace regulations may or may not require these immunizations.

# Hepatitis B

Cal/OSHA guidelines require that healthcare workers who perform tasks that may involve exposure to blood or bodily fluids must have hepatitis B vaccination made available to them within 10 working days of initial assignment. The employee must also be given free information about the efficacy, safety, and benefits of vaccination [30].

The hepatitis B vaccine is given in a series of three injections at 0, 1, and 6 months. If one of the injections is missed, the series does not need to be restarted. The CDC recommends if the series is interrupted, the second or third dose should be administered as soon as possible; the second and third doses should be separated by an interval of at least eight weeks [24]. No booster is necessary. Follow-up serologic testing two months after vaccination (to ensure efficacy) is recommended. The provision of employer-supplied hepatitis B vaccination may be delayed until after probable exposure for employees whose sole exposure risk is the provision of first aid.

The high risk of hepatitis B virus exposure among healthcare personnel makes it imperative that clinical dental personnel be vaccinated. Vaccination can protect both workers and patients from hepatitis B virus infection and, whenever possible, should be completed when dentists or other dental care personnel are in training [10].

# Influenza

Influenza is primarily transmitted from person to person via large, virus-laden droplets generated when infected persons cough or sneeze. These large droplets can settle on the mucosal surfaces of the upper respiratory tracts of susceptible persons who are within 3 feet of infected persons. Transmission may also occur through direct contact or indirect contact with respiratory secretions, such as when touching surfaces contaminated with influenza virus and then touching the eyes, nose, or mouth. The CDC strongly recommends that all healthcare personnel, especially those who have contact with patients at high risk, who have high-risk medical conditions, or who are older than 50 years of age, receive an annual (seasonal) influenza vaccination [24].

# Measles, Mumps, and Rubella (MMR)

Vaccination for measles, mumps, and rubella is typically given in a single combination vaccine. The CDC notes that, regardless of birth year, individuals should receive two doses of measles, two doses of mumps, and one dose of rubella live-virus vaccine to be considered protected. MMR is given in a series of two injections, at least 28 days apart. Because the vaccine is often combination, most individuals will receive two doses of rubella-containing vaccine, with no adverse effect [24].

# Tetanus and Diphtheria (Toxoids) and Acellular Pertussis (Tdap)

Vaccination for tetanus is recommended for all DHCP, regardless of age. The CDC recommends receiving the vaccine as soon as feasible if Tdap has not already been received, and regardless of interval from the last tetanus and diphtheria (Td) immunization. Routine boosters are recommended every 10 years thereafter [24].

# Varicella

The varicella-zoster virus is responsible for chickenpox and shingles. The CDC recommends the varicella-zoster vaccine for all DHCP who do not have evidence of immunity, defined as: written documentation of two doses of varicella vaccine; laboratory evidence of immunity or confirmation of disease; diagnosis or verification of acute disease by a health-care provider; or diagnosis or verification of herpes zoster by a health-care provider; While the varicella vaccine is recommended, the CDC does note that serologic testing before vaccination is likely to be cost-effective, as 71% to 93% of adults without a history of varicella are immune [24]. Immunization is considered complete after a series of two doses, spaced four to eight weeks apart [24].

# TRAINING AND EDUCATION

Dental personnel should also fulfill all federal and state requirements for infection control training. New employees, or employees being transferred into jobs involving tasks or activities with potential exposure to blood or OPIM, must receive bloodborne pathogen training before assignment to tasks in which an occupational exposure may occur. Retraining is required annually or when changes in procedures or tasks affecting occupational exposure occur. Employees should be provided access to a qualified trainer to answer questions during the training session [9; 10].

# CONCLUSION

Effective infection control techniques are critical to reducing the incidence of infections in dental facilities. Antiseptic techniques and antibiotics will kill micro-organisms, while proper hand hygiene will block their transmission. Gloves, gowns, and masks remove DHCP from the transmission cycle by protecting them from contact with micro-organisms. Transmission-Based Precautions and isolation techniques help patients avoid being vectors of transmission. Engineering controls help to make the workplace safer, while administrative controls ensure that written protocols are in place and followed. Lastly, ensuring that all DHCP are immune or vaccinated can help decrease the availability of potential hosts.

# DENTAL BOARD OF CALIFORNIA GENERAL PROVISIONS: SECTION 1005. MINIMUM STANDARDS FOR INFECTION CONTROL

The Dental Board of California General Provisions: Section 1005. Minimum Standards for Infection Control is available online at https://govt.westlaw.com/calregs/Document/IDB85BD734C8111EC89E5000D3A7C4BC3.

Customer Information/Answer Sheet/Evaluation insert located between pages 68-69.

# #58584 Infection Control for Dental Professionals: The California Requirement

# COURSE TEST - #58584 INFECTION CONTROL FOR DENTAL PROFESSIONALS: THE CALIFORNIA REQUIREMENT

This is an open book test. Please record your responses on the Answer Sheet. A passing grade of at least 70% must be achieved in order to receive credit for this course.

# This 2 CE Credit Hour activity must be completed by January 31, 2028.

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AGD SUBJECT CODE: 148.

This course meets the Dental Board of California's requirements for 2 units of continuing education. Dental Board of California course #02-3841-00452.

- 1. The California Division of Occupational Safety and Health (Cal/OSHA) adopted the nation's first aerosol transmissible disease (ATD) standard in
  - A) 1981.
  - B) 1991.
  - C) 2003.
  - D) 2009.

# 2. California dental offices must comply with the ATD standard if they

- A) do not treat patients with identified ATD cases.
- B) treat patients with suspected or confirmed illnesses that require Airborne or Droplet Precautions.
- C) refrain from performing aerosol-generating dental procedures on patients identified as a possible ATD transmission risk.
- D) All of the above
- 3. The average risk for infection after a needlestick or cut exposure to hepatitis C virus-infected blood is approximately
  - A) 0.3%.
  - B) 1.8%.
  - C) 3%.
  - D) 18%.
- 4. Of the following, which generally poses the greatest risk for airborne infection?
  - A) Splatter
  - B) Droplets
  - C) Aerosols
  - D) Unwashed hands
- 5. Standard Precautions apply to contact with all of the following, EXCEPT:
  - A) Blood
  - B) Sweat
  - C) Intact skin
  - D) Mucous membranes

- 6. The OSHA Bloodborne Pathogens Standard mandates the wearing of masks, eye protection, and face shields
  - A) without removal all day for all patients.
  - B) only for invasive procedures, such as surgery.
  - C) for all forms of patient contact, regardless of risk.
  - D) when blood or other potentially infectious material exposures are likely.
- Studies have shown that which of the following types of gloves have the highest failure rates?
  - A) Vinyl
  - B) Latex  $(x) = \sum_{i=1}^{n} \frac{1}{i}$
  - C) Nitrile
  - D) Surgical gloves
- 8. Devices connected to the dental water system that enter the patient's mouth should be flushed for how long after each patient?
  - A) No more than 15 seconds
  - B) At least 20 seconds
  - C) At least 90 seconds
  - D) Exactly 2 minutes
- 9. Which of the following is NOT a regulated waste found in dental practice settings?
  - A) Extracted teeth
  - B) Contaminated sharp items
  - C) Gauze saturated with blood
  - D) Disposable gloves, masks, and gowns
- 10. Postexposure prophylaxis, or the provision of medications after a substantial exposure in order to reduce the likelihood of infection, is available for
  - A) HIV.
  - B) hepatitis B.
  - C) hepatitis C.
  - D) Both A and B

# Responsibilities and Requirements of Prescribing Schedule II Opioid Drugs

This Board-approved course fulfills the California requirement for 2 hours of the responsibilities and requirements of prescribing Schedule II opioids education.

### Audience

This course is designed for dental professionals who may alter prescribing practices or intervene to prevent drug diversion and inappropriate opioid use.

### **Course Objective**

The purpose of this course is to provide dental professionals who prescribe or distribute opioids with an appreciation for the complexities of opioid prescribing and the dual risks of litigation due to inadequate pain control and drug diversion or misuse in order to provide the best possible patient care and to prevent a growing social problem.

#### Learning Objectives

Upon completion of this course, you should be able to:

- 1. Apply epidemiologic trends in opioid use and misuse to current practice so at-risk patient populations can be more easily identified, assessed, and treated.
- 2. Outline practices for pain management in dentistry.
- 3. Evaluate behaviors that may indicate drug seeking or diverting as well as approaches for patients suspected of misusing opioids.
- 4. Discuss the regulatory requirements for prescribers and dispensers.
- 5. Describe the dental office procedures for managing vulnerable or substance use disorder patients.

#### Faculty

Mark Rose, BS, MA, LP, is a licensed psychologist in the State of Minnesota with a private consulting practice and a medical research analyst with a biomedical communications firm. Earlier healthcare technology assessment work led to medical device and pharmaceutical sector experience in new product development involving cancer ablative devices and pain therapeutics. Along with substantial experience in addiction research, Mr. Rose has contributed to the authorship of numerous papers on CNS, oncology, and other medical disorders. He is the lead author of papers published in peerreviewed addiction, psychiatry, and pain medicine journals and has written books on prescription opioids and alcoholism published by the Hazelden Foundation. He also serves as an Expert Advisor and Expert Witness to law firms that represent disability claimants or criminal defendants on cases related to chronic pain, psychiatric/substance use disorders, and acute pharmacologic/toxicologic effects. Mr. Rose is on the Board of Directors of the Minneapolis-based International Institute of Anti-Aging Medicine and is a member of several professional organizations.

#### **Faculty Disclosure**

Contributing faculty, Mark Rose, BS, MA, LP, has disclosed no relevant financial relationship with any product manufacturer or service provider mentioned.

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#### Division Planner/Director Disclosure

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AGD Subject Code 346.

This course meets the Dental Board of California's requirements for 2 units of continuing education.

Dental Board of California course #02-3841-00409.

#### **Special Approvals**

This course fulfills the California requirement for 2 hours of education on responsibilities and requirements of prescribing Schedule II opioids.

#### About the Sponsor

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# INTRODUCTION

Pain is the leading reason for seeking medical care, and pain management is a large part of many dental professionals' practice. Opioid analgesics are approved by the U.S. Food and Drug Administration (FDA) for moderate and severe pain and are broadly accepted in acute pain, cancer pain, and end-of-life care, but are controversial in chronic noncancer pain. In response to the long-standing neglect of severe pain, indications for opioid analgesic prescribing were expanded in the 1990s, followed by inappropriate prescribing and increasing abuse, addiction, diversion, and overdose through the 2000s. In tandem with the continued under-treatment of pain, these practice patterns led to needless suffering from uncontrolled pain, opioid analgesic addiction, and overdose. Opioid analgesic prescribing and associated overdose peaked in 2011 with both now in multi-year decline.

Patients show substantial opioid response variations in analgesia and tolerability and may exhibit a range of psychological, emotional, and behavioral responses that reflect inadequate pain control, an emerging opioid use problem, or both. Clinician delivery of best possible care to patients with pain requires appreciation of the complexities of opioid prescribing and the dual risks of inadequate pain control and inappropriate use, drug diversion, or overdose. A foundation for appropriate opioid prescribing is the understanding of factual data that clarify the prevalence, causality, and prevention of serious safety concerns with opioid prescribing.

# SCOPE OF THE PROBLEM

Inappropriate opioid analgesic prescribing for pain is defined as the non-prescribing, inadequate prescribing, excessive prescribing, or continued prescribing despite evidence of ineffectiveness of opioids [1]. Appropriate opioid prescribing is essential to achieve pain control; to minimize patient risk of abuse, addiction, and fatal toxicity; and to minimize societal harms from diversion. The foundation of appropriate opioid prescribing is thorough patient assessment, treatment planning, and follow-up and monitoring. Essential for proper patient assessment and treatment planning is comprehension of the clinical concepts of opioid abuse and addiction, their behavioral manifestations in patients with pain, and how these potentially problematic behavioral responses to opioids both resemble and differ from physical dependence and pseudodependence. Prescriber knowledge deficit has been identified as a key obstacle to appropriate opioid prescribing and, along with gaps in policy, treatment, attitudes, and research, contributes to widespread inadequate treatment of pain [2].

The extent of opioid analgesic use in the United States in the 2000s was unprecedented in the country's history and unparalleled anywhere in the world. Before 1990, physicians in the United States were skeptical of prescribing opioids for chronic noncancer pain. In 2017, 20% of adults are prescribed an opioid such as oxycodone and hydrocodone for chronic pain, and sales of opioid analgesics totaled approximately \$7 billion in 2016 [10; 33].

Worldwide consumption of opioid analgesics has increased dramatically in the past few decades, with the United States driving a substantial proportion of this increase. For example, the 1990 global consumption of hydrocodone was 4 tons (3,628 kg), compared with the 2009 consumption of 39 tons (35,380 kg); 99% of this was consumed in the United States. Similarly, 3 tons (2,722 kg) of oxycodone were consumed globally in 1990, versus 77 tons (69,853 kg) in 2009, of which 62 tons (56,245 kg or 81%) were consumed in the United States [3]. With only 4.5% of the world's population, the United States annually consumes more than 80% of all opioid supplies, including [4]:

- 99% of all hydrocodone
- 80% of all oxycodone
- 58% of all methadone
- 54% of all hydromorphone
- 49% of all fentanyl
- 43% of all meperidine

This disproportionate rate of opioid consumption reflects sociocultural and economic factors and standards of clinical medicine.

Before it was halted in 2011, the Drug Abuse Warning Network (DAWN) provided estimates of the health consequences of nonmedical use of individual drugs, including opioid medications [6]. DAWN indicates that opioid abuse is a growing problem in the United States. In 2005 and 2011, hydrocodone and its combinations accounted for 51,225 and 97,183 emergency department visits, respectively. Oxycodone and its combinations resulted in 42,810 visits to the emergency department in 2005; this number increased to 175,229 visits in 2011 [7; 8]. Visits for nonmedical use of all opioids increased from 217,594 to 420,040 during the six-year period. In 2016–2017, there were 127,101 nonmedical opioid emergency department visits [39]. While this number is an improvement from previous years, nonmedical use accounts for 47.6% of all emergency department visits related to opioids [39].

A 2018 study found that dentists prescribe 8.6% of all opioids in the United States [5]. Dentists and other oral health practitioners have a key role in effectively managing acute pain conditions, including mild postoperative pain resulting from a simple dental extraction, in addition to chronic maxillofacial pain.

# PAIN MANAGEMENT APPROACHES IN DENTISTRY

Dental professionals should know the best clinical practices in opioid prescribing, including the associated risks of opioids, approaches to the assessment of pain and function, and pain management modalities. Pharmacologic and nonpharmacologic approaches should be used on the basis of current knowledge in the evidence base or best clinical practices. Patients with moderate-to-severe chronic pain who have been assessed and treated, over a period of time, with non-opioid therapy or nonpharmacologic pain therapy without adequate pain relief, are considered to be candidates for a trial of opioid therapy [9; 10]. Initial treatment should always be considered individually determined and as a trial of therapy, not a definitive course of treatment [11].

In 2022, the CDC published an updated guideline for the prescription of opioids to manage all types of pain [34]. The updated clinical practice guideline is intended to achieve improved communication between clinicians and patients about the risks and benefits of pain treatment, including opioid therapy for pain; improved safety and effectiveness for pain treatment, resulting in improved function and quality of life for patients experiencing pain; and a reduction in the risks associated with long-term opioid therapy, including opioid use disorder, overdose, and death [34]. It is important to remember that inappropriately limiting necessary opioid medications to address patients' pain can be damaging and should be avoided.

# ACUTE PAIN

Long-term opioid use often begins with treatment of acute pain. Many acute pain conditions can be managed most effectively with nonopioid medications. Nonsteroidal anti-inflammatory drugs (NSAIDs) have been found to be more effective than opioids for surgical dental pain, and the American Dental Association recommends NSAIDs as first-line treatment for acute dental pain management [5].

When opioids are used for acute pain, dentists should prescribe the lowest effective dose of immediate-release opioids in a quantity no greater than that needed for the expected duration of severe pain. In most cases, three days or less will be sufficient; more than seven days will rarely be needed [10]. However, it is important to note that this guideline is based on emergency department prescribing guidelines for non-traumatic nonsurgical pain [12]. It may be necessary to prescribe for longer periods in patients with acute severe pain.

With postoperative, acute, or intermittent pain, analgesia often requires frequent titration, and the two- to four-hour analgesic duration with short-acting hydrocodone, morphine, and oxycodone is more effective than extended-release formulations. Short-acting opioids are also recommended in patients who are medically unstable or with highly variable pain intensity [13; 14; 15].

# CHRONIC PAIN

If opioids are used, they should be combined with nonpharmacologic therapy and non-opioid pharmacologic therapy, as appropriate. Clinicians should consider opioid therapy only if expected benefits for pain and function are anticipated to outweigh risks to the patient [10].

Opioid therapy for chronic pain should be presented as a trial for a pre-defined period (e.g.,  $\leq$  30 days). The goals of treatment should be established with all patients prior to the initiation of opioid therapy, including reasonable improvements in pain, function, depression, anxiety, and avoidance of unnecessary or excessive medication use [1; 10]. The treatment plan should describe therapy selection, measures of progress, and other diagnostic evaluations, consultations, referrals, and therapies.

The need for frequent progress and benefit/risk assessments during the trial should be included in patient education. Patients should also have full knowledge of the warning signs and symptoms of respiratory depression. Prescribers should carefully reassess evidence of benefits and risks when increasing the dosage to  $\geq$ 50 mg morphine equivalent dose (MED) per day. Decisions to titrate dose to  $\geq$ 90 mg MED/day should be avoided or carefully justified [10; 40].

Prescribers should be knowledgeable of federal and state opioid prescribing regulations. Issues of equianalgesic dosing, close patient monitoring during all dose changes, and crosstolerance with opioid conversion should be considered. If necessary, treatment may be augmented, with preference for nonopioids and immediate-release opioids over long-acting/ extended-release opioids. Taper opioid dose when no longer needed [16].

# CREATING A TREATMENT PLAN AND ASSESSMENT OF ADDICTION RISK

Information obtained by patient history, physical examination, and interview, from family members, a spouse, or state prescription drug monitoring program (PDMP), and from the use of screening and assessment tools can help the clinician to stratify the patient according to level of risk for developing problematic opioid behavioral responses (*Table 1*) [17; 28]. Low-risk patients receive the standard level of monitoring, vigilance, and care. Moderate-risk patients should be considered for an additional level of monitoring and provider contact, and high-risk patients are likely to require intensive and structured monitoring and follow-up contact, additional consultation with psychiatric and addiction medicine specialists, and limited supplies of short-acting opioid formulations [10; 26].

Before deciding to prescribe an opioid analgesic, clinicians should perform and document a detailed patient assessment that includes [1]:

- Pain indications for opioid therapy
- Nature and intensity of pain

- Past and current pain treatments and patient response
- Comorbid conditions
- Pain impact on physical and psychological function
- Social support, housing, and employment
- Home environment (i.e., stressful or supportive)
- Pain impact on sleep, mood, work, relationships, leisure, and substance use
- Patient history of physical, emotional, or sexual abuse

If substance abuse is active, in remission, or in the patient's history, consult an addiction specialist before starting opioids [1]. In active substance abuse, do not prescribe opioids until the patient is engaged in treatment/recovery program or other arrangement made, such as addiction professional comanagement and additional monitoring. When considering an opioid analgesic (particularly those that are extended-release or long-acting), one must always weigh the benefits against the risks of overdose, abuse, addiction, physical dependence and tolerance, adverse drug interactions, and accidental exposure by children [10; 16].

Screening and assessment tools can help guide patient stratification according to risk level and inform the appropriate degree of structure and monitoring in the treatment plan. It should be noted that despite widespread endorsement of screening tools used to help determine patient risk level, most tools have not been extensively evaluated, validated, or compared to each other, and evidence of their reliability is poor [17; 28].

# RISK ASSESSMENT TOOLS

# Opioid Risk Tool (ORT)

The Opioid Risk Tool (ORT) is a five-item, patient-administered assessment to help predict aberrant drug-related behavior. The ORT is also used to establish patient risk level through categorization into low, medium, or high levels of risk for aberrant drug-related behaviors based on responses to questions of previous alcohol/drug abuse, psychological disorders, and other risk factors [18].

# Screener and Opioid Assessment for Patients with Pain-Revised (SOAPP-R)

The Screener and Opioid Assessment for Patients with Pain-Revised (SOAPP-R) is a patient-administered, 24-item screen with questions addressing history of alcohol/substance use, psychological status, mood, cravings, and stress. Like the ORT, the SOAPP-R helps assess risk level of aberrant drug-related behaviors and the appropriate extent of monitoring [18; 19].

# Screening Instrument or Substance Abuse Potential (SISAP)

The Screening Instrument or Substance Abuse Potential (SISAP) tool is a self-administered, five-item questionnaire addressing history developed used to predict the risk of opioid misuse. The SISAP is used to identify patients with a history of alcohol/substance abuse and improve pain management by

#### RISK STRATIFICATION FOR PATIENTS PRESCRIBED OPIOIDS

Low Risk
Definable physical pathology with objective signs and reliable symptoms Clinical correlation with diagnostic testing, including MRI, physical examination, and interventional diagnostic techniques With or without mild psychological comorbidity With or without minor medical comorbidity No or well-defined and controlled personal or family history of alcoholism or substance abuse Age 45 years or older High levels of pain acceptance and active coping strategies High motivation and willingness to participate in multimodal therapy and attempting to function at normal levels
Medium Risk
<ul> <li>Significant pain problems with objective signs and symptoms confirmed by radiologic evaluation, physical examination, or diagnostic interventions</li> <li>Moderate psychological problems, well controlled by therapy</li> <li>Moderate coexisting medical disorders that are well controlled by medical therapy and are not affected by chronic opioid therapy (e.g., central sleep apnea)</li> <li>Develops mild tolerance but not hyperalgesia without physical dependence or addiction</li> <li>History of personal or family history of alcoholism or substance abuse</li> <li>Pain involving more than three regions of the body</li> <li>Defined pathology with moderate levels of pain acceptance and coping strategies</li> <li>Willing to participate in multimodal therapy, attempting to function in normal daily life</li> </ul>
High Risk
Widespread pain without objective signs and symptoms Pain involving more than three regions of the body Aberrant drug-related behavior History of alcoholism or drug misuse, abuse, addiction, diversion, dependency, tolerance, or hyperalgesia Major psychological disorders Age younger than 45 years HIV-related pain High levels of pain exacerbation and low levels of coping strategies Unwilling to participate in multimodal therapy, not functioning close to a near normal lifestyle
HIV = human immunodeficiency syndrome, MRI = magnetic resonance imaging.
Source: [17; 28] Table 1

facilitating focus on the appropriate use of opioid analgesics and therapeutic outcomes in the majority of patients who are not at risk of opioid abuse, while carefully monitoring those who may be at greater risk [18].

#### CAGE and CAGE-AID

The original CAGE (Cut down, Annoyed, Guilty, and Eyeopener) Questionnaire consisted of four questions designed to help clinicians determine the likelihood that a patient was misusing or abusing alcohol. These same four questions were modified to create the CAGE-AID (adapted to include drugs), revised to assess the likelihood of current substance abuse [20].

#### Diagnosis, Intractability, Risk, and Efficacy (DIRE) Score

The Diagnosis, Intractability, Risk, and Efficacy (DIRE) risk assessment score is a clinician-rated questionnaire that is used to predict patient compliance with long-term opioid therapy [18; 21]. Patients scoring lower on the DIRE tool are poor candidates for long-term opioid analgesia.

# INFORMED CONSENT AND TREATMENT AGREEMENTS

The initial opioid prescription is preceded by a written informed consent or "treatment agreement" [1]. This agreement should address potential side effects, tolerance and/ or physical dependence, drug interactions, motor skill impairment, limited evidence of long-term benefit, misuse, dependence, addiction, and overdose. Informed consent documents should include information regarding the risk/ benefit profile for the drug(s) being prescribed. The prescribing policies should be clearly delineated, including the number/ frequency of refills, early refills, and procedures for lost or stolen medications.

The treatment agreement also outlines joint physician and patient responsibilities. The patient agrees to using medications safely, refraining from "doctor shopping," and consenting to routine urine drug testing (UDT). The prescriber's responsibility is to address unforeseen problems and prescribe scheduled refills. Reasons for opioid therapy change or discontinuation should be listed. Agreements can also include sections related to follow-up visits, monitoring, and safe storage and disposal of unused drugs.

# PERIODIC REVIEW AND MONITORING

When implementing a chronic pain treatment plan that involves the use of opioids, the patient should be frequently reassessed for changes in pain origin, health, and function [1]. This can include input from family members and/or the state PDMP. During the initiation phase and during any changes to the dosage or agent used, patient contact should be increased. At every visit, chronic opioid response may be monitored according to the "5 A's" [1; 23]:

- Analgesia
- Activities of daily living
- Adverse or side effects
- Aberrant drug-related behaviors
- Affect (i.e., patient mood)

Signs and symptoms that, if present, may suggest a problematic response to the opioid and interference with the goal of functional improvement include [24; 29]:

- Excessive sleeping or days and nights turned around
- Diminished appetite
- Short attention span or inability to concentrate
- Mood volatility, especially irritability
- Lack of involvement with others
- Impaired functioning due to drug effects
- Use of the opioid to regress instead of re-engaging in life
- Lack of attention to hygiene and appearance

The decision to continue, change, or terminate opioid therapy is based on progress toward treatment objectives and absence of adverse effects and risks of overdose or diversion [1]. Satisfactory therapy is indicated by improvements in pain, function, and quality of life. Brief assessment tools to assess pain and function may be useful, as may UDTs. Treatment plans may include periodic pill counts to confirm adherence and minimize diversion.

#### Assessment Tools

# VIGIL

VIGIL is the acronym for a five-step risk management strategy designed to empower clinicians to appropriately prescribe opioids for pain by reducing regulatory concerns and to give pharmacists a framework for resolving ambiguous opioid analgesic prescriptions in a manner that preserves legitimate patient need while potentially deterring diverters. The components of VIGIL are:

- Verification: Is this a responsible opioid user?
- Identification: Is the identity of this patient verifiable?

- Generalization: Do we agree on mutual responsibilities and expectations?
- Interpretation: Do I feel comfortable allowing this person to have controlled substances?
- Legalization: Am I acting legally and responsibly?

The foundation of VIGIL is a collaborative physician/pharmacist relationship [25].

# Current Opioid Misuse Measure (COMM)

The Current Opioid Misuse Measure (COMM) is a 17-item patient self-report assessment designed to help clinicians identify misuse or abuse in patients being treated for chronic pain. Unlike the ORT and the SOAPP-R, the COMM identifies aberrant behaviors associated with opioid misuse in patients already receiving long-term opioid therapy [26]. Sample questions include: In the past 30 days, how often have you had to take more of your medication than prescribed? In the past 30 days, how much of your time was spent thinking about opioid medications (e.g., having enough, taking them, dosing schedule)?

### Pain Assessment and Documentation Tool (PADT)

Guidelines by the CDC, the Federation of State Medical Boards (FSMB), and the Joint Commission stress the importance of documentation from both a healthcare quality and medicolegal perspective. Research has found widespread deficits in chart notes and progress documentation with patients with chronic pain receiving opioid therapy, and the Pain Assessment and Documentation Tool (PADT) was designed to address these shortcomings [46]. The PADT is a cliniciandirected interview, with most sections (e.g., analgesia, activities of daily living, adverse events) consisting of questions asked of the patient. However, the potential aberrant drug-related behavior section must be completed by the physician based on his or her observations of the patient.

# The Brief Intervention Tool

The Brief Intervention Tool is a 26-item, "yes-no," patientadministered questionnaire used to identify early signs of opioid abuse or addiction. The items assess the extent of problems related to drug use in several areas, including drug use-related functional impairment [22].

#### CONCURRENT USE OF BENZODIAZEPINES

Patients who are unable to undergo dental treatment due to excessive fear, anxiety, or phobias and who do not respond to dental behavior modification techniques require pharmacotherapy. In many cases, this involves the use of benzodiazepines, such as diazepam, triazolam, and lorazepam. However, in patients who are also prescribed opioids, there are risks. In 2019, 16% of persons who died of an opioid overdose also tested positive for benzodiazepines [44]. Combining benzodiazepines with opioids is unsafe because both classes of drug cause central nervous system depression and sedation and can decrease respiratory drive—the usual cause of overdose

# #55290 Responsibilities and Requirements of Prescribing Schedule II Opioid Drugs

fatality. Both classes have the potential for drug dependence and addiction. The CDC recommends that dentists avoid prescribing benzodiazepines concurrently with opioids whenever possible [10].

#### CONSULTATION AND REFERRAL

It is important to seek consultation or patient referral when input or care from a pain, psychiatry, addiction, or mental health specialist is necessary. Dentists who prescribe opioids should become familiar with opioid addiction treatment options (including licensed opioid treatment programs for methadone and office-based opioid treatment for buprenorphine) if referral is needed [1].

Ideally, providers should be able to refer patients with active substance abuse who require pain treatment to an addiction professional or specialized program. In reality, these specialized resources are scarce or non-existent in many areas [1]. Therefore, each provider will need to decide whether the risks of continuing opioid treatment while a patient is using illicit drugs outweigh the benefits to the patient in terms of pain control and improved function [48].

### DOCUMENTATION

As noted, documentation is a necessary aspect of all patient care, but it is of particular importance when opioid prescribing is involved. All clinicians should maintain accurate, complete, and up-to-date medical records, including all written or telephoned prescription orders for opioid analgesics and other controlled substances, all written instructions to the patient for medication use, and the name, telephone number, and address of the patient's pharmacy [1]. Good records demonstrate that a service was provided to the patient and that the service was medically necessary. Regardless of the treatment outcome, thorough medical records protect the prescriber.

# PATIENT EDUCATION ON THE USE AND DISPOSAL OF OPIOIDS

Patients and caregivers should be counseled regarding the safe use and disposal of opioids. As part of its mandatory Risk Evaluation and Mitigation Strategy (REMS) for extended-release/ long-acting opioids, the U.S. Food and Drug Administration (FDA) has developed a patient counseling document with information on the patient's specific medications, instructions for emergency situations and incomplete pain control, and warnings not to share medications or take them unprescribed [16]. A copy of this form may be accessed online at https:// www.fda.gov/media/114694/download.

When prescribing opioids, clinicians should provide patients with the following information [16]:

- Product-specific information
- Taking the opioid as prescribed
- Importance of dosing regimen adherence, managing missed doses, and prescriber contact if pain is not controlled

- Warning and rationale to never break or chew/ crush tablets or cut or tear patches prior to use
- Warning and rationale to avoid other central nervous system depressants, such as sedative-hypnotics, anxiolytics, alcohol, or illicit drugs
- Warning not to abruptly halt or reduce the opioid without physician oversight of safe tapering when discontinuing
- The potential of serious side effects or death
- Risk factors, signs, and symptoms of overdose and opioid-induced respiratory depression, gastrointestinal obstruction, and allergic reactions
- The risks of falls, using heavy machinery, and driving
- Warning and rationale to never share an opioid analgesic
- Rationale for secure opioid storage
- Warning to protect opioids from theft
- Instructions for disposal of unneeded opioids, based on product-specific disposal information

There are no universal recommendations for the proper disposal of unused opioids, and patients are rarely advised of what to do with unused or expired medications [49]. According to the FDA, most medications that are no longer necessary or have expired should be removed from their containers, mixed with undesirable substances (e.g., cat litter, used coffee grounds), and put into an impermeable, nondescript container (e.g., disposable container with a lid or a sealed bag) before throwing in the trash [50]. Any personal information should be obscured or destroyed. The FDA recommends that certain medications, including oxycodone/acetaminophen (Percocet), oxycodone (OxyContin tablets), and transdermal fentanyl (Duragesic Transdermal System), be flushed down the toilet instead of thrown in the trash [31; 50]. The FDA provides a free toolkit of materials (e.g., social media images, fact sheets, posters) to raise awareness of the serious dangers of keeping unused opioid pain medicines in the home and with information about safe disposal of these medicines. The Remove the Risk Outreach toolkit is updated regularly and can be found at https://www.fda.gov/drugs/ensuring-safe-use-medicine/ safe-opioid-disposal-remove-risk-outreach-toolkit [31]. Patients should be advised to flush prescription drugs down the toilet only if the label or accompanying patient information specifically instructs doing so.

The American College of Preventive Medicine has established best practices to avoid diversion of unused drugs and educate patients regarding drug disposal [49]:

- Consider writing prescriptions in smaller amounts.
- Educate patients about safe storing and disposal practices.
- Give drug-specific information to patients about the temperature at which they should store their medications. Generally, the bathroom is not the best storage

place. It is damp and moist, potentially resulting in potency decrements, and accessible to many people, including children and teens, resulting in potential theft or safety issues.

- Ask patients not to advertise that they are taking these types of medications and to keep their medications secure.
- Refer patients to community "take back" services overseen by law enforcement that collect controlled substances, seal them in plastic bags, and store them in a secure location until they can be incinerated. Contact your state law enforcement agency or visit https://www.dea.gov to determine if a program is available in your area.

# DISCONTINUING OPIOID THERAPY

The decision to continue or end opioid prescribing should be based on a physician-patient discussion of the anticipated benefits and risks. An opioid should be discontinued with resolution of the pain condition, intolerable side effects, inadequate analgesia, lack of improvement in quality of life despite dose titration, deteriorating function, or significant aberrant medication use [1; 10].

Clinicians should provide patients physically dependent on opioids with a safely structured tapering protocol. Withdrawal is managed by the prescribing physician or referral to an addiction specialist. Patients should be reassured that opioid discontinuation is not the end of treatment; continuation of pain management will be undertaken with other modalities through direct care or referral.

As a side note, cannabis use by patients with chronic pain receiving opioid therapy has traditionally been viewed as a treatment agreement violation that is grounds for termination of opioid therapy. However, some now argue against cannabis use as a rationale for termination or substantial treatment and monitoring changes, especially considering the increasing legalization of medical use at the state level [48].

# DENTAL OFFICE PROCEDURES FOR MANAGING VULNERABLE OR SUBSTANCE USE DISORDER PATIENTS

### IDENTIFICATION OF DRUG DIVERSION/SEEKING BEHAVIORS

Research has more closely defined the location of prescribed opioid diversion into illicit use in the supply chain from the manufacturer to the distributor, retailer, and the end user (the pain patient). This information carries with it substantial public policy and regulatory implications. The 2019 National Survey on Drug Use and Health asked non-medical users of prescription opioids how they obtained their most recently used drugs [51]. Among persons 12 years of age or older, 38.6% obtained their prescription opioids from a friend or relative for free, 34.7% got them through a prescription from one doctor (vs. 17.3% in 2009–2010), 9.5% bought them from a friend or relative, and 3.2% took them from a friend or relative without asking [51]. Less frequent sources included a drug dealer or other stranger (6.5%); multiple doctors (2.0%); and theft from a doctor's office, clinic, hospital, or pharmacy (0.9%) (vs. 0.2% in 2009–2010) [51].

There are certain behaviors that are suggestive of an emerging opioid use disorder. The most suggestive behaviors are [45; 47; 48]:

- Selling medications
- Prescription forgery or alteration
- Injecting medications meant for oral use
- Obtaining medications from nonmedical sources
- Resisting medication change despite worsening function or significant negative effects
- Loss of control over alcohol use
- Using illegal drugs or non-prescribed controlled substances
- Recurrent episodes of:
  - Prescription loss or theft
  - Obtaining opioids from other providers in violation of a treatment agreement
  - Unsanctioned dose escalation
  - Running out of medication and requesting early refills

Behaviors with a lower level of evidence for their association with opioid misuse include [45; 47; 48]:

- Aggressive demands for more drug
- Asking for specific medications
- Stockpiling medications during times when pain is less severe
- Using pain medications to treat other symptoms
- Reluctance to decrease opioid dosing once stable
- In the earlier stages of treatment:
  - Increasing medication dosing without provider permission
  - Obtaining prescriptions from sources other than the pain provider
  - Sharing or borrowing similar medications from friends/family

#### INTERVENTIONS FOR SUSPECTED OR KNOWN ADDICTION OR DRUG DIVERSION

There are a number of actions that prescribers and dispensers can take to prevent or intervene in cases of drug diversion. These actions can be generally categorized based on the various mechanisms of drug diversion.

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Prevention is the best approach to addressing drug diversion. As noted, the most common source of nonmedical use of prescribed opioids is from a family member or friend, through sharing, buying, or stealing. To avoid drug sharing among patients, healthcare professionals should educate patients on the dangers of sharing opioids and stress that "doing prescription drugs" is the same as "using street drugs" [49]. In addition, patients should be aware of the many options available to treat chronic pain aside from opioids. To prevent theft, patients should be advised to keep medications in a private place and to refrain from telling others about the medications being used.

Communication among providers and pharmacies can help to avoid inappropriate attainment of prescription drugs through "doctor shopping." Prescribers should keep complete and up-todate records for all controlled substance prescribing. When possible, electronic medical records should be integrated between pharmacies, hospitals, and managed care organizations [49]. If available, it is also best practice to periodically request a report from the state's prescription reporting program to evaluate the prescribing of opioids to your patients by other providers [49].

When dealing with patients suspected of drug seeking/diversion, first inquire about prescription, over-the-counter, and illicit drug use and perform a thorough examination [43; 49]. Pill counting and/or UDT may be necessary to investigate possible drug misuse. Photo identification or other form of identification and social security number may be required prior to dispensing the drug, with proof of identity documented fully. If a patient is displaying suspicious behaviors, consider prescribing for limited quantities [43].

If a patient is found to be abusing prescribed opioids, this is considered a violation of the treatment agreement and the clinician must make the decision whether or not to continue the therapeutic relationship. While dentists have the option of withdrawing from a case, they should notify the patient (or authorized decision maker) long enough in advance to permit the patient to secure another care provider and facilitate transfer of care, when appropriate [42]. Patients may also be given resources and/or recommendations to help them locate a new dentist.

Patients with chronic pain found to have an ongoing substance abuse problem or addiction should be referred to a pain specialist for continued treatment. Theft or loss of controlled substances is reported to the DEA. If drug diversion has occurred, the activity should be documented and a report to law enforcement should be made [38].

# CONSIDERATIONS FOR PATIENTS UNDERGOING TREATMENT FOR OPIOID USE DISORDER

Medication-assisted therapy for the treatment of opioid use disorder often includes the use of buprenorphine, which reduces withdrawal symptoms and the desire to use opioids without causing the cycle of highs and lows associated with opioid misuse. The comprehensive approach of buprenorphine combined with counseling and other behavioral therapies is often one of the most effective ways to treat opioid use disorder [27]. However, buprenorphine is highly acidic, and dental problems have been reported with orally dissolving buprenorphinecontaining formulations, including increased risk for tooth decay, cavities, oral infections, and loss of teeth. These complications can be serious and have been reported even in patients with no history of dental issues. Despite these risks, buprenorphine is an important treatment option for opioid use disorder and pain, and the benefits of these medicines clearly outweigh the risks.

The American Dental Association recommends instructing patients taking oral buprenorphine therapy should be instructed to rinse their mouths 30 minutes after use of a strip/tab [30]. After one hour, patients should brush their teeth. These patients should also be instructed to adhere to good oral hygiene practices and to drink more water to combat potential xerostomia. Sugary beverages and smoking/vaping should be limited or avoided, if possible. Prescription fluoride toothpaste or trays should be considered [30].

It is also essential to consider the impact of medicationassistant opioid use disorder treatment on dental pain management. Naltrexone is an opioid antagonist and will block the action of opioids used to manage dental pain. In addition, buprenorphine/methadone therapy increases patients' tolerance for other opioids. Any dental pain management plans should take these potential issues into account.

# REGULATORY REQUIREMENTS FOR PRESCRIBERS AND DISPENSERS

# COMPLIANCE WITH STATE AND FEDERAL LAWS

In response to the rising incidence in prescription opioid abuse, addiction, diversion, and overdose since the late 1990s, the FDA has mandated opioid-specific REMS to reduce the potential negative patient and societal effects of prescribed opioids. Other elements of opioid risk mitigation include FDA partnering with other governmental agencies, state professional licensing boards, and societies of healthcare professionals to help improve prescriber knowledge of appropriate and safe opioid prescribing and safe home storage and disposal of unused medication [24].

Several regulations and programs at the state level have been enacted in an effort to reduce prescription opioid abuse, diversion, and overdose, including [37]:

- Physical examination required prior to prescribing
- Tamper-resistant prescription forms
- Pain clinic regulatory oversight
- Prescription limits
- Prohibition from obtaining controlled substance prescriptions from multiple providers
- Patient identification required before dispensing

• Immunity from prosecution or mitigation at sentencing for individuals seeking assistance during an overdose

# CONTROLLED SUBSTANCES LAWS/RULES

The U.S. Drug Enforcement Administration (DEA) is responsible for formulating federal standards for the handling of controlled substances. In 2011, the DEA began requiring every state to implement electronic databases that track prescribing habits, referred to as PDMPs. Specific policies regarding controlled substances are administered at the state level [36].

According to the DEA, drugs, substances, and certain chemicals used to make drugs are classified into five distinct categories or schedules depending upon the drug's acceptable medical use and the drug's abuse or dependency potential [35]. The abuse rate is a determinate factor in the scheduling of the drug; for example, Schedule I drugs are considered the most dangerous class of drugs with a high potential for abuse and potentially severe psychological and/or physical dependence.

#### STATE-SPECIFIC LAWS AND RULES

Most states have established laws and rules governing the prescribing and dispensing of opioid analgesics. It is each prescriber's responsibility to have knowledge of and adhere to the laws and rules of the state in which he or she prescribes.

# CONCLUSION

Opioid analgesic medications can bring substantial relief to patients suffering from pain. However, the inappropriate use, abuse, and diversion of prescription drugs in America, particularly prescription opioids, has increased dramatically in recent years and has been identified as a national public health epidemic. A set of clinical tools, guidelines, and recommendations are now available for prescribers who treat patients with opioids. By implementing these tools, the clinician can effectively address issues related to the clinical management of opioid prescribing, opioid risk management, regulations surrounding the prescribing of opioids, and problematic opioid use by patients. In doing so, healthcare professionals are more likely to achieve a balance between the benefits and risks of opioid prescribing, optimize patient attainment of therapeutic goals, and avoid the risk to patient outcome, public health, and viability of their own practice imposed by deficits in knowledge.

# APPENDIX: LAWS AND REGULATIONS IN CALIFORNIA

#### HEALTH AND SAFETY CODE

#### DIVISION 10. UNIFORM CONTROLLED SUBSTANCES ACT

CHAPTER 4. Prescriptions

#### **ARTICLE 1. Requirements of Prescriptions**

§11165.4. (a) (1) (A) (i) A health care practitioner authorized to prescribe, order, administer, or furnish a controlled substance shall consult the patient activity report or information from the patient activity report obtained from the CURES database to review a patient's controlled substance history for the past 12 months before prescribing a Schedule II, Schedule III, or Schedule IV controlled substance to the patient for the first time and at least once every six months thereafter if the prescriber renews the prescription and the substance remains part of the treatment of the patient.

- (ii) If a health care practitioner authorized to prescribe, order, administer, or furnish a controlled substance is not required, pursuant to an exemption described in subdivision (c), to consult the patient activity report from the CURES database the first time the health care practitioner prescribes, orders, administers, or furnishes a controlled substance to a patient, the health care practitioner shall consult the patient activity report from the CURES database to review the patient's controlled substance history before subsequently prescribing a Schedule II, Schedule III, or Schedule IV controlled substance to the patient and at least once every six months thereafter if the prescriber renews the prescription and the substance remains part of the treatment of the patient.
- (iii) A health care practitioner who did not directly access the CURES database to perform the required review of the controlled substance use report shall document in the patient's medical record that they reviewed the CURES database generated report within 24 hours of the controlled substance prescription that was provided to them by another authorized user of the CURES database.
- (B) For purposes of this paragraph, "first time" means the initial occurrence in which a health care practitioner, in their role as a health care practitioner, intends to prescribe, order, administer, or furnish a Schedule II, Schedule III, or Schedule IV controlled substance to a patient and has not previously prescribed a controlled substance to the patient.
- (2) A health care practitioner shall review a patient's controlled substance history that has been obtained from the CURES database no earlier than 24 hours, or the previous business day, before the health care practitioner prescribes, orders, administers, or furnishes a Schedule II, Schedule III, or Schedule IV controlled substance to the patient.

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- (b) The duty to consult the CURES database, as described in subdivision (a), does not apply to veterinarians or pharmacists.
- (c) The duty to consult the CURES database, as described in subdivision (a), does not apply to a health care practitioner in any of the following circumstances:
  - If a health care practitioner prescribes, orders, or furnishes a controlled substance to be administered to a patient in any of the following facilities or during a transfer between any of the following facilities, or for use while on facility premises:
    - (A) A licensed clinic, as described in Chapter 1 (commencing with Section 1200) of Division 2.
    - (B) An outpatient setting, as described in Chapter 1.3 (commencing with Section 1248) of Division 2.
    - (C) A health facility, as described in Chapter 2 (commencing with Section 1250) of Division 2.
    - (D) A county medical facility, as described in Chapter 2.5 (commencing with Section 1440) of Division 2.
    - (E) Another medical facility, including, but not limited to, an office of a health care practitioner and an imaging center.
    - (F) A correctional clinic, as described in Section 4187 of the Business and Professions Code, or a correctional pharmacy, as described in Section 4021.5 of the Business and Professions Code.
  - (2) If a health care practitioner prescribes, orders, administers, or furnishes a controlled substance in the emergency department of a general acute care hospital and the quantity of the controlled substance does not exceed a nonrefillable seven-day supply of the controlled substance to be used in accordance with the directions for use.
  - (3) If a health care practitioner prescribes, orders, administers, or furnishes a controlled substance to a patient as part of the patient's treatment for a surgical, radiotherapeutic, therapeutic, or diagnostic procedure and the quantity of the controlled substance does not exceed a nonrefillable seven-day supply of the controlled substance to be used in accordance with the directions for use, in any of the following facilities:
    - (A) A licensed clinic, as described in Chapter 1 (commencing with Section 1200) of Division 2.
    - (B) An outpatient setting, as described in Chapter 1.3 (commencing with Section 1248) of Division 2.
    - (C) A health facility, as described in Chapter 2 (commencing with Section 1250) of Division 2.
    - (D) A county medical facility, as described in Chapter 2.5 (commencing with Section 1440) of Division 2.

- (E) A place of practice, as defined in Section 1658 of the Business and Professions Code.
- (F) Another medical facility where surgical procedures are permitted to take place, including, but not limited to, the office of a health care practitioner.
- (4) If a health care practitioner prescribes, orders, administers, or furnishes a controlled substance to a patient who is terminally ill, as defined in subdivision (c) of Section 11159.2.
- (5) (A) If all of the following circumstances are satisfied:
  - (i) It is not reasonably possible for a health care practitioner to access the information in the CURES database in a timely manner.
  - (ii) Another health care practitioner or designee authorized to access the CURES database is not reasonably available.
  - (iii) The quantity of controlled substance prescribed, ordered, administered, or furnished does not exceed a nonrefillable seven-day supply of the controlled substance to be used in accordance with the directions for use and no refill of the controlled substance is allowed.
  - (B) A health care practitioner who does not consult the CURES database under subparagraph (A) shall document the reason they did not consult the database in the patient's medical record.
- (6) If the CURES database is not operational, as determined by the department, or cannot be accessed by a health care practitioner because of a temporary technological or electrical failure. A health care practitioner shall, without undue delay, seek to correct the cause of the temporary technological or electrical failure that is reasonably within the health care practitioner's control.
- (7) If the CURES database cannot be accessed because of technological limitations that are not reasonably within the control of a health care practitioner.
- (8) If consultation of the CURES database would, as determined by the health care practitioner, result in a patient's inability to obtain a prescription in a timely manner and thereby adversely impact the patient's medical condition, provided that the quantity of the controlled substance does not exceed a nonrefillable seven-day supply if the controlled substance were used in accordance with the directions for use.
- (d) (1) A health care practitioner who fails to consult the CURES database, as described in subdivision (a), shall be referred to the appropriate state professional licensing board solely for administrative sanctions, as deemed appropriate by that board.

- (2) This section does not create a private cause of action against a health care practitioner. This section does not limit a health care practitioner's liability for the negligent failure to diagnose or treat a patient.
- (e) All applicable state and federal privacy laws govern the duties required by this section.
- (f) The provisions of this section are severable. If any provision of this section or its application is held invalid, that invalidity shall not affect other provisions or applications that can be given effect without the invalid provision or application.
- (g) This section shall become operative on July 1, 2021, or upon the date the department promulgates regulations to implement this section and posts those regulations on its internet website, whichever date is earlier.

#### CALIFORNIA BUSINESS AND PROFESSIONS CODE

#### **DIVISION 2. HEALING ARTS**

#### **CHAPTER 1.** General Provisions

#### **ARTICLE 7.5. Health Care Practitioners**

§688. (a) A health care practitioner authorized to issue a prescription pursuant to Section 4040 shall have the capability to issue an electronic data transmission prescription, as defined under Section 4040, on behalf of a patient and to transmit that electronic data transmission prescription to a pharmacy selected by the patient.

- (b) (1) A pharmacy, pharmacist, or other practitioner authorized under California law to dispense or furnish a prescription pursuant to Section 4040 shall have the capability to receive an electronic data transmission prescription on behalf of a patient.
  - (2) A pharmacy, pharmacist, or other practitioner authorized under California law to dispense or furnish a prescription pursuant to Section 4040 shall not refuse to dispense or furnish an electronic data transmission prescription solely because the prescription was not submitted via, or is not compatible with, the proprietary software of the pharmacy, pharmacist, or other dispensing practitioner.
  - (3) A pharmacy, pharmacist, or other practitioner authorized under California law to dispense or furnish a prescription pursuant to Section 4040 may decline to dispense or furnish an electronic data transmission prescription submitted via a software that fails to meet any of the following:
    - (A) Adheres to the National Council for Prescription Drug Programs SCRIPT standard, as modified from time to time.
    - (B) Complies with the prescription content requirements set forth in Section 4040.

- (C) For a controlled substance prescription, complies with Parts 1300, 1304, 1306, and 1311 of Title 21 of the Code of Federal Regulations, as amended from time to time.
- (D) Complies with the federal Health Insurance Portability and Accountability Act of 1996, the California Confidentiality of Medical Information Act, or the security and confidentiality requirements prescribed to by the pharmacy, pharmacist, or other practitioner authorized pursuant to Section 4040.
- (c) For a prescription for a controlled substance, as defined by Section 4021, generation and transmission of the electronic data transmission prescription shall comply with Parts 1300, 1304, 1306, and 1311 of Title 21 of the Code of Federal Regulations, as amended from time to time.
- (d) A prescription prescribed by a health care practitioner shall be issued as an electronic data transmission prescription. This subdivision shall not apply to prescriptions issued pursuant to subdivision (e).
- (e) Subdivision (d) shall not apply to any of the following:
  - (1) The prescription is issued pursuant to Section 11159.2 of the Health and Safety Code.
  - (2) An electronic data transmission prescription is unavailable due to a temporary technological or electrical failure. For purposes of this paragraph, "temporary technological or electrical failure" means failure of a computer system, application, or device, or the loss of electrical power to that system, application, or device, or any other service interruption affecting the certified electronic data transmission prescription application used to transmit the prescription.
  - (3) The prescribing health care practitioner is issuing a prescription to be dispensed by a pharmacy located outside California.
  - (4) (A) The prescription is issued in a hospital emergency department or urgent care clinic and one or more of the following conditions are present:
    - (i) The patient resides outside California.
    - (ii) The patient resides outside the geographic area of the hospital.
    - (iii) The patient is homeless or indigent and does not have a preferred pharmacy.
    - (iv) The prescription is issued at a time when a patient's regular or preferred pharmacy is likely to be closed.
    - (B) Under any of the conditions described in subparagraph (A), a prescription shall be electronically issued but does not require electronic transmission and may be provided directly to the patient.
  - (5) The prescription is issued by a veterinarian.
  - (6) The prescription is for eyeglasses or contact lenses.

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- (7) The prescription is issued by a prescribing health care practitioner serving as a volunteer in a free clinic and receives no remuneration for their services.
- (8) The prescribing health care practitioner and the dispenser are the same entity.
- (9) The prescription is issued by a prescribing health care practitioner under circumstances whereby the practitioner reasonably determines that it would be impractical for the patient to obtain substances prescribed by an electronic data transmission prescription in a timely manner, and the delay would adversely impact the patient's medical condition.
- (10) The prescription that is issued includes elements not covered by the latest version of the National Council for Prescription Drug Programs' SCRIPT standard, as amended from time to time.
- (11) (A) The prescriber registers with the California State Board of Pharmacy in a manner and format determined by the board, stating that they meet one or more of the following criteria:
  - (i) Their practice is located in the area of an emergency or disaster declared by a federal, state, or local government.
  - (ii) They issue 100 or fewer prescriptions per calendar year.
  - (iii) They are unable to issue electronic data transmission prescriptions due to circumstances beyond their control.
  - (B) The prescriber shall annually submit the registration required in subparagraph (A) to the California State Board of Pharmacy and maintain documentation of the circumstances qualifying them for exemption under subparagraph (A).
  - (C) The California State Board of Pharmacy shall post a list of prescribers meeting the requirements of subparagraph (A) on its internet website.
- (f) A health care practitioner who issues a prescription for a controlled substance but does not transmit the prescription as an electronic data transmission prescription shall document the reason in the patient's medical record as soon as practicable and within 72 hours of the end of the technological or electrical failure that prevented the electronic data transmission of the prescription.
- (g) (1) A pharmacy that receives an electronic data transmission prescription from a prescribing health care practitioner who has issued the prescription but has not dispensed the medication to the patient shall, at

the request of the patient or a person authorized to make a request on behalf of the patient, immediately transfer or forward the electronic data transmission prescription to an alternative pharmacy designated by the requester, unless one of the following applies:

- (A) The action would result in a violation of any state or federal law.
- (B) The action is not supported by the latest version of the National Council for Prescription Drug Programs SCRIPT standard, as amended from time to time.
- (2) If a pharmacy is prohibited from transferring or forwarding electronic data transmission prescriptions, as specified in paragraph (1), to a designated alternative pharmacy, and that prohibition is subsequently removed, then that pharmacy shall implement, within one year from the date the prohibition is removed, the necessary provisions to allow for the transferring or forwarding of an electronic data transmission prescription.
- (h) If a pharmacy, or its staff, is aware than an attempted transmission of an electronic data transmission prescription failed, is incomplete, or is otherwise not appropriately received, the pharmacy shall immediately notify the prescribing health care practitioner.
  - (i) A pharmacist who receives a written, oral, or faxed prescription shall not be required to verify that the prescription properly falls under one of the exceptions in subdivision
     (e). Pharmacists may continue to dispense medications from legally valid written, oral, or fax prescriptions pursuant to this division.
  - (j) A health care practitioner, pharmacist, or pharmacy who fails to meet the applicable requirements of this section shall be referred to the appropriate state professional licensing board solely for administrative sanctions, as deemed appropriate by that board. This section does not create a private right of action against a health care practitioner. This section does not limit a health care practitioner's liability for the negligent failure to diagnose or treat a patient.
- (k) This section shall not apply to a health care practitioner, pharmacist, or pharmacy when providing health care services to an inmate, individual on parole, or youth under the jurisdiction of the Department of Corrections and Rehabilitation.

# Customer Information/Answer Sheet/Evaluation insert located between pages 68-69.

# COURSE TEST - #55290 RESPONSIBILITIES AND REQUIREMENTS OF PRESCRIBING SCHEDULE II OPIOID DRUGS

This is an open book test. Please record your responses on the Answer Sheet. A passing grade of at least 70% must be achieved in order to receive credit for this course.

# This 2 CE Credit Hour activity must be completed by January 31, 2027.

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Designations of Credit: NetCE designates this activity for 2 continuing education credits.

AGD SUBJECT CODE: 346.

This course meets the Dental Board of California's requirements for 2 units of continuing education. Dental Board of California course #02-3841-00409.

# 1. Inappropriate opioid analgesic prescribing for pain is defined as

- A) non-prescribing.
- B) inadequate prescribing.
- C) continued prescribing despite evidence of ineffectiveness of opioids.
- D) All of the above

# 2. When opioids are used for acute pain, clinicians should prescribe

- A) the highest safe dose.
- B) extended-release opioids.
- C) a quantity no greater than that needed for the expected duration of severe pain.
- D) All of the above
- 3. A patient prescribed opioids for chronic pain who is 65 years of age and displays high levels of pain acceptance and active coping strategies is considered at what level of risk for developing problematic opioid behavioral responses?
  - A) Low
  - B) Medium
  - C) High
  - D) Severe

# 4. The Screener and Opioid Assessment for Patients with Pain-Revised (SOAPP-R)

- A) consists of 5 items.
- B) is patient administered.
- C) diagnoses depression in the past month.
- D) assesses the likelihood of current substance abuse.

# 5. Which of the following is NOT one of the 5 A's of monitoring chronic opioid response?

- A) Analgesia
- B) Acceptance
- C) Affect (i.e., patient mood)
- D) Aberrant drug-related behaviors
- 6. Combining benzodiazepines with opioids is unsafe because
  - A) it can increase respiratory drive.
  - B) patients will not understand the differences between the two drug classes.
  - C) both classes of drug cause central nervous system depression and sedation.
  - D) All of the above
- 7. Which of the following statements regarding the disposal of opioids is TRUE?
  - A) Patients are almost always advised of what to do with unused or expired medications.
  - B) There are no universal recommendations for the proper disposal of unused opioids.
  - C) According to the FDA, most medications should be flushed down the toilet instead of thrown in the trash.
  - D) All of the above

Test questions continue on next page  $\rightarrow$ 

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- 8. The most common source of nonmedical use of prescribed opioids is from
  - A) a friend or relative for free.
  - B) a prescription from one doctor.
  - C) purchase from a drug dealer or other stranger.
  - D) theft from a doctor's office, clinic, hospital, or pharmacy.
- 9. Which of the following behaviors is the most suggestive of an emerging opioid use disorder?
  - A) Asking for specific medications
  - B) Injecting medications meant for oral use
  - C) Reluctance to decrease opioid dosing once stable
  - D) Stockpiling medications during times when pain is less severe

- 10. Which government agency is responsible for formulating federal standards for the handling of controlled substances?
  - A) Institutes of Medicine
  - B) U.S. Drug Enforcement Administration
  - C) Office of National Drug Control Policy
  - D) U.S. Department of Health and Human Services

Be sure to transfer your answers to the Answer Sheet located on the envelope insert located between pages 68–69. DO NOT send these test pages to NetCE. Retain them for your records. **PLEASE NOTE: Your postmark or facsimile date will be used as your test completion date.** 

#### Audience

This course is designed for all dental professionals.

#### **Course Objective**

The purpose of this course is to provide dental professionals with the knowledge, skills, and strategies necessary to provide culturally competent and responsive care to all patients.

#### Learning Objectives

Upon completion of this course, you should be able to:

- 1. Define cultural competence, implicit bias, and related terminology.
- 2. Outline social determinants of health and barriers to providing care.
- 3. Discuss best practices for providing culturally competent care to various patient populations.
- 4. Discuss key aspects of creating a welcoming and safe environment, including avoidance of discriminatory language and behaviors.

#### Faculty

Alice Yick Flanagan, PhD, MSW, received her Master's in Social Work from Columbia University, School of Social Work. She has clinical experience in mental health in correctional settings, psychiatric hospitals, and community health centers. In 1997, she received her PhD from UCLA, School of Public Policy and Social Research. Dr. Yick Flanagan completed a year-long post-doctoral fellowship at Hunter College, School of Social Work in 1999. In that year she taught the course Research Methods and Violence Against Women to Masters degree students, as well as conducting qualitative research studies on death and dying in Chinese American families.

Previously acting as a faculty member at Capella University and Northcentral University, Dr. Yick Flanagan is currently a contributing faculty member at Walden University, School of Social Work, and a dissertation chair at Grand Canyon University, College of Doctoral Studies, working with Industrial Organizational Psychology doctoral students. She also serves as a consultant/subject matter expert for the New York City Board of Education and publishing companies for online curriculum development, developing practice MCAT questions in the area of psychology and sociology. Her research focus is on the area of culture and mental health in ethnic minority communities.

# Faculty Disclosure

Contributing faculty, Alice Yick Flanagan, PhD, MSW, has disclosed no relevant financial relationship with any product manufacturer or service provider mentioned.

#### **Division Planner**

Mark J. Szarejko, DDS, FAGD

**Senior Director of Development and Academic Affairs** Sarah Campbell

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#### Designations of Credit

NetCE designates this activity for 4 continuing education credits.

AGD Subject Code 558.

This course meets the Dental Board of California's requirements for 4 units of continuing education.

Dental Board of California course #04-3841-00405.

#### About the Sponsor

The purpose of NetCE is to provide challenging curricula to assist healthcare professionals to raise their levels of expertise while fulfilling their continuing education requirements, thereby improving the quality of healthcare.

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- Read the following course.
- Complete the test and evaluation.
- Return your Customer Information/Answer Sheet/ Evaluation and payment to NetCE by mail or complete online at www.NetCE.com/CADN25.
- A full Works Cited list is available online at www. NetCE.com.

# INTRODUCTION

Culturally competent care has been defined as "care that takes into account issues related to diversity, marginalization, and vulnerability due to culture, race, gender, and sexual orientation" [1]. A culturally competent person is someone who is aware of how being different from the norm can be marginalizing and how this marginalization may affect seeking or receiving health care [1]. To be effective cross-culturally with any diverse group, healthcare professionals must have awareness, sensitivity, and knowledge about the culture involved, enhanced by the use of cross-cultural communication skills [2; 3].

Healthcare professionals are accustomed to working to promote the healthy physical and psychosocial development and well-being of individuals within the context of the greater community. For years, these same professionals have been identifying at-risk populations and developing programs or making referrals to resources to promote the health and safety of at-risk groups. But, because of general assumptions, persistent stereotypes, and implicit and explicit biases, culturerelated healthcare disparities persist [2]. In the increasingly diverse landscape of the United States, assessing and addressing culture-related barriers to care are a necessary part of health care. This includes seeking to improve one's cultural competence and identifying blind spots and biases.

# DEFINITIONS

# CULTURAL COMPETENCE

In healthcare, cultural competence is broadly defined as practitioners' knowledge of and ability to apply cultural information and appreciation of a different group's cultural and belief systems to their work [4]. It is a dynamic process, meaning that there is no endpoint to the journey to becoming culturally aware, sensitive, and competent. Some have argued that cultural curiosity is a vital aspect of this approach.

# CULTURAL HUMILITY

Cultural humility refers to an attitude of humbleness, acknowledging one's limitations in the cultural knowledge of groups. Practitioners who apply cultural humility readily concede that they are not experts in others' cultures and that there are aspects of culture and social experiences that they do not know. From this perspective, patients are considered teachers of the cultural norms, beliefs, and value systems of their group, while practitioners are the learners [5]. Cultural humility is a lifelong process involving reflexivity, self-evaluation, and self-critique [6].

# DISCRIMINATION

Discrimination has traditionally been viewed as the outcome of prejudice [7]. It encompasses overt or hidden actions, behaviors, or practices of members in a dominant group against members of a subordinate group [8]. Discrimination has also been further categorized as lifetime, which consists of major discreet discriminatory events, or everyday, which is subtle, continual, and part of day-to-day life and can have a cumulate effect on individuals [9].

# DIVERSITY

Diversity "encompasses differences in and among societal groups based on race, ethnicity, gender, age, physical/mental abilities, religion, sexual orientation, and other distinguishing characteristics" [10]. Diversity is often incorrectly conceptualized into singular dimensions as opposed to multiple and intersecting diversity factors [11].

# INTERSECTIONALITY

Intersectionality is a term to describe the multiple facets of identity, including race, gender, sexual orientation, religion, sex, and age. These facets are not mutually exclusive, and the meanings that are ascribed to these identities are inter-related and interact to create a whole [12]. This term also encompasses the ways that different types and systems of oppression intersect and affect individuals.

# PREJUDICE

Prejudice is a generally negative feeling, attitude, or stereotype against members of a group [13]. It is important not to equate prejudice and racism, although the two concepts are related. All humans have prejudices, but not all individuals are racist. The popular definition is that "prejudice plus power equals racism" [13]. Prejudice stems from the process of ascribing every member of a group with the same attributes [14].

# RACISM

Racism is the "systematic subordination of members of targeted racial groups who have relatively little social power...by members of the agent racial group who have relatively more social power" [15]. Racism is perpetuated and reinforced by social values, norms, and institutions.

There is some controversy regarding whether unconscious (implicit) racism exists. Experts assert that images embedded in our unconscious are the result of socialization and personal observations, and negative attributes may be unconsciously applied to racial minority groups [16]. These implicit attributes affect individuals' thoughts and behaviors without a conscious awareness.

Structural racism refers to the laws, policies, and institutional norms and ideologies that systematically reinforce inequities, resulting in differential access to services such as health care, education, employment, and housing for racial and ethnic minorities [17; 18].

# **BIAS: IMPLICIT AND EXPLICIT**

In a sociocultural context, biases are generally defined as negative evaluations of a particular social group relative to another group. Explicit biases are conscious, whereby an individual is fully aware of his/her attitudes and there may be intentional behaviors related to these attitudes [19]. For example, an individual may openly endorse a belief that women are weak and men are strong. This bias is fully conscious and is made explicitly known. The individual's ideas may then be reflected in his/her work as a manager.

FitzGerald and Hurst assert that there are cases in which implicit cognitive processes are involved in biases and conscious availability, controllability, and mental resources are not [20]. The term "implicit bias" refers to the unconscious attitudes and evaluations held by individuals. These individuals do not necessarily endorse the bias, but the embedded beliefs/ attitudes can negatively affect their behaviors [21; 22; 23; 24]. Some have asserted that the cognitive processes that dictate implicit and explicit biases are separate and independent [24].

Implicit biases can start as early as 3 years of age. As children age, they may begin to become more egalitarian in what they explicitly endorse, but their implicit biases may not necessarily change in accordance to these outward expressions [25]. Because implicit biases occur on the subconscious or unconscious level, particular social attributes (e.g., skin color) can quietly and insidiously affect perceptions and behaviors [26]. According to Georgetown University's National Center on Cultural Competency, social characteristics that can trigger implicit biases include [27]:

- Age
- Disability
- Education
- English language proficiency and fluency
- Ethnicity
- Health status
- Disease/diagnosis (e.g., human immunodeficiency virus [HIV])
- Insurance
- Obesity
- Race
- Socioeconomic status
- Sexual orientation, gender identity, or gender expression
- Skin tone
- Substance use

An alternative way of conceptualizing implicit bias is that an unconscious evaluation is only negative if it has further adverse consequences on a group that is already disadvantaged or produces inequities [20; 28]. Disadvantaged groups are marginalized in the healthcare system and vulnerable on multiple levels; health professionals' implicit biases can further exacerbate these existing disadvantages [28].

When the concept of implicit bias was introduced in the 1990s, it was thought that implicit biases could be directly linked to behavior. Despite the decades of empirical research, many questions, controversies, and debates remain about the dynamics and pathways of implicit biases [21].

Specific conditions or environmental risk factors have been associated with an increased risk for certain implicit biases, including [130; 131]:

- Stressful emotional states (e.g., anger, frustration)
- Uncertainty
- Low-effort cognitive processing
- Time pressure
- Lack of feedback
- Feeling behind with work
- Lack of guidance
- Long hours
- Overcrowding
- High-crises environments
- Mentally taxing tasks
- Juggling competing tasks

# ROLE OF INTERPROFESSIONAL COLLABORATION AND PRACTICE

The study of implicit bias is appropriately interdisciplinary, representing social psychology, medicine, health psychology, neuroscience, counseling, mental health, gerontology, gender/sexuality studies, religious studies, and disability studies [28]. Therefore, implicit bias empirical research and curricula training development lends itself well to interprofessional collaboration and practice (ICP).

The main characteristics of ICP allow for implicit and explicit biases to be addressed by the interprofessional team. One of the core features of ICP is sharing—professionals from different disciplines share their philosophies, values, perspectives, data, and strategies for planning of interventions [29]. ICP also involves the sharing of roles, responsibilities, decision making, and power [30]. Everyone on the team employs their expertise, knowledge, and skills, working collectively on a shared, patientcentered goal or outcome [30; 31].

Another feature of ICP is interdependency. Instead of working in an autonomous manner, each team member's contributions are valued and maximized, which ultimately leads to synergy [29]. At the heart of this are two other key features: mutual trust/respect and communication [31]. In order to share responsibilities, the differing roles and expertise are respected.

Experts have recommended that a structural or critical theoretical perspective be integrated into core competencies in healthcare education to teach students about implicit bias, racism, and health disparities [32]. This includes [32]:

- Values/ethics: The ethical duty for health professionals to partner and collaborate to advocate for the elimination of policies that promote the perpetuation of implicit bias, racism, and health disparities among marginalized populations.
- Roles/responsibilities: One of the primary roles and responsibilities of health profes-sionals is to analyze how institutional and organizational factors promote racism and implicit bias and how these factors contribute to health disparities. This analysis should extend to include one's own position in this structure.
- Interprofessional communication: Ongoing discussions of implicit bias, perspective taking, and counter-stereotypical dialogues should be woven into day-to-day practice with colleagues from diverse disciplines.
- Teams/teamwork: Health professionals should develop meaningful contacts with marginalized communities in order to better understand whom they are serving.

Adopting approaches from the fields of education, gender studies, sociology, psychology, and race/ethnic studies can help build curricula that represent a variety of disciplines [33]. Students can learn about and discuss implicit bias and its impact, not simply from a health outcomes perspective but holistically. Skills in problem-solving, communication, leadership, and teamwork should be included [33].

# SOCIAL DETERMINANTS OF HEALTH

Social determinants of health are the conditions in the environments where people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks. These circumstances are shaped by the distribution of money, power, and resources at global, national, and local levels. Healthy People 2030 groups social determinants of health into five categories [34]:

- Economic stability
- Education access and quality
- Health care access and quality
- Social and community context
- Neighborhood and built environment

These factors have a major impact on people's health, wellbeing, and quality of life. Examples of social determinants of health include [34]:

- Safe housing, transportation, and neighborhoods
- Racism, discrimination, and violence
- Education, job opportunities, and income
- Access to nutritious foods and physical activity opportunities
- Polluted air and water
- Language and literacy skills

Social determinants of health also contribute to wide health disparities and inequities. For example, people who lack access to grocery stores with healthy foods are less likely to have good nutrition, which raises the risk of heart disease, diabetes, and obesity and lowers life expectancy compared with those who have easier access to healthy foods [34].

Promoting healthy choices will not eliminate these and other health disparities. Instead, public health organizations and their partners must take action to improve the conditions in people's environments. Healthcare providers play a role by identifying factors affecting the health of their patients, providing resources (when appropriate), and advocating for healthy environments.

# ECONOMIC STABILITY

In the United States, 1 in 10 people live in poverty, and many people are unable afford healthy foods, health care, and housing. People with steady employment are less likely to live in poverty and more likely to be healthy, but many people have trouble finding and keeping a job. People with disabilities, injuries, or chronic conditions (e.g., arthritis) may be especially limited in their ability to work. In addition, many people with steady work still do not earn enough to afford the things they need to stay healthy [34]. Employment programs, career counseling, and high-quality childcare opportunities can help more people find and keep jobs. In addition, policies to help people pay for food, housing, health care, and education can reduce poverty and improve health and well-being [34].

# HEALTH CARE ACCESS AND QUALITY

Many people in the United States are unable to access the healthcare services they need. About 1 in 10 people in the United States lack health insurance, and people without insurance are less likely to have a primary care provider and be able to afford the healthcare services and medications they need. Strategies to increase insurance coverage rates are critical for making sure more people get important healthcare services, including preventive care and treatment for chronic illnesses [34].

In some cases, patients are not recommended health care services (e.g., cancer screenings) because they do not have a primary care provider or because they live too far away from healthcare providers who offer them. Interventions to increase access to healthcare professionals and improve communication—in person or remotely—can help more people get the care they need [34].

### SOCIAL AND COMMUNITY CONTEXT

People's relationships and interactions with family, friends, co-workers, and community members can have a major impact on their health and well-being. Many people face challenges and dangers they are not able to control, including unsafe neighborhoods, discrimination, or trouble affording the things they need. This can have a negative impact on health and safety throughout life.

Positive relationships at home, at work, and in the community can help reduce these negative impacts. But some people (e.g., children whose parents are in jail, adolescents who are bullied) often do not get support from loved ones or others. Interventions to help people access the social and community support they need are critical for improving health and well-being [34]. Healthy People 2030 objectives in this category focus on increasing the proportion of children and adolescents who have an adult they can talk to about serious problems, improving community health literacy, increasing the likelihood that an individual talks to friends or family about their health, and expanding access to online healthcare services [34].

# BARRIERS TO PROVIDING CARE

Culturally diverse patients experience a variety of barriers when seeking health and mental health care, including:

- Immigration status
- Lower socioeconomic status
- Language barriers
- Cultural differences

- Lack of or poor health insurance coverage
- Fear of or experiences with provider discrimination
- Mistrust of healthcare systems

Such obstacles can interfere with or prevent access to treatment and services, compromise appropriate referrals, affect compliance with recommendations, and result in poor outcomes. Culturally competent providers build and maintain rich referral resources to meet patients' assorted needs.

Encountering discrimination when seeking health or mental health services is a barrier to optimal care and contributor to poorer outcomes in under-represented groups. Some providers will not treat patients because of moral objections, which can affect all groups, but particularly those who are gender and/or sexual minorities, religious minorities, and/or immigrants. In fact, in 2016, Mississippi and Tennessee passed laws allowing health providers to refuse to provide services if doing so would violate their religious beliefs [35]. However, it is important to remember that providers are obligated to act within their profession's code of ethics and to ensure patients receive the best possible care.

# BEST PRACTICES FOR CULTURALLY RESPONSIVE CARE

The U.S. Department of Health and Human Services has outlined steps important to incorporate in evaluation and treatment planning processes to ensure culturally competent clinical and programmatic decisions and skills [36].

The first step is to engage patients. In nonemergent situations, it is important to establish rapport before asking a series of assessment questions or delving deeply into history taking. Providers should use simple gestures as culturally appropriate (e.g., handshakes, facial expressions, greetings) to help establish a first impression. The intent is that all patients feel understood and seen following each interaction. Culturally responsive interview behaviors and paperwork should be used at all times [36].

When engaging in any patient teaching, remember that individuals may be new to the specific language or jargon and expectations of the diagnosis and care process. Patients should be encouraged to collaborate in every step of their care. This consists of seeking the patient's input and interpretation and establishing ways they can seek clarification. Patient feedback can then be used to help identify cultural issues and specific needs. If appropriate, collaboration should extend to include family and community members.

Assessment should incorporate culturally relevant themes in order to more fully understand patients and identify their cultural strengths and challenges. Themes include [36]:

Immigration history

- Cultural identity and acculturation
- Membership in a subculture
- Beliefs about health, healing, and help-seeking
- Trauma and loss

In some cases, it may be appropriate and beneficial to obtain culturally relevant collateral information, with the patient's permission, from sources other than the patient (e.g., family or community members) to better understand beliefs and practices that shape the patient's cultural identity and understanding of the world.

Practitioners should work to identify screening and assessment tools that have been translated into or adapted for other languages and have been validated for their particular population group(s). An instrument's cultural applicability to the population being served should be assessed, keeping in mind that research is limited on the cross-cultural applicability of specific test items or questions, diagnostic criteria, and concepts in evaluative and diagnostic processes [36].

Typically, culturally responsive care establishes holistic treatment goals that include objectives to improve physical health and spiritual strength; utilizes strengths-based strategies that fortify cultural heritage, identity, and resiliency; and recognizes that treatment planning is a dynamic process that evolves along with an understanding of patient history and treatment needs.

In addition to these general approaches, specific considerations may be appropriate for specific populations. While discussion of every possible patient subgroup is outside of the scope of this course, some of the most common factors are outlined in the following sections [36].

# RACIAL BACKGROUNDS

Race and color impact the ways in which individuals interact with their environments and are perceived and treated by others. Race is defined as groups of humans divided on the basis of inherited physical and behavioral differences. As part of the cultural competence process and as a reflection of cultural humility, practitioners should strive to learn as much as possible about the specific racial/ethnic populations they serve [37]. However, considerable diversity exists within any specific culture, race, or ethnicity [37]. Cultural beliefs, traditions, and practices change over time, both through generations and within an individual's lifetime. It is also possible for the differences between two members of the same racial/ethnic group to be greater than the differences between two people from different racial/ethnic groups. Within-group variations in how persons interact with their environments and specific social contexts are also often present.

As with all patients, it is vital to actively listen and critically evaluate patient relationships. All practitioners should seek to educate themselves regarding the experiences of patients who are members of a community that differs from their own. Resources and opportunities to collaborate may be available from community organizations and leaders. Finally, preferred language and immigration/migration status should be considered. Interpreters should be used when appropriate, with adherence to best practices for the use of interpretation services. Stressing confidentiality and privacy is particularly important for undocumented workers or recent immigrants, who may be fearful of deportation.

# **Black Patients**

"Black" or "African American" is a classification that serves as a descriptor; it has sociopolitical and self-identification ramifications. The U.S. Census Bureau defines African Americans or Black Americans as persons "having origins in any of the Black racial groups of Africa" [38].

According to the U.S. Census, African Americans number 46.9 million as of 2020 [39]. By 2060, it is projected they will comprise 17.9% of the U.S. population [40]. This group tends to be young; 30% of the African American population in the United States is younger than 18 years of age. In 2019, the median age for this group was 35 years [41]. In terms of educational attainment, 89.4% of African Americans 25 years of age or older had a high school diploma or completed college in 2020 [39]. Texas has the largest African American population, at 3.9 million [41].

Historical adversity and institutional racism contribute to health disparities in this group. For the Black population, patient assessment and treatment planning should be framed in a context that recognizes the totality of life experiences faced by patients. In many cases, particularly in the provision of mental health care, equality is sought in the providerpatient relationship, with less distance and more disclosing. Practitioners should assess whether their practices connect with core values of Black culture, such as family, kinship, community, and spirituality. Generalized or Eurocentric treatment approaches may not easily align with these components of the Black community [42]. Providers should also consider the impact of racial discrimination on health and mental health among Black patients. Reports indicate that expressions of emotion by Black patients tend to be negatively misunderstood or dismissed; this reflects implicit or explicit biases.

# Asian Patients

As of 2019, 22.9 million Americans identified as Asian [43]. Between 2000 and 2019, Asians experienced the greatest growth compared with any other racial group at 81% [44; 45]. The Chinese group represents the largest Asian subgroup in the United States, and it is projected that this population will grow to 35.7 million between 2015 and 2040 [46; 47]. In 2019, Chinese Americans (excluding Taiwanese Americans) numbered at 5.2 million [43]. They also have the highest educational attainment; 54.6% of Asians 25 years of age or older had a bachelor's degree or higher in 2019 [43].

"Asian" is a single term widely used to describe individuals who have kinship and identity ties to Asia, including the Far East, Southeast Asia, and the Indian subcontinent [48]. This encompasses countries such as China, Japan, Korea, Vietnam,

Cambodia, Thailand, India, Pakistan, and the Philippines. Pacific Islander is often combined with Asian American in census data. The Pacific Islands include Hawaii, Guam, Samoa, Fiji, and many others [48]. There are more than 25 Asian/ Pacific Islander groups, each with a different migration history and widely varying sociopolitical environments in their homelands [49].

Asian American groups have differing levels of acculturation, lengths of residency in the United States, languages, Englishspeaking proficiency, education attainment, socioeconomic statuses, and religions. For example, there are approximately 32 different languages spoken among Asian Americans, and within each Asian subgroup (e.g., Chinese), multiple dialects may be present [49; 50]. In 2019, California had the largest Asian American population, totaling 5.9 million [44].

Recommended best practices when caring for Asian American patients include:

- Create an advisory committee using representatives from the community.
- Incorporate cultural knowledge and maintain flexible attitudes.
- Provide services in the patients' primary language.
- Develop culturally specific questionnaires for intake to capture information that may be missed by standard questionnaires.
- Emphasize traditional values and incorporate traditional practices (e.g., acupuncture) into treatment plans, when appropriate and desired.
- Explore patient coping mechanisms that draw upon cultural strengths.

# Latino/a/x or Hispanic Patients

In 2020, the Hispanic population in the United States numbered 60.6 million [51]. The majority of the Hispanic population in the United States (63.3%) identify themselves as being of Mexican descent [53]. Approximately 27% of the U.S. Hispanic population identify as Puerto Rican, Cuban, Salvadoran, Dominican, Guatemalan, Colombian, Honduran, Ecuadorian, or Peruvian [54].

In 2020, the Hispanic population comprised 18.7% of the U.S. population [51]. As such, they are the largest ethnic minority group in the United States. By 2060, Hispanics are expected to represent 31% of the U.S. population [55]. They are also a young group, with a median age of 29.8 years [51]. In 2019, the three states with the largest Hispanic population growth were Texas (2 million), California (1.5 million), and Florida (1.4 million); these three states have the largest Hispanic populations overall [52].

When involved in the care of Latinx/Hispanic individuals, practitioners should strive to employ *personalismo* (warm, genuine communication) and recognize the importance of *familismo* (the centrality of the family). More flexible scheduling strate-

gies may be more successful with this group, if possible, and some patients may benefit from culturally specific treatment and ethnic and gender matching with providers. Aspects of Latino culture can be assets in treatment: strength, perseverance, flexibility, and an ability to survive.

# Native American Patients

The Native American population is extremely diverse. According to the U.S. Census, the terms "Native American," "American Indian," or "Alaskan Native" refer to individuals who identify themselves with tribal attachment to indigenous groups of North and South America [56]. In the United States, there are 574 federally recognized tribal governments and 324 federally recognized reservations [57].

In 2020, it was reported that there were 7.1 million Native Americans in the United States, which is approximately 2% of the U.S. population [57]. By 2060, this number is projected to increase to 10.1 million, or 2.5% of the total population [57].

In general, this group is young, with a median age of 31 years, compared with the general median age of 37.9 years [58]. As of 2018, the states with the greatest number of residents identifying as Native American are Alaska, Oklahoma, New Mexico, South Dakota, and Montana [59]. In 2016, this group had the highest poverty rate (26.2%) of any racial/ethnic group [58].

Listening is an important aspect of rapport building with Native American patients, and practitioners should use active listening and reflective responses. Assessments and histories may include information regarding patients' stories, experiences, dreams, and rituals and their relevance. Interruptions and excessive questioning should be avoided if at all possible. Extended periods of silence may occur, and time should be allowed for patients to adjust and process information. Practitioners should avoid asking about family or personal matters unrelated to presenting issues without first asking permission to inquire about these areas. Native American patients often respond best when they are given suggestions and options rather than directions.

# White American Patients

In 2021, 76.3% of the U.S. population identified as White alone [60]. The U.S. Census Bureau defines White race as person having origins in any of the original peoples of Europe, the Middle East, or North Africa [38]. While the proportion of population identifying as White only has decreased between 2010 and 2020, the numbers of persons identifying as White and another race/ethnicity increased significantly. The White population in the United States is diverse in its religious, cultural, and social composition. The greatest proportion of this group reports a German ancestry (17%), followed by Irish (13%), English (10%), and Italian (7%) [61].

Providers can assume that most well-accepted treatment approaches and interventions have been tested and evaluated with White American individuals, particularly men. However, approaches may need modification to suit class, ethnic, religious, and other factors.

Providers should establish not only the patient's ethnic background, but also how strongly the person identifies with that background. It is also important to be sensitive to persons multiracial/multiethnic heritage, if present, and how this might affect their family relationships and social experiences. Assumption of White race should be avoided, as White-passing persons of color have their own unique needs.

# **Multiracial Patients**

Racial labels do not always have clear meaning in other parts of the world; how one's race is defined can change according to one's current environment or society. A person viewed as Black in the United States can possibly be viewed as White in Africa. Racial categories also do not easily account for the complexity of multiracial identities. An estimated 3% of United States residents (9 million individuals) indicated in the 2010 Census that they are of more than one race [149]. The percentage of the total United States population who identify as being of mixed race is expected to grow significantly in coming years, and some estimate that it will rise as high as one in five individuals by 2050 [36; 150].

Multiracial individuals often report feeling not fully embraced by any racial or ethnic group, and mistaken identity is a common issue. A small study of multiracial patients assessed their healthcare experiences and noted six commonly encountered microaggressions: mistaken identity, mistaken relationships, fixed forms, entitled examiner, pervasive stereotypes, and intersectionality [144]. It is important to avoid assuming race/ culture based only on appearance and to take into account the patient's self-reported identity.

### RELIGIOUS, CULTURAL, AND ETHNIC BACKGROUNDS

Religion, culture, beliefs, and ethnic customs can influence how patients understand health concepts, how they take care of their health, and how they make decisions related to their health. Without proper training, clinicians may deliver medical advice without understanding how health beliefs and cultural practices influence the way that advice is received. Asking about patients' religions, cultures, and ethnic customs can help clinicians engage patients so that, together, they can devise treatment plans that are consistent with the patients' values [37].

Respectfully ask patients about their health beliefs and customs and note their responses in their medical records. Address patients' cultural values specifically in the context of their health care. For example, one may ask [37]:

- "Is there anything I should know about your culture, beliefs, or religious practices that would help me take better care of you?"
- "Do you have any dietary restrictions that we should consider as we develop a food plan to help you lose weight?"
- "Your condition is very serious. Some people like to know everything that is going on with their illness, whereas others may want to know what is most

important but not necessarily all the details. How much do you want to know? Is there anyone else you would like me to talk to about your condition?"

- "What do you call your illness and what do you think caused it?"
- "Do any traditional healers advise you about your health?"

Practitioners should avoid stereotyping based on religious or cultural background. Each person is an individual and may or may not adhere to certain cultural beliefs or practices common in his or her culture. Asking patients about their beliefs and way of life is the best way to be sure you know how their values may impact their care [37].

The following sections provide a glimpse of the beliefs and practices of the major world religions. This overview is meant only to give a very simple, brief summary of the general ideology of each religion. By no means are all of the rites or beliefs described practiced by all members of each religion; likewise, not all religious rites or beliefs are discussed for each religion. As always, individualized assessment is encouraged.

# Judaism

Judaism emerged in the Southern Levant (an area in the Middle East) in about 2000 B.C.E. [136]. There are approximately 13 million Jewish people in the world–6 million in North America, 4.3 million in Asia, and 2.5 million in Europe [137]. Jewish descent is traced through the maternal line, but the choice to practice Judaism is made by the individual. In Jewish tradition, the Torah is believed to be the word of God and the ultimate authority.

There are three tenets of Judaism. The first tenet is monotheism; there is one God who created the universe and continues to rule [138]. The second tenet is that the Jews were chosen to receive the law of God (Yahweh) and to serve as role models for humankind [138]. The third tenet refers to the covenant, which is a contractual agreement between God and the Jewish people. According to the agreement, they will be rewarded if they obey God and keep his commandments; failing to do so would result in divine retribution. Also, they believe that studying the Torah and faithfulness to God and his commandments may hasten the arrival of the Messiah [136; 138].

Jewish law focuses on dietary practices, the Sabbath, and annual holidays or festivals. Observing the dietary laws is called keeping kosher. One's home is considered the table of the Lord, and therefore certain animals considered unclean (e.g., pork, shellfish) are not to be eaten. However, animals with split hooves and animals that chew their cud are acceptable. Acceptable animals must be slaughtered correctly, must have the blood drained from them, and must not be served with dairy products. Those who adhere to kosher laws have separate sets of dishes and utensils for preparing and serving meat, dairy products, and Passover meals [138, 139]. Passover, Rosh Hashanah, and Yom Kippur are major festivals observed by members of the faith.

#### Christianity

Christianity emerged in the 1st century C.E. It is the largest religion in North America, and there are approximately 2 billion followers worldwide [136]. There are three major divisions in Christianity: Roman Catholicism, Eastern Orthodoxy, and Protestantism [136; 138]. Christianity is based on the life and teachings of Jesus Christ, and followers believe that salvation and eternal life can be obtained through their belief in Jesus [137]. The concept of the Trinity is also basic to Christian belief. Although God is perceived as one, God is also expressed in three roles: Father (Creator), Son (Redeemer), and the Holy Spirit (Sustainer) [138; 139].

Baptism and the Eucharist or Holy Communion are the primary sacraments celebrated in most Christian churches [138]. Baptism symbolizes the forgiveness of sins, new life, and initiation into the Christian church. During the baptism, persons are either immersed in water or water is sprinkled or poured over them. Eucharist or Holy Communion is a ritual meal in which bread and wine are taken in remembrance of the body and blood of Jesus that was broken and shed at the cross [136]. Major Christian holidays include Easter (commemorating the death and resurrection of Jesus Christ) and Christmas (celebrating the birth of Jesus).

Christians consider the Bible to be the word of God. It is composed of 66 to 81 separate books (depending on denomination). Christians hold various perspectives on the nature, purpose, and approaches to the interpretation of the Bible.

#### Islam

Islam is the fastest-growing religion in the United States and throughout the world [140]. Members of Islam are called Muslims, and approximately 3.45 million live in the United States [140]. Islam began in Arabia around 570–632 C.E. and was founded by the prophet Muhammad. It is a monotheistic religion whose followers believe there is one God and that Muhammad was his last Prophet. They believe the Qur'an (or Koran) is the literal word of God (or Allah in Arabic) that was revealed to Muhammad and mediated by Gabriel, the angel of revelation [138]. Arabic is the language used in Islamic prayer/ liturgy [137]. Major festivals or holidays include Al-Hijra, Milad un Nabi, Ramadan, Eid al-Fitr, Eid al-Adha, Day of Ashura, and Laylatul Qadr.

Most Muslims are of one of two denominations: Sunni and Shia. While various denominations may have slightly different beliefs or translations, Islam has six major doctrines. The first is the belief in divine unity, or tawhid [136; 138]. The second is the belief in angels as agents of God. Angels have many functions, such as carrying messages to prophets and watching over and keeping track of people. The third is a belief in prophecy as revealed in the Qur'an. The fourth involves belief in scripture (Qur'an), and the fifth is the belief in Judgment Day and life after death [136; 138]. On the Last Day (or final judgment), both the living and the dead will be judged. The faithful will be rewarded, and the unfaithful will be cast into hell. Finally, the sixth doctrine is the Divine Decree and Predestination. It suggests that Allah has already determined who will receive eternal salvation [136; 138].

The Five Pillars are the core beliefs and practices of Islam. The first is the Shahada (profession of faith)-the belief that there is no god but Allah, and Muhammad is his messenger [136]. The second pillar is the Salat (ritual prayer). Muslims pray facing Mecca five times every day: at dawn, noon, midafternoon, sunset, and evening [138]. The prayers are usually performed on a rug or mat specifically for this purpose. Zakat (almsgiving) is the third pillar of Islam. Muslims are expected to donate a certain portion of their income to community members in need [138]. Sawm (or fasting) is the fourth pillar of Islam. During the daylight hours of Ramadan, healthy adult Muslims are expected to abstain from food, drink, and sexual relations. This is a time of reflecting, renewing faith, and being grateful for everything Allah has given [138]. The fifth pillar of Islam is Hajj (pilgrimage). After 16 years of age, every Muslim in good health and whose finances permit is expected to visit the holy city of Mecca, located in present-day Saudi Arabia.

# Hinduism

Hinduism is one of the world's oldest religions, dating back to about 1500 B.C.E. [138]. Unlike other major religions, it was not founded by a single person but was born of many religious beliefs and philosophies [138]. Hinduism originated in India, and today it is the third-largest religion in the world. There are approximately 1.1 billion adherents worldwide and 2.3 million adherents in the United States [141]. Hinduism is a polytheistic religion with three major deities: Shiva, Vishnu, and Brahma [138]. There are many sacred texts in Hinduism, including The Ramayana, an epic tale of Lord Rama's victory over the 10-headed demon Ravana, and The Mahabharata, the world's longest epic poem that is an historical account of the birth of Hinduism along with a code of ethics for the faithful [136]. Major Hindu festivals include Makar Sankranti, Holi, Diwali, Mahashivratri, Vasant Panchami, Rama Navami, and Janmashtami/Krishna Jayanti.

Two concepts are central to Hinduism: karma and reincarnation. Karma refers to the spiritual principle of cause and effect. In short, people's circumstances are the result of present and past-life actions of good or evil [136]. Hindus also believe in the continuous cycle of life, death, and rebirth (reincarnation) that continues until the soul "transcends all pain and pleasure and release itself from all fears and attachments" [138]. This state is called samsara or transmigration [138].

The Hindu temple is a cultural center where people come to sing, read sacred texts, and perform rituals [136]. The chanting of mantra called pathas is a traditional Hindu practice and is believed to have transformative power. Puja or daily worship is an important aspect of Hinduism. It entails the offering of food, incense, flowers, fruits, ashes, and other articles to an image of a deity [138]. Tirthas refer to pilgrimage sites and holy places in Hinduism [138].

# Buddhism

There are approximately 3 million Buddhists in the United States and about 488 million worldwide [141]. Buddhism was founded in northeastern India by Siddhartha Gautam, whose name was later changed to the Buddha or Enlightened One. At 29 years of age, the Buddha sought knowledge from several forest yogis and learned meditation techniques. After six years, Buddhists believe Gautama found enlightenment while meditating under a Bodhi tree and was released from the cycle of rebirths [138]. He began promoting the idea of a middle path that focused on purity of thought and deed. Buddha believed awareness was the path to overcoming death [136]. He did not want to be worshiped as a god or savior. Instead, he believed his role was to help people find their path to freedom and enlightenment.

The Four Noble Truths and the Eightfold Path are essential to understanding Buddhism. The Four Noble Truths have been identified as the first teaching given by Buddha [137]:

- There is suffering in life.
- Human desire is the cause of suffering.
- The end of human suffering is possible.
- The Eightfold Path is how one achieves nirvana.

Collectively, the Four Noble Truths explain why humans suffer and how to overcome suffering. Within the Four Noble Truths is found the Eightfold Path. Wangu describes the Eightfold Path as consisting of the right opinion, right intentions, right speech, right conduct, right livelihood, right effort, right mindfulness, and right concentration [138]. These eight paths are grouped into three key elements of Buddhist practice: morality, wisdom, and concentration [138].

Buddhists engage in rituals such as chanting and placing flowers, candles, and incense before an image of Buddha. Buddhists celebrate many holidays and festivals, most of which commemorate important events in the life of the Buddha. Every year, Buddhists celebrate Vesak, a festival that commemorates Buddha's birth, enlightenment, and death. During each quarter of the moon, followers of Buddhism participate in a ceremony called Uposatha [136]. This observance allows Buddhists to renew their commitment to their teachings. Buddhist New Year is a time for reflection of past lives and identifying and rectifying mistakes [136].

# Confucianism

Confucianism is described as a way of life, philosophy, religion, or ethical code by which to live [138]. It was developed from the teachings of Confucius, who was born around 551 B.C.E. [138]. These teachings focus on good conduct, wisdom, and proper social relationships. Confucius has had a great influence on Chinese culture. Although temples were built to honor him, he is not perceived as a god. The temples are used for public ceremonies only and not as places of worship [138].

Confucianism advocates eight key concepts. The first is Jen, which translates as love, human-heartedness, and goodness

[138]. The second concept is Chun-tzu, which refers to a state of centeredness whereby one exhibits Confucians' values effortlessly and without the need for self-monitoring. The third concept is Li, or a sense of order in one's life that coincides with social convention. The fourth concept is Te, or the appropriate use of power by leaders and authority figures. The fifth concept is Wen, which refers to the cultural arts (e.g., music, drama, poetry) that help to maintain unity in society [138]. The remaining concepts are Chi (the wisdom of proper action), Hsin (integrity), and Yi (righteousness or justice).

### Taoism

Taoism (pronounced DOW-ism) is a Chinese philosophy and religion dating back to the fourth century B.C.E. [136]. Tao means "the way," and it has no founder or central figures. Taoists do not worship a god. Instead, they focus on coming into harmony with Tao, the cosmic energy that blows through everything. Taoism emphasizes what is natural and going with the flow of life. Today, there are about 20 million Taoists, and most followers live in China, Taiwan, or Southeast Asia [136].

Meditation is an important practice, and the goal of meditation is to come into harmony with the universe [136]. The philosophy is found in a text, the *Tao-te-Ching* (*Classic Way and Its Power*), dating back to the third century B.C.E. and attributed to Lao Tzu [138].

### Shintoism

Shintoism began during prehistoric times on the Japanese islands [138]. Today, Shinto is the religion of Japan, and it has approximately 112 million followers; more than 75% of them follow Buddhism as well [138]. Like Taoism, Shinto has no founder or central figure. It teaches that all things in the world are imbued with a spirit (kami). Therefore, Shinto followers revere nature in all forms [138].

Most of the deities associated with Shinto are related to nature, such as the sky, earth, heavenly bodies, and storms [136]. However, deities are not different from humans, because everything is imbued with spirit. Everything is connected, including rocks, trees, dust, water, animals, and humans [138].

Shinto has no fixed doctrine and no scripture or sacred text. However, ancient prayers are passed down via oral tradition. Shinto followers worship primarily individually rather than in groups, and followers engage in purification rituals (e.g., handwashing) [138]. Worship occurs outside the shrine, and worshipers usually bring offerings of food or coins for the spirit (*kami*). These offerings are not given as sacrifices but as signs of gratitude [138]. Some followers write prayers on slips of paper and leave them nearby.

# New Age Spirituality

The New Age movement became popular in Western society in the 1970s [142]. The precise definition of the term differs among scholars largely due to its highly eclectic range of spiritual beliefs and practices [142; 143]. The movement takes many shapes and is continually changing. However, there are some
common features that distinguish it from other religions, such as followers who [136]:

- Look forward to a society that reunites the wisdom of both science and religion
- Adopt holistic and alternative healing methods
- Embrace a wide array of traditional and nontraditional spiritual beliefs and practices
- Accept the existence of a universal energy that undergirds and permeates all of existence

Adherents believe healing can occur when individuals connect with this universal energy and learn to use it. This energy has been called by many names by different cultures, including *chi* (Chinese), *ki* (Japanese), *prana* (Sanskrit), *mana* (Pacific Islander), or the use of self as a final authority [136].

#### GENDER

Gender identity is a vital aspect of a person's experience of the world and of themselves. It also impacts the ways in which the world perceives and treats individuals, with a clear effect on the effective provision of health and mental health care. This section will focus on persons presenting as cisgender male or female; special considerations for those who are transgender, non-binary, or gender nonconforming will be explored in the next section.

An increasing amount of research is supporting a relationship between men's risk for disease and death and male gender identity, and the traditional male role has been shown to conflict with the fostering of healthy behaviors [62; 63]. Male gender identity is related to a tendency to take risks, and the predilection for risky behavior begins in boyhood [63; 64; 65]. In addition, boys are taught that they should be self-reliant and independent and should control their emotions, and societal norms for both boys and men dictate that they maintain a strong image by denying pain and weakness [62; 64; 65].

Issues related to male gender identity have several important implications for health. First, risky behavior is associated with increased morbidity and mortality. Second, the concept of masculinity leads to inadequate help- and information-seeking behavior and a reduced likelihood to engage in behavior to promote health [62; 64; 65]. These behaviors appear to be rooted in a decreased likelihood for men to perceive themselves as being ill or at risk for illness, injury, or death [62]. Third, male gender identity, coupled with lower rates of health literacy, creates special challenges for effectively communicating health messages to men [66; 67; 68]. Gender differences in health-related behaviors are consistent across racial/ethnic populations, although specific behaviors vary according to race/ethnicity [63].

Men's beliefs about masculinity and traditional male roles affect health communication, and healthcare practitioners should consider male-specific beliefs and perceptions when communicating with male patients. For example, because men tend to focus on present rather than future health, concepts of fear, wellness, and longevity often do not work well in health messages [69]. Instead, healthcare practitioners should focus more on "masculine" concepts, such as strength, safety, and performance, all of which tie into men's perceptions of their roles as providers and protectors.

Although men are more likely than women to lack a regular healthcare provider and to avoid seeking help or information, women are more likely to have a chronic condition requiring regular monitoring and are more likely to have forgone necessary health care due to the cost [70]. In general, women are disproportionately affected by stresses related to caregiving, and this can be a barrier to help-seeking. Caregiving has been socialized as a feminine role, and two out of every three caregivers in the United States are women, meaning they provide daily or regular support to children, adults, or people with chronic illnesses or disabilities [145]. Women who are caregivers have a greater risk for poor physical and mental health, including depression and anxiety.

Women are more likely than men to be diagnosed with a mental health disorder, and more than 20% of women in the United States experienced a mental health condition in the past year [146]. In addition to being disproportionately affected, mental health conditions, such as depression and bipolar disorder, can manifest differently in or have different impacts on women than men. Much of the research into women's health has focused on the perinatal period, which limits our knowledge of how mental illness affects women's lives.

There is also some evidence that women's pain is less likely to be taken seriously and controlled than male patients. A series of four studies found a relative gender-pain exaggeration bias, wherein perceivers believe women, relative to men, to be emotionally dramatizing and therefore more likely to exaggerate versus downplay their pain [147]. This bias may lead perceivers to interpret women's, relative to men's, pain reports as overstatements, inauthentic, or dramatized.

Providing gender-sensitive care to women involves overcoming the limitations imposed by the dominant medical model in women's health. This requires theoretical bases that do not reduce women's health and illness experience into a disease. This philosophy incorporates explanations of health and empowers women to effectively and adequately deal with their situations. The major components incorporated into the development of sensitive care include:

- Gender is a central feature.
- Women's own voices and experiences are reflected.
- Diversities and complexities are incorporated into women's experiences.
- Theorists reflect about underlying androcentric and ethnocentric assumptions.
- Sociopolitical contexts and constraints of women's experiences are considered.
- Guidelines for practice with specific groups of women are provided.

## GENDER AND SEXUAL MINORITIES

The gender and sexual minority (GSM) population is a diverse group that can be defined as a subculture. It includes homosexual men, lesbian women, bisexual persons, transgender individuals, and those questioning their sexual identity, among others. The GSM population is diverse, representing all ages and all socioeconomic, ethnic, educational, and religious backgrounds. The population has been described as "hidden and invisible," "marginalized," and "stigmatized." As a result, the unique health and safety needs of the population have often been overlooked or ignored. Clear definitions of the concepts related to sexual identity will be helpful. The following is a glossary of terms used in discussions of this group [71; 72; 73; 74; 75; 76]:

Asexual/aromantic: An individual who does not experience sexual attraction. There is considerable diversity in individuals' desire (or lack thereof) for romantic or other relationships.

**Bisexual:** An adjective that refers to people who relate sexually and affectionately to both women and men.

**Coming-out process:** A process by which an individual, in the face of societal stigma, moves from denial to acknowledging his/her sexual orientation. Successful resolution leads to self-acceptance. Coming out is a lifelong process for lesbian, gay, bisexual, and transgender persons and their families and friends as they begin to tell others at work, in school, at church, and in their communities.

**Gay**: The umbrella term for GSM persons, although it most specifically refers to men who are attracted to and love men. It is equally acceptable and more accurate to refer to gay women as "lesbians."

Gender and sexual minorities (GSM): A term meant to encompass lesbian, gay, bisexual, trans, queer/questioning, intersex/intergender, asexual/ally (LGBTQIA) people as well as less well-recognized groups, including aromantic, two-spirited, and gender-fluid persons.

Heterosexism: An institutional and societal reinforcement of heterosexuality as the privileged and powerful norm.

Heterosexuality: Erotic feelings, attitudes, values, attraction, arousal, and/or physical contact with partners of the opposite gender.

Homophobia: A negative attitude or fear of non-straight sexuality or GSM individuals. This may be internalized in the form of negative feelings toward oneself and self-hatred. Called "internalized homophobia," it may be manifested by fear of discovery, denial, or discomfort with being LGBTQIA, low self-esteem, or aggression against other lesbians and gay men.

Homosexuality: The "persistent sexual and emotional attraction to members of one's own gender" as part of the continuum of sexual expression. Typically not used to describe people. LGBTQIA: An acronym used to refer to the lesbian, gay, bisexual, transgender/transsexual, queer/questioning, intersex/intergender, asexual/ally community. In some cases, the acronym may be shortened for ease of use or lengthened for inclusivity. Members of this group may also be referred to as gender and sexual minorities (GSM).

**Queer:** An umbrella term to describe persons with a spectrum of identities and orientations that are outside of the heteronormative standard.

**Sexual identity**: The inner sense of oneself as a sexual being, including how one identifies in terms of gender and sexual orientation.

Sexual orientation: An enduring emotional, romantic, sexual, and/or affectionate attraction to another person. Individuals may experience this attraction to someone of the same gender, the opposite gender, both genders, or gender nonconforming.

**Transgender**: An umbrella term describing a number of distinct gender positions and identities including: crossdressing, transsexual, nonbinary, and intersex.

One's intrapersonal acceptance or rejection of societal stereotypes and prejudices, the acceptance of one's self-identity as a sexual minority, and how much one affiliates with other members of the GSM community varies greatly among individuals [77]. Some authors stress the diversity within the GSM community by discussing "GSM populations" [78]. For example, it is understandable that a GSM population living in rural areas of the United States would have little in common with a GSM population living in urban areas or "gay-friendly" neighborhoods. Additionally, mental health experts have suggested that "GSM community" symbolizes a single group of individuals who express their sexuality differently than the majority of heterosexual individuals. However, many distinct communities have been identified, including lesbian, gay, bisexual, and transgender [79]. Each community is different from the other as well as different from the heterosexual community. A culturally competent healthcare provider should keep this diversity in mind so that vital differences among these smaller groups are not lost when thinking of the GSM population in general.

Commonalities exist among the GSM communities as well. For example, many adolescents, whether gay, lesbian, bisexual, transgender, or questioning their sexual identity, lack sexual minority role models to assist with successful psychosocial development [79].

The subtle and pervasive ways that discomfort with GSM individuals may be manifested have been examined and, in some instances, categorized as "cultural heterosexism," which is characterized by the stigmatization in thinking and actions found in our nation's cultural institutions, such as the educational and legal systems [80]. "Cultural heterosexism fosters individual antigay attitudes by providing a ready-made system of values and stereotypical beliefs that justify such prejudice

as natural" [81]. Perhaps the paucity of information about the GSM community in basic professional education has been a reflection of cultural heterosexism. Writers, funding sources, and publishers have been exposed to the same cultural institutions for many years.

Individuals generally begin to absorb these institutional attitudes as children and may consequently develop "psychologic heterosexism," which may also manifest as antigay prejudice. Many individuals, as children, have little contact with someone who is openly gay and, as a result, may not be able to associate homosexuality with an actual person. Instead, they may associate it with concepts such as "sin," "sickness," "predator," "outsider," or some other negative characteristic from which the individual wants to maintain distance [81]. Psychologic heterosexism involves (among other factors) considering sexual identity and determining that one does not want to think further about it. The direction of this thinking is undeniably negative, resulting in an environment that allows antigay hostility [81]. The impact of antigay prejudice on the physical and mental health of members of the LGBTQIA community and their families should not be underestimated [82; 83].

Sexual minority individuals also are not immune to societal attitudes and may internalize negative aspects of the antigay prejudice experience. Anxiety, depression, social withdrawal, and other reactions may result [2, 84]. While the study of psychologic heterosexism, both blatant and subtle, is in the early stages of research, it has had a measurable impact on the mental health of the GSM community [85; 86; 87; 88].

Examples of the range of manifestations of heterosexism and/ or homophobia in our society are readily available. Without difficulty, each example presented here may be conceptualized as related to the emotional or physical health of a GSM individual or family member:

- A kindergarten student calls another child an LGBTQ+ slur but does not really know what he is saying.
- A teenage girl allows herself to become pregnant, "proving" her heterosexuality to herself, her family, and her friends.
- A parent worries that her 12-year-old daughter is still a "tomboy."
- An office employee decides to place a photo of an old boyfriend in her office rather than a photo of her gender-nonconforming partner of five years.
- A college student buries himself in his studies in an effort to ignore his same-sex feelings and replace feelings of isolation.
- Two teenage girls, thought by peers to be transgender individuals, are assaulted and killed while sitting together in an automobile.
- A female patient is told by a healthcare provider that her haircut makes her look like a lesbian and is examined roughly.

• A gay man chooses not to reveal his sexual identity to his healthcare provider out of fear of a reduction or withdrawal of healthcare services.

The manifestations of heterosexism have inhibited our learning about the LGBTQIA population and its needs [78]. Gay patients have feared open discussion about their health needs because of potential negative reactions to their self-disclosure. Prejudice has impacted research efforts by limiting available funding [77]. All of these factors emphasize that the healthcare education system has failed to educate providers and researchers about the unique aspects of LGBTQIA health [83; 89].

#### Common Myths

Many myths surround homosexuality; a few are outlined below. The origin of these myths may be better understood after examining the history of homosexuality as well as the attitudes toward human sexuality in general. The history of the development of societal norms related to homosexuality includes misconceptions developed during times when research was not available on which to build a scientific knowledge base [82; 90; 91; 92].

Myth: Sexual orientation is a choice.

Fact: No consensus exists among scientists about the reasons that an individual develops his/her sexual orientation. Some research has shown that the bodies and brains of gay men and women differ subtly in structure and function from their heterosexual counterparts; however, no findings have conclusively shown that sexual orientation is determined by any particular factor or set of factors. Many people confuse sexual orientation with sexual identity. The reader may consider reviewing the definitions of these terms when further considering this myth.

Myth: Gay men and lesbians can be easily identified because they have distinctive characteristics.

Fact: Most gay and lesbian individuals conform to the majority of society in the way they dress and act. Further, a person's appearance is not necessarily an indication of sexual or romantic interests.

Myth: Gay individuals are child molesters.

Fact: This is a very damaging and heterosexist position. According to experts in the field of sexual abuse, the vast majority of those who molest children are heterosexual. The average offender is a White heterosexual man whom the child knows.

Myth: Gay people want to come into our schools and recruit our children to their "lifestyle."

Fact: Efforts to bring issues related to LGBTQIA history and rights into schools are not efforts to "convert," just as education on European history is not an effort to glamorize or "convert" to European identity. The intent has been to teach a more complete history of the world and to prevent children from mistreating LGBTQIA individuals, who are often the subjects of harassment and physical attacks. There is no evidence that people could be "recruited" to a gay sexual orientation, even if someone wanted to do this.

## AGE

Elderly patients should be routinely screened for health and mental health conditions using tools specifically developed for this population, in spite of some practitioners' discomfort with asking questions about sensitive topics. These populationappropriate assessments may be included in other health screening tools [93].

Wellness and purpose have become important emphases when working with older adults [94]. In the past, aging was associated with disability, loss, decline, and a separation from occupational productivity. Although patient growth and positive change and development are values that practitioners embrace, the unconscious acceptance of societal myths and stereotypes of aging may prevent practitioners from promoting these values in elderly individuals [95].

## Common Myths of Aging

Society holds several myths about the elderly. Many of these myths may be easily disputed based on data from the U.S. Census and other studies.

Myth: Most older adults live alone and are isolated.

Fact: In 2018, 70% of men and 46% of women 65 years and older were married. An estimated 28% lived alone [96]. According to a survey conducted in 2009, 9 out of 10 individuals 65 years of age and older stated they talked to family and friends on a daily basis [97]. In 2016, an estimated 20% of the U.S. population lived in a household comprised of two adult generations or a grandparent or at least one other generation, compared with 12% in 1980 [97; 98]. This multigenerational household trend particularly affects those 65 years and older, with 21% of these individuals living in multigenerational households in 2016. This group was second only to individuals 25 to 29 years of age (33%) [98]. Several factors have contributed to this trend, including growing racial and ethnic diversity and adults getting married later [97; 98].

#### Myth: Most older adults engage in very minimal productive activity.

Fact: In 2016, 18.6% of persons 65 years and older were employed or actively looking for work, and this population represents approximately 8% of the total labor force in the United States [99]. The elderly are more engaged in self-employed activities than younger persons. In 2016, 16.4% of those 65 years of age and older were self-employed, compared with an average of 5.5% of those 16 years to 64 years of age [100].

#### Myth: Life satisfaction is low among the elderly.

Fact: Data from the Berkeley Older Generation Study indicate that many elders are quite satisfied with their life [101]. More than one-third (36%) of persons older than 59 years of age and 15% of those older than 79 years of age stated they were currently experiencing the best time in their lives. A 2009 survey found that 60% of individuals 65 years of age and older stated they were very happy. A 2012 survey found that 65% of individuals 65 years of age and older indicated that the past year of their life has been normal or better than normal, and more than 80% of respondents agreed with the statement, "I have a strong sense of purpose and passion about my life and my future" [102]. Most of the factors that predict happiness for the young, such as good health and financial stability, also apply to the elderly. Older adults tend to report higher levels of well-being in part due to the quality of their social relationships [103].

## PERSONS WITH MENTAL OR PHYSICAL DISABILITY

Americans with disabilities represent a large and heterogeneous segment of the population. The prevalence of disability varies by age group and definition. Based on the U.S. Census Bureau's 2013 American Community Survey (ACS), which describes disability in terms of functional limitations, 12.6% of the civilian U.S. noninstitutionalized population has a disability, defined as difficulty in hearing or vision, cognitive function, ambulation, self-care, or independent living [104]. The U.S. Department of Education, which uses categorical disability labels, estimates that 13% of children and youth 3 to 21 years of age have a disability (defined as specific learning disabilities, speech or language impairments, intellectual disability, emotional disturbance, hearing impairments, orthopedic impairments, other health impairments, visual impairments, multiple disabilities, deaf-blindness, autism, traumatic brain injury, or developmental delay) [104].

People with disabilities experience many health disparities. Some documented disparities include poorer self-rated health; higher rates of obesity, smoking, and inactivity; fewer cancer screenings (particularly mammography and Pap tests); fewer breast-conserving surgeries when breast cancer is diagnosed; and higher rates of death from breast or lung cancer [104].

Disability cultural competence requires appreciation of social model precepts, which recognize patients' rights to seek care that meets their expectations and values. The social model of disability has been characterized as centering disability as a social creation rather than an attribute of the patient [105]. As such, disability requires a social/political response in order to improve environmental factors affecting access and acceptance [105]. This involves adoption of person-first language, acknowledgement of social and environmental factors impacting persons abilities, and confronting disability-associated stigma.

# VETERANS

The effects of military service and deployment to military combat on the individual and the family system are wide-reaching. According to the U.S. Department of Defense, there were 3.5 million current military personnel in 2020 and 18.3 million veterans in 2017 [132; 133]. The Army has the largest number of active duty members, followed by the Navy, the Air Force, and the Marine Corps [132]. Military service presents its own set of risk and protective factors for a variety of mental health issues, including post-traumatic stress disorder (PTSD), traumatic brain injury (TBI), depression and suicide, substance

abuse, and interpersonal violence. In particular, transitioning from combat back to home life can be particularly trying for veterans and their families.

As the number of military conflicts and deployments has increased since 2001, the need to identify and provide better treatment to veterans and their families has become a greater priority. The first step in providing optimal care is the identification of veterans and veteran families during initial assessments, with an acknowledgement that veterans may be any sex/gender and are present in all adult age groups [133].

Unfortunately, veterans and military families often do not voluntarily report their military service in healthcare appointments. In 2015, the American Medical Association updated its recommendations for social history taking to include military history and veteran status [134]. In addition, the American Academy of Nursing has designed the Have You Ever Served? Initiative to encourage health and mental health professionals to ask their patients about military service and related areas of concern [135]. This program provides pocket cards, posters, and resource links for professionals working with veterans and their families. Recommended questions for intake include [135]:

- Have you or has someone close to you ever served in the military?
- When did you serve?
- Which branch?
- What did you do while you were in the military?
- Were you assigned to a hostile or combative area?
- Did you experience enemy fire, see combat, or witness casualties?
- Were you wounded, injured, or hospitalized?
- Did you participate in any experimental projects or tests?
- Were you exposed to noise, chemicals, gases, demolition of munitions, pesticides, or other hazardous substances?

#### DIETARY CONSIDERATIONS

Cultural or personal beliefs can also impact the dietary needs of patients, which, in turn, can affect their health and adherence to prescribed treatments. For example, health issues related to fasting may arise among Buddhists, Hindus, Muslims, and some Christian patients, as well as persons of other faiths. This may particularly become an issue during extended fasts, such as the Muslim observance of Ramadan, which continues for one month [148]. Fasting is done during Ramadan as a spiritual exercise and is mandatory for all healthy adults. Those exempt from Ramadan fasting include children (prior to the onset of puberty); developmentally disabled individuals; the elderly; those who are acutely or chronically ill, for whom fasting would be detrimental to health; travelers who have journeyed more than approximately 50 miles; and pregnant, menstruating, or breastfeeding women [148]. Practitioners should advise all patients for whom fasting would prevent healing or adequate care (e.g., inability to take medication) to postpone or abstain from the ritual, if possible [148].

Another dietary consideration for some patients is whether medications contain animal-sourced ingredients. Vegetarians, vegans, Jewish people, Muslims, and others may need to know which products are from animal sources. Common examples of meds that contain ingredients from animals include:

- Desiccated thyroid from pig thyroid glands
- Heparin from pig intestines
- Pancreatic enzymes from pig pancreases
- Certain vaccines grown in eggs
- Conjugated estrogens from pregnant mares' urine

In addition, the gelatin used to make capsules and even some tablets and vaccines is often hydrolyzed collagen from animal tissues. Over-the-counter medications and supplements that may have animal-source ingredients include glucosamine (from shellfish), vitamin D3 (from lanolin, or sheep's wool), calcium (from oyster shells or bone meal), and omega-3 fatty acids (from fish oils).

# PROMOTING CULTURALLY SENSITIVE COMMUNICATION

Communication, the process of sending a message from one party to another, consists of both verbal and nonverbal components. Verbal and nonverbal communications are embedded within the culture of the parties disseminating the information. Communication is complex and multilayered because it involves unstated, implicit rules about a variety of factors, including physical distance between parties, tone of voice, acceptable topics of discussion, physical contact, and amount of eye contact [106]. Each of these variables is influenced by the perception of the level of formality/informality of the situation. Frequently, misunderstandings occur because the decoding and interpretation of these nonverbal cues are not accurate.

The verbal component of communication is just as complicated. Certainly, similarity in language shared by both parties enhances communication, but assuming that both parties in a conversation speak the same language, how the information is interpreted is still influenced by a host of factors. Linguists have posited that approximately 14,000 different meanings and interpretations can be extracted from the 500 most common English words [107]. Consequently, practitioners must be aware of the different communication styles held by diverse ethnic minority patients, as the clinical communication process is the primary vehicle by which problems and solutions are identified and conveyed [108].

Styles of communication can be classified from high- to lowcontext [109]. High-context cultures are those cultures that disseminate information relying on shared experience, implicit messages, nonverbal cues, and the relationship between the two parties [107; 110]. Members of these cultural groups tend to listen with their eyes and focus on how something was said or conveyed [106; 109]. On the other hand, low-context cultures rely on verbal communication or what is explicitly stated in the conversation [107]. Consequently, low-context communicators listen with their ears and focus on what is being said [106; 109; 110]. Western culture, including the United States, can be classified as a low-context culture. On the other hand, groups from collectivistic cultures, such as Asian/Pacific Islanders, Hispanics, Native Americans, and African Americans, are from high-context cultures [109].

Communicators from high-context cultures generally display the following characteristics [106; 107; 110; 111]:

- Use of indirect modes of communication
- Use of vague descriptions
- Less talk and less eye contact
- Interpersonal sensitivity
- Use of feelings to facilitate behavior
- Assumed recollection of shared experiences
- Reliance on nonverbal cues such as gestures, tone of voice, posture, voice level, rhythm of speaking, emotions, and pace and timing of speech
- Assimilation of the "whole" picture, including visual and auditory cues
- Emotional speech
- Use of silence
- Use of more formal language, emphasizing hierarchy between parties

On the other hand, low-context communicators can typically be described as [106; 107; 110]:

- Employing direct patterns of communication
- Using explicit descriptions and terms
- Assuming meanings are described explicitly
- Utilizing and relying minimally on nonverbal cues
- Speaking more and often raising their voices (more animated, dramatic)
- Often being impatient to get to the point of the discussion
- Using more informal language; less emphasis on hierarchy, more equality between parties (more friendly)
- Being more comfortable with fluidness and change

 Uncomfortable using long pauses and storytelling as a means of communicating

Understanding the distinctions between individuals who come from high- and low-context cultures can promote cultural sensitivity. However, it is vital that practitioners take heed of several words of caution. First, it is important not to assume that two individuals sharing the same culture (e.g., low-context culture) will automatically have a shared script for communicating. Second, it is important to not immediately classify an individual into a low- or high-context culture because of their ethnicity. A Chinese American man may not necessarily be a high-context communicator because he is Asian. A host of factors, such as level of acculturation, upbringing and socialization, education, and family immigration history, will all play a role in how one learns to communicate. Third, a major criticism of the discussion of low-/high-context cultures is that they reinforce dualism and ultimately oversimplify the complexities and nuances of communication [112].

Learning to communicate effectively also requires an understanding of how different conversational traits influence the communication process, or how information is conveyed and interpreted. Again, the goal of this section is not to simply dichotomize individuals' conversational styles into categories, but rather to understand the factors that play a role in how someone makes a decision on how to communicate [106].

As long as there are two parties involved in a conversation, nonverbal communication is inevitable, and it becomes salient particularly when it is processed from one culture to another. Nonverbal communication is any behavior (including gestures, posture, eye contact, facial expressions, and body positions) that transcends verbal or written forms of communication [113]. Nonverbal communication can enhance or reinforce what is said verbally, and conversely, it can completely contradict the message communicated verbally. It can also end up replacing what was verbally communicated if both parties do not share a native language [114].

In Western culture, communication is more direct and eye contact is highly valued. When eye contact is not maintained, many Westerners assume that the party is hiding pertinent information. However, in some cultures, reducing eye contact is a sign of respect [108]. Conversely, patients may interpret direct and indirect gazes differently. For example, in one study, Japanese individuals tended to rate faces with a direct gaze as angry and less pleasant compared with Finnish participants [115].

The amount of social space or distance between two communicating parties is culturally charged as well. Depending upon the social context, Westerners tend to maintain a distance of about three feet, or an arm's length, in conversations [107]. In a public setting, where both parties are engaged in a neutral, nonpersonal topic, Westerners will feel encroached upon and uncomfortable if an individual maintains a closer conversational distance. However, in other cultures, such as Latino and Middle Eastern, a closer distance would be the

norm [107]. Chung recommends that in a clinical setting the practitioner allow patients to set the tone and social distance [116]. The practitioner can sit first and permit the patient to select where they want to sit.

Cross-cultural communication is by no means simple, and there is no set of rules to merely abide by. Instead, promoting culturally sensitive communication is an art that requires practitioners to self-reflect, be self-aware, and be willing to learn. Therefore, as practitioners become skilled in noticing nonverbal behaviors and how they relate to their own behaviors and emotions, they will be more able to understand their own level of discomfort and comprehend behavior from a cultural perspective [106].

# CULTURALLY SENSITIVE ASSESSMENT GUIDELINES

Practitioners may be categorized as either disease-centric or patient-centric [117]. Disease-centered practitioners are concerned with sign/symptom observation and, ultimately, diagnosis. On the other hand, patient-centered practitioners focus more on the patient's experience of the illness, subjective descriptions, and personal beliefs [117]. Patient-centered practice involves culturally sensitive assessment. It allows practitioners to move assessment and practice away from a pathology-oriented model and instead acknowledge the complex transactions of the individual's movement within, among, and between various systems [118].

Practitioners who engage in culturally sensitive assessment nonjudgementally obtain information related to the patient's cultural beliefs, overall perspective, and specific health beliefs [119]. They also allow the patient to control the timing [120].

The goal is to avoid the tendency to misinterpret health concerns of ethnic minority patients. Panos and Panos have developed a qualitative culturally sensitive assessment process that focuses on several domains [119]. Each domain includes several questions a practitioner may address in order to ensure that he or she is providing culturally responsive care.

Alternatively, Kleinman suggests that the practitioner ask the patient what he or she thinks is the nature of the problem [121]. He highlights the following types of questions that may be posed to the patient [121]:

- Why has the illness/problem affected you?
- Why has the illness had its onset now?
- What course do you think the illness will follow?
- How does the illness affect you?
- What do you think is the best or appropriate treatment? What treatment do you want?
- What do you fear most about the illness and its treatment?

Similar to Kleinman's culturally sensitive assessment questions, Galanti has proposed the 4 Cs of Culture [122]:

- What do you call the problem?
- What do you think caused it?
- How do you cope with the problem?
- What questions or concerns do you have about the problem or treatment?

Pachter proposed a dynamic model that involves several tiers and transactions, similar to Panos and Panos' model [123]. The first component of Pachter's model calls for the practitioner to take responsibility for cultural awareness and knowledge. The professional must be willing to acknowledge that they do not possess enough or adequate knowledge in health beliefs and practices among the different ethnic and cultural groups they come in contact with. Reading and becoming familiar with medical anthropology is a good first step.

The second component emphasizes the need for specifically tailored assessment [123]. Pachter advocates the notion that there is tremendous diversity within groups. Often, there are many intersecting variables, such as level of acculturation, age at immigration, educational level, and socioeconomic status, that influence health ideologies. Finally, the third component involves a negotiation process between the patient and the professional [123]. The negotiation consists of a dialogue that involves a genuine respect of beliefs. The professional might recommend a combination of alternative and Western treatments.

Beckerman and Corbett further recommend that recently immigrated families be assessed for [124]:

- Coping and adaptation strengths
- Issues of loss and adaptation
- The structure of the family in terms of boundaries and hierarchies after immigration
- Specific emotional needs
- Acculturative stress and conflict for each family member

Practitioners should seek to understand the sociopolitical context of the origin country [125]. A migration narrative is also recommended, whereby an individual provides a story of their migration history. Asking about how long the family has been in the United States, who immigrated first, who was left behind, and what support networks are lacking gives the practitioner an overview of the individual's present situation [126]. The theme of loss is very important to explore. Types of losses may include family and friends left behind, social status, social identity, financial resources, and familiarity [126]. For refugees and newly immigrated individuals and families, assessment of basic needs (e.g., food, housing, transportation) is necessary [125].

Culturally sensitive assessment involves a dynamic framework whereby the practitioner engages in a continual process of questioning. Practitioners should work to recognize that there are a host of factors that contribute to patients' multiple identities (e.g., race, gender, socioeconomic status, religion) [127].

# CREATING A WELCOMING AND SAFE ENVIRONMENT

Improving access to care can be facilitated, in part, by providing a welcoming environment. The basis of establishing a safe and welcoming environment for all patients is security, which begins with inclusive practice and good clinician-patient rapport. Shared respect is critical to a patient's feeling of psychological well-being. Security can also be fostered by a positive and safe physical setting. For patients who are acutely ill, both the illness experience and treatment process can produce trauma. This is particularly true if involuntary detainment or hospitalization is necessary, but exposure to other individuals' narratives of experienced trauma or observing atypical behaviors from individuals presenting as violent, disorganized, or harmful to themselves can also be traumatic. As such, care environments should be controlled in a way to minimize traumatic stress responses. Providers should keep this in mind when structuring the environment (e.g., lighting, arrangement of space), creating processes (e.g., layout of appointments or care systems, forms), and providing staff guidance (e.g., nonverbal communication, intonation, communication patterns). During each encounter, the patient's perception of safety is impacted by caretakers and ancillary staff.

Experts recommend the adoption and posting of a nondiscrimination policy that signals to both healthcare providers and patients that all persons will be treated with dignity and respect [128]. Also, checklists and records should include options for the patient defining their race/ethnicity, preferred language, gender expression, and pronouns; this can help to better capture information about patients and be a sign of acceptance to that person. If appropriate, providers should admit their lack of experience with patient subgroups and seek guidance from patients regarding their expectations of the visit. Front office staff should avoid discriminatory language and behaviors. For example, staff should avoid using gender-based pronouns, both on the phone and in person. Instead of asking, "How may I help you, sir?" the staff person could simply ask, "How may I help you?" Offices that utilize electronic health records should have a system to track and record the gender, name, and pronoun of all patients. This can be accomplished by standardizing the notes field to document a preferred name and pronoun for all patients [129]. Some persons who identify as non-binary (i.e., neither or both genders) may prefer that plural pronouns (e.g., they) be used.

Questions should be framed in ways that do not make assumptions about a patient's culture, gender identity, sexual orientation, or behavior. Language should be inclusive, allowing the patient to decide when and what to disclose. Assurance of confidentiality should be stressed to the patient to allow for a more open discussion, and confidentiality should be ensured if a patient is being referred to a different healthcare provider. Asking open-ended questions can be helpful during a history and physical.

The FACT acronym may be helpful for healthcare providers. Providers should:

- Focus on those health issues for which the individual seeks care
- Avoid intrusive behavior
- Consider people as individuals
- Treat individuals according to their gender

Training office staff to increase their knowledge and sensitivity toward persons will also help facilitate a positive experience for patients.

# CONCLUSION

Culture serves as a lens through which patients and practitioners filter their experiences and perceptions. Patients will bring their unique life stories and concerns to the practitioner, and their cultural values and belief systems will inevitably shape how the problem is defined and their beliefs about what is effective in solving the problem. However, the cultural backgrounds and values of patients are not necessarily scripts that define behavior, and when practitioners view culture as a strength and not a pathology, practitioners will be able to more effectively join with patients to mobilize change.

# Customer Information/Answer Sheet/Evaluation insert located between pages 68-69.

# COURSE TEST - #57510 INTERCULTURAL COMPETENCE AND PATIENT-CENTERED CARE

This is an open book test. Please record your responses on the Answer Sheet. A passing grade of at least 70% must be achieved in order to receive credit for this course.

# This 4 CE Credit Hour activity must be completed by September 30, 2026.

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This course meets the Dental Board of California's requirements for 4 units of continuing education. Dental Board of California course #04-3841-00405.

- 1. A nurse acknowledges that she still has a lot to learn about different racial and ethnic minority groups. She is willing to learn from her patients and assume the role of learner. This nurse is demonstrating
  - A) diversity.
  - B) reflexivity.
  - C) explicit bias.
  - D) cultural humility.
- 2. Intersectionality is a term to describe the multiple facets of identity, including race, gender, sexual orientation, religion, sex, and age.
  - A) True
  - B) False
- 3. An alternative way of conceptualizing implicit bias is that an unconscious evaluation is only negative if it has further adverse consequences on a group that is already disadvantaged or produces inequities.
  - A) True
  - B) False

- 4. Which of the following is NOT a risk factor in triggering implicit biases for health professionals?A) Uncertainty
  - B) Cognitive dissonance
  - C) Time pressure to make a rapid decision
  - D) Heavy workload and feeling behind schedule
- 5. All of the following are categories of social determinants, EXCEPT:
  - A) Race
  - B) Economic stability
  - C) Health care access and quality
  - D) Social and community context
- 6. Which of the following has been identified as a core value of Black culture?
  - A) Spirituality
  - B) Community
  - C) Family/kinship
  - D) All of the above
- 7. Native American patients often respond best when they are given directions rather than suggestions and options.
  - A) True
  - B) False

Test questions continue on next page 🗕

#### 8. Male gender identity is related to

- A) risk avoidance.
- B) emotional demonstration.
- C) denying pain and weakness.
- D) teamwork and help-seeking.

#### 9. Cultural heterosexism is characterized by

- A) negative feelings toward oneself and self-hatred.
- B) A negative attitude or fear of non-straight sexuality or GSM individuals.
- C) considering sexual identity and determining that one does not want to think further about it.
- D) the stigmatization in thinking and actions found in cultural institutions, such as educational and legal systems.

# 10. Persons with disability experience higher rates of all of the following, EXCEPT:

- A) Obesity
- B) Smoking
- C) Cancer screening
- D) Breast and lung cancer mortality

# 11. Low-context cultures rely on verbal communication or what is explicitly stated in the conversation.

- A) True
- B) False

# 12. Which of the following is a typical characteristic of communication in high-context cultures?

- A) Use of more informal language
- B) Speaking more and often raising one's voice
- C) Assumption that meanings are described explicitly
- D) Reliance on interpreting eye contact, gestures, and tone of voice

# 13. Which of the following is an attribute of patient-centered practice?

- A) The practitioner focuses on observed signs and symptoms.
- B) The practitioner is concerned with identifying the disease pathology.
- C) The practitioner focuses on the subjective description of the illness.
- D) The practitioner is not influenced by how the client/patient defines the illness.
- 14. The basis of establishing a safe and welcoming environment for all patients is
  - A) security.
  - B) autonomy.
  - C) beneficence.
  - D) maintaining distance.
- 15. It is never appropriate for providers to admit their lack of experience with patient subgroups or to seek guidance from patients.
  - A) True
  - B) False

Be sure to transfer your answers to the Answer Sheet located on the envelope insert located between pages 68–69. DO NOT send these test pages to NetCE. Retain them for your records.

# PLEASE NOTE: Your postmark or facsimile date will be used as your test completion date.

#### Audience

This course is designed for dentists, dental hygienists, and dental assistants.

#### **Course Objective**

The purpose of this course is to provide dental healthcare professionals with a comprehensive update on healthcare-related issues affecting women.

#### Learning Objectives

Upon completion of this course, you should be able to:

- 1. Discuss the role that oral health plays in the overall health of women.
- 2. Describe the oral health manifestations associated with puberty and menstruation.
- 3. Discuss the changes in the oral cavity associated with oral contraceptives and pregnancy.
- 4. Identify the various types of cancer that affect women and describe how cancer treatments relate to women's oral health.
- 5. Describe the role of hormone replacement therapy for the treatment of perimenopausal and menopausal symptoms.
- 6. Identify strategies for the treatment and prevention of osteoporosis.
- 7. Identify dental issues relevant to cardiovascular disease.
- 8. Compare and contrast symptomatology and treatment of sexually transmitted infections.
- 9. Identify the signs of eating disorders that may be identified by dental health professionals.
- 10. Discuss the role of the dental health professional in identifying signs and symptoms associated with domestic violence.

#### Faculty

William E. Frey, DDS, MS, FICD, graduated from the University of California School of Dentistry, San Francisco, California, in 1966. In 1975, he completed residency training in Periodontics and received a Master's degree from George Washington University. Dr. Frey retired from the United States Army Dental Corps in 1989 after 22 years of service. Throughout the course of his professional career, he has continuously practiced dentistry, the first 7 years as a general dentist and the past more than 40 as a periodontist. His military experience included the command of a networked Dental Activity consisting of five dental clinics. In his last assignment, he was in charge of a 38-chair facility. Colonel Frey was selected by the Army to serve on two separate occasions as the Chair of the Periodontal Department in Army General Dentistry Residency Training Programs.

Dr. Frey is the founder and president of Perio Plus, a practice management firm specializing in creating individually-designed hygiene and periodontal care programs for general dentists. He is also the creator of the Inspector Gum patient education series.

#### Faculty Disclosure

Contributing faculty, William E. Frey, DDS, MS, FICD, has disclosed no relevant financial relationship with any product manufacturer or service provider mentioned.

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#### **Designations of Credit**

NetCE designates this activity for 5 continuing education credits.

AGD Subject Code 149.

This course meets the Dental Board of California's requirements for 5 units of continuing education.

Dental Board of California course #05-3841-00382.

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# INTRODUCTION

In the last century, a virtual "knowledge explosion" has taken place with regard to women's health issues. In addition, there have been changes in the roles assumed by women in the home and in the workplace. Alterations and improvements in the pharmacologic and surgical treatment of many women's illnesses and health issues have also impacted outcomes and altered perspectives for long-term well-being and quality of life. For the dental healthcare professional, an expanded appreciation and knowledge of women's health issues means more than just understanding the issues that directly impact oral health. Ongoing research and emerging information investigating possible mechanisms of action and confirming links between oral health and a woman's overall well-being makes it imperative that dental professionals expand their knowledge of medicine. The information in this course has relevance and application to the daily practice of dentistry as conscientious healthcare professionals assume an expanded role in the total care of their patients.

# PERIODONTAL DISEASE OVERVIEW

Periodontal disease is one of the most common of human diseases. It is an infectious condition resulting in the destruction of the supporting apparatus of the teeth, the periodontal ligament, and alveolar bone. Its pathogenesis is inflammatory in nature, initiated by the accumulation of bacteria at or beneath the gingival margin in dental plaques and biofilms. There are an estimated 700 or more bacterial species in residence in the oral cavity. Their accumulation in various combinations and relative proportions create diverse and complex microbiologic communities that persist in great numbers in close proximity to the adjacent soft tissues of the sulcular wall [1; 2].

The inflammatory response produced by these masses of micro-organisms results in an increase in epithelial turnover and a thinning and ulceration of the epithelial lining. The systemic circulation is thereby made accessible to a vast array and quantity of bacterial products, such as lipopolysaccharides (LPS), hydrolytic enzymes, and peptidoglycan fragments. The host response also produces cytokines and biologic mediators, such as interleukins and prostaglandins, in substantial amounts that also have ready access to the systemic circulation [3; 4]. It is reasonable to speculate then that the presence of large numbers of bacteria, their products, and the products of the host response, all with ready access to the systemic circulation, may have an influence on overall health.

# WOMEN'S HEALTH OVERVIEW

In the recent past when healthcare professionals thought about "women's health," their attention focused primarily on the patient's reproductive health. Times have changed. Women are assuming control over the elements and occurrences that may potentially impact their health and wish to make informed choices relative to every aspect of their health care. The definition of women's health has become not merely the absence of illness or disability, but has expanded to a broader, more comprehensive approach, encompassing physical, emotional, spiritual, and social dimensions of total well-being. Women appreciate healthcare professionals who listen and understand the full dimension of their concerns.

Although there are more women than men in the United States, women have long been underrepresented in medical research. To respond to this crucial need, the National Institutes of Health (NIH) in 1990 established the Office of Research on Women's Health (ORWH), which developed a research agenda to correct the gaps of knowledge in women's health. As a result, a record number of studies have been conducted, and more are underway, into areas such as heart disease, female cancers, gynecologic health, and osteoporosis, thus improving both the body of knowledge and therapeutic strategies for gender-specific disorders. The ORWH has specified research priorities for the 21st century that include research on: the health of girls and women across the life span; sex and gender factors; biomedical, behavioral, and psychosocial factors; socioeconomic and geographic factors; women with disabilities; and the advancement of women in biomedical research careers [5].

Oral health is an important part of an individual's general health and well-being. This was a critical conclusion reached in the Surgeon General's report on oral health in America, which was first published in 2000 [6]. There are a number of oral-health issues unique to women, many of which are directly related to shifts in hormone levels during puberty, menses, pregnancy, and menopause [7]. Oral bacteria may also have an influence on a number of systemic illnesses impacting women. There is epidemiologic and clinical evidence of an increased risk of mortality due to stroke, myocardial infarction, and other causes in older patients with periodontal disease; a bidirectional effect between periodontitis and systemic diseases seems to exist [8; 9; 10; 11; 12; 13; 14]. Researchers are continuing to expand and strengthen their understanding of the ways in which periodontitis and other oral-health conditions are associated with specific women's health concerns.

Many of the health problems that affect women today are amenable to community and public health approaches. Dentists, dental hygienists, and dental assistants are in a position to make a difference. Equipped with the information in this course, professionals whose main concern is oral health will expand their knowledge of women's healthcare issues and, with this knowledge, enhance their appreciation and understanding of the challenges women face. They should then be better equipped to identify and counsel their female patients on a number of health-related issues and to assist them in obtaining access and care for all of their health concerns.

# PUBERTY AND MENSTRUATION

The onset of menstruation, or menarche, is the most discernible female benchmark of puberty. Menarche now begins at an earlier age in Western nations, most likely because of improved nutrition and health care; higher relative weight is strongly correlated with the likelihood of having reached menarche at a younger age. Young women in the United States typically experience menarche at 12 or 13 years of age [15].

The members of the dental health team can provide factual information and clarify any myths or misconceptions about menstruation that their young female patients may have. There are also changes associated with menstruation that can have a direct bearing on oral health. When young women enter puberty, the changes in estrogen levels can be reflected by changes in the gingival tissues. The relative proportions of anaerobes in the subgingival plaque may change, coinciding with fluctuations in the normal hormonal cycle. Symptoms of gingivitis often follow a pattern that coincides with the menstrual cycle [16]. Nodular hyperplastic reactions that are histologically similar to inflammatory hyperplasia may take place. These areas frequently involve the interdental papillae and can be very red and exuberant in appearance. Patients with a familial history of juvenile periodontitis should be closely monitored for signs of periodontal disease, and appropriate therapy should be initiated at the earliest possible time. Referral for specialty evaluation is highly recommended [17].

Bleeding can become more extensive after oral surgery during the time of menses, and salivary glands may swell. A small rise in tooth mobility may also be detectable. Many women report that oral aphthous ulcers tend to appear during the luteal phase of their menstrual cycle [18]. These changes, however, are not universal and may vary in severity from one woman to another as levels of estrogen and progesterone fluctuate during the normal cycle. Dentists, hygienists, and dental assistants should educate patients on the importance of good dental hygiene and effective plaque control that can minimize the increase in gingivitis during menses.

Dysmenorrhea, or painful menstruation, usually occurs at or one day prior to the onset of menstruation and decreases during the menstrual cycle. Primary dysmenorrhea is painful menstruation with no detectable organic disease. Prostaglandins, produced by the uterus in high concentrations during menses, are the primary cause of the cramping pain. These prostaglandins increase uterine contractility and decrease uterine arterial flow, causing ischemia. The chief complaints of women with dysmenorrhea include cramps, abdominal pain, headache, malaise, and fatigue, plus aching in the back and thighs and gastrointestinal symptoms. Drug therapy

includes prostaglandin inhibitors such as ibuprofen (e.g., Advil, Motrin), naproxen (e.g., Anaprox, Naprosyn, Aleve), and oral contraceptives [19]. Nonpharmacologic treatments include moderate exercise, rest, applications of moderate heat to the abdomen, balanced nutrition, and biofeedback.

Secondary dysmenorrhea is associated with pelvic pathology. Conditions that most frequently contribute to secondary dysmenorrhea include endometriosis, pelvic inflammatory disease (PID), uterine prolapse, or the presence of an intrauterine device (IUD). Because primary and secondary dysmenorrhea may coexist, an accurate differential diagnosis is important [19].

Premenstrual syndrome (PMS) is a cluster of symptoms that occurs two to three days before the onset of menstruation and then disappears during the first few days of the menstrual period. While the symptoms can vary greatly among women, they follow a consistent pattern of timing and symptomatology in each individual. Clinicians recommend that women keep a log for three months, which allows their individual patterns of PMS to be identified with greater accuracy, and thus appropriate therapeutic regimens can be recommended. Nonpharmacologic treatments include decreasing sodium and sugar intake, restricting caffeine, and performing regular exercise. Supplemental vitamin therapy, including B-complex vitamins, and especially B6, is effective for some individuals. Other pharmacologic treatments include prostaglandin inhibitors and diuretics [20]. Sleep and rest are important as well.

# GYNECOLOGIC HEALTH

# YEAST INFECTIONS

Vaginitis is caused by a wide variety of organisms. These organisms can produce symptoms such as burning, itching, and vaginal discharge. Asymptomatic colonization may occur as well. Trends suggest that the incidence of yeast infections in particular is increasing, in part because of the widespread use of antimicrobial therapy. An estimated 75% of women will have at least one episode of vulvovaginal candidiasis, and 40% to 50% will have two or more episodes [21]. The organism most often responsible for vulvovaginal candidiasis is the fungus *Candida albicans*. Other species (e.g., *C. glabrata* and *C. tropicalis*) may also cause vulvovaginal candidiasis is also commonly called moniliasis or referred to as a yeast infection [21; 23; 24; 25].

A growing number of healthy, asymptomatic women now harbor *C. albicans*. A change in the vaginal environment and pH may cause the candida organisms to grow, resulting in the symptoms of vaginitis. The risk of yeast infections increases when women take an antibiotic for an infection in another part of the body that inadvertently impacts the balance of the normal flora of the vagina. Because these bacteria, by their presence, limit growth of *Candida*, their elimination may result in proliferation and the clinical signs and symptoms of a yeast infection [21; 22; 23; 24; 26].

This issue is particularly relevant for dentists if they routinely prescribe broad-spectrum antibiotics. As a result of research and education efforts, most dentists, as well as many of their patients, are aware of the risk of the development of a yeast infection when using broad-spectrum antimicrobial agents. Subsequently, these drugs are being prescribed less often than in the past. It is important to note that some women are more prone to develop yeast infections than other women and may do so even when antibiotics are not taken.

## Treatment

Over-the-counter antifungal medications (e.g., clotrimazole, miconazole nitrate) are available [21]. These medications are convenient and economical for women who are well informed on the etiology and symptoms of fungal infections. If the vulva is also infected, a cream is available for topical application in addition to the intravaginal insertions. Yeast infections may be treated for three to seven days with these agents. An infection that does not respond to topical treatment might respond to prescription medications, such as fluconazole, which is a 150mg pill given in a one-time dose [21]. Candidiasis itself does not pose a serious health risk; however, any infection that does not respond to treatment should be taken seriously [21; 24]

# ENDOMETRIOSIS

Endometriosis is a condition in which cells from the uterine lining are found in other locations within the pelvic cavity. In women with endometriosis, endometrial cells have traveled through the fallopian tubes and implanted on other structures, such as the bladder, rectum, ovaries, and the outside surfaces of the uterus, vulva, and vagina. The exact incidence of endometriosis is unknown, but as many as 33% of women seen for pelvic pain, infertility, or pelvic mass are ultimately diagnosed with endometriosis [27]. The symptoms are caused by changes in the endometrial patches with the hormonal cycle. These patches thicken and bleed just like normally functioning endometrial tissues. The symptoms increase in severity over the years as the patches grow. Women with endometriosis often complain of pain, pelvic heaviness, hypermenorrhea, and pain radiating to the thighs. Scar tissue, infertility, and distortion or blockage of the affected structures may result.

The diagnosis of endometriosis is confirmed by laparoscopic identification of the patches. Treatment options vary, depending on the severity of the condition and the woman's childbearing choices. Because endometriosis may cause infertility, treatment should not be greatly delayed when childbearing is desired. Oral contraceptives are often helpful, as is treatment with danazol. Mild endometriosis is treated by surgically removing the endometrial patches. Women with severe endometriosis who do not wish to have children may consider hysterectomy [28].

# ORAL CONTRACEPTIVES

Oral contraceptives (OC) are most commonly combinations of a progestational compound, such as norgestimate, and an estrogenic compound, such as ethinyl estradiol. In a general sense, their action mimics pregnancy, but they differ both in composition and action from the hormones that occur naturally. The apparent mode of action is by suppression of gonadotropins through the pituitary-hypothalamic axis, inhibiting ovulation. This hormonal suppression also alters the endometrium, lowering the likelihood of implantation, and affects the consistency of the cervical mucus, preventing sperm from entering the uterus [16; 29].

There is an increased risk of several potentially serious conditions for patients taking OC. These include thromboembolism, myocardial infarction, stroke, hepatic neoplasm, and gallbladder disease. The risk, however, is very small in healthy women without other underlying risk factors, such as hypertension, hyperlipidemias, obesity, and diabetes. Smoking is a substantial risk factor in the incidence of myocardial infarction for patients 35 years of age and older who take OC [30; 31; 32].

Gingival inflammation is a common side effect among women taking birth control pills, apparently due to changes in the microcirculation. There is also an alteration in the relative proportions in the established bacterial flora associated with the intake of these hormones. *Prevotella* species may overgrow disproportionately through a favorable increase in its nutritional supply, as female sex hormones may stereochemically resemble and substitute for the naphthoquinones needed by *Prevotella* [16; 33; 34]. Reports have also shown shifts in the makeup of saliva in women taking OC and other sex hormones. Salivary flow may change as well, with alteration in the rate of parotid and submandibular salivary secretions. There are also conflicting reports of chronic dry mouth in some women [35; 36].

Published studies have indicated a greater incidence of postoperative localized osteitis in women taking OC after they have had their mandibular third molars removed. One retrospective review found that alveolar osteitis occurred in 37.9% of women taking OC and in 8.9% of women not taking OC at the time of third molar extraction [37]. This may be related to the effect that birth control pills have on blood clotting. In one study, 40% of patients experiencing postoperative complications after third molar removal were users of OC [33]. It was speculated that the increase of fibrinolytic activity associated with the use of OC accounted for the high incidence of postoperative complications. Such an increase was speculated to be associated with lysis of the formed clot and subsequent "dry socket" formation. As a result, some researchers have suggested that the risk of developing postextraction osteitis may be reduced by performing extractions on days 23 to 28 of the pill cycle, which are nonestrogenic days [33; 38; 39; 40]. One study found that socket irrigation following extraction significantly increased dry socket formation [41]. A systematic review of surgical techniques suggested that placing platelet

rich plasma or platelet rich fibrin in sockets may reduce the incidence of osteitis [42]. A study evaluating the impact of OC on women's periodontal health found that women who used OC had higher gingival-index scores and clinical attachment loss than nonusers [43].

Birth control pills, once absorbed in the stomach, are conjugated in the liver and enter the intestine in a conjugated, inactive form. The resident gut micro-organisms serve to restore the drug to its active form. It has been postulated that the effect of poorly absorbed, broad-spectrum antibiotics might significantly reduce the gut flora, thereby hindering this "reactivation" and resulting in the ineffectiveness of the drug and perhaps an unplanned pregnancy. The antibiotic effect is controversial. However, for as long as the manufacturer's precautions listed for an antibiotic include its possible effect on OC, it is prudent for all clinicians choosing to prescribe one of these antibiotics to advise their patients of the possible effect. Patients should be counseled to use an alternative form of birth control while taking the antibiotic [44; 45; 46].

# PREGNANCY

A number of changes in the oral cavity have been associated with pregnancy, including caries, perimylolysis, tooth mobility, xerostomia, pregnancy granuloma, and ptyalism/sialorrhea [18]. Perhaps most commonly, the hormonal changes that occur during pregnancy have been linked with gingivitis. Shifts in hormone levels may cause changes in the established microbiota, with overgrowth of certain bacteria species, increases in the ratio of bacterial anaerobes to aerobes, and changes in the proportions of P. intermedia, Bacteroides melaninogenicus, and Porphyromonas gingivalis [18; 47; 48]. Pre-existing subclinical gingivitis may become exacerbated during pregnancy so that clinical signs become apparent, including swelling, redness, bleeding, and tenderness [49]. These signs may begin to be noticeable in the second trimester and peak around the eighth month. Anterior teeth may be more apparently involved than the posterior. Mouth breathing is a potential exacerbating factor. A woman who has poor oral hygiene runs the risk of even greater gingival problems, although gingivitis can develop in women with no changes in their plaque-management behavior. Postpartum studies have shown that after delivery, the mother's level of gingivitis decreases as the constituency of the microbiota changes back to approximate its prepregnancy status. With the inflammation comes an increase in tooth mobility. Xerostomia is also reported in a high percentage of patients.

In a study published in 2010, researchers evaluated the way in which changing hormone levels influenced the gingival tissues in 48 pregnant and 28 nonpregnant women. In analyses of the subjects clinically and microbiologically, the researchers found that the proportions of the subgingival pathogens did not differ during pregnancy but did differ significantly after delivery. Patients who were *P. gingivalis*-positive presented with increased gingival inflammation that was not related to plaque

[48]. Receptors for female sex hormones are located on human gingiva. The presence of progesterone, for example, may lead to greater gingival exudate. The inflammatory response also appears to be triggered as levels of estrogen and progesterone rise [47; 50; 51; 52].

In addition to generalized gingival changes, a solitary, tumorlike growth, frequently referred to as a "pregnancy tumor" or "pregnancy granuloma," may appear. This lesion is often found associated with anterior interdental areas and has a histologic appearance similar to a pyogenic granuloma. Often, the lesion will regress after delivery, so decisions about surgical removal are best delayed until some time postpartum. Also, removal of the lesion during pregnancy may result in a recurrence [18].

Women in their childbearing years should be informed of the increased likelihood of developing gingivitis and other conditions that may accompany pregnancy. Advice on how they might reduce their risk should be given, including increasing the frequency of their visits with their dental hygienist and optimizing the effectiveness of their plaque control.

Some women may experience gestational diabetes. When, through their clinical findings and the reaction to treatment procedures, clinicians suspect that a patient may have diabetes, an expanded heath history should be obtained, with inquiries regarding relatives who may have the disease or whether the patient has experienced diabetes during past pregnancies. Diabetics have a compromised ability to deal with infections, including periodontal disease. Research has also suggested that periodontal disease may influence the course of diabetes and affect glycemic control, with reviews suggesting that the influence is bidirectional [53; 54; 55; 56; 57; 58]. Evidence also is accumulating that periodontitis may play a role in increasing the incidence of new cases of type 2 diabetes and possibly gestational diabetes [57]. Results of a two-year study demonstrated that patients with severe periodontitis at the baseline examination had a sixfold increased risk of poor glycemic control (glycated hemoglobin greater than 9%) at follow-up. An intervention study conducted in 1992 evaluated the effects of scaling and root planing and systemic doxycycline given over a two-week period on glycemic control [53]. The results suggested that there were potential systemic benefits of this approach in treating diabetic patients. Results of one study on 50 patients with diabetes and generalized periodontitis found that scaling and root planing resulted in a statistically significant reduction in the clinical parameters of diabetes [59]. Patients with better-controlled diabetes appear to derive the most benefit [60].

# PRETERM LOW-BIRTH-WEIGHT INFANTS

While infant mortality rates have declined, low birth weight in preterm infants remains a significant cause of infant morbidity and mortality. In spite of increased efforts to diminish these outcomes through preventive interventions during prenatal care that addresses traditional risk factors, these efforts appear to have only a minimal impact on the number of preterm lowbirth-weight (PLBW) infants, with some research indicating weight increases of less than 1% [61]. Researchers are thereby investigating other, previously unrecognized risk factors that may contribute to the continuing prevalence of PLBW infants.

A number of studies have indicated that women with periodontal disease have an increased risk of preterm births [18; 62; 63; 64]. A PLBW baby is defined as one born before the 37th week of gestation, weighing less than five pounds, six ounces. In a study of 124 pregnant or postpartum mothers at the University of North Carolina School of Dentistry, those who delivered preterm newborns were more likely to have significantly worse periodontal disease than a comparable group of women who delivered normal birth weight infants. The researchers concluded that periodontal disease is a statistically significant risk factor for preterm low birth weight, with an adjusted odds ratio of 7.9 [62]. Another study of 870 women with pregnancy-associated gingivitis conducted by the Department of Conservative Dentistry in Santiago, Chile, found that periodontal treatment significantly reduced the incidence of preterm labor and/or low birth weight infants [65]. However, the results of more recent studies find limited and/or insufficient evidence to conclude that periodontal disease or its treatment led to a reduction in PLBW infants [66; 67]. Nevertheless, the American Academy of Periodontology has recommended that periodontal evaluations be a part of a woman's overall healthcare program as periodontal disease can impact a woman's health in a variety of ways throughout her life [68].

Although ongoing studies are exploring the way in which oral infections may trigger preterm births, several pieces of the puzzle have been postulated as to how the disease may affect delivery timing. For example, other types of maternal infections, including genitourinary infections, have been linked to premature labor, and certain bacteria similar to organisms associated with periodontal disease have been detected in the genital tracts of women at a higher risk for preterm birth. Within the oral cavity, periodontal plaque triggers an inflammatory process that leads to increases in levels of a number of substances, including prostaglandin E2 (PGE2) and tumor necrosis factor-alpha (TNF-a) molecules. The elevated presence of PGE2 can yield a molecule whose configuration is quite similar to oxytocin, which can induce labor. Thus, the presence of chemicals such as PGE2 may trigger preterm delivery [16; 69]. A study found that maternal periodontal disease is associated with systemic inflammation and elevated serum C-reactive protein (CRP) levels, a marker of inflammatory processes, and other studies have shown that a very high CRP level early in pregnancy is a risk factor for preterm delivery [70; 71]. One case-control study investigated the utility of inflammation markers as predictors of preterm birth by exploring longitudinal changes in interleukin (IL)-1B, IL-6, IL-10, TNF-a, and CRP in pregnant women [72]. Results indicate that maternal inflammation markers, particularly IL-6 and IL-10, are associated with increased risk of preterm birth, with associations varying by etiology of preterm delivery and gestational age at sample collection [72].

The relationship between infection, especially genitourinary infections, and adverse pregnancy outcomes has been well documented in both animal and human studies. University of North Carolina researchers found that gingival crevicular fluid levels of PGE2 are significantly elevated in mothers of preterm low-birth-weight infants, compared with mothers of normal birth weight controls. Specifically, four micro-organisms associated with progressing periodontitis (i.e., Bacteroides forsythus, P. gingivalis, Actinobacillus actinomycetemcomitans, and Treponema denticola) were found in greater amounts in the mothers of preterm low birth weight infants, compared to controls [73]. In a separate study at Columbia University School of Dental and Oral Surgery, mothers of low birth weight infants had significantly increased levels of B. forsythus and Campylobacter rectus, as well as consistently higher levels of other species [74]. Results of one study found an association between certain maternal and fetal genes and increased risk of premature birth when mothers are exposed to urinary tract or vaginal infection [75].

A number of other factors are known to contribute to the incidence of preterm infants, which, in 2021, accounted for 10.5% of all live births [76]. It has also been reported that preterm births account for 35% of all U.S. healthcare spending for infants and 10% of spending for children as a whole [77]. In 2016, the average first-year medical costs (inpatient and outpatient care) were approximately four times greater for preterm (\$49,140) than for term infants (\$13,024) [76]. Widely acknowledged risk factors include a poor diet, maternal age younger than 20 years or older than 35 years, multifetal pregnancies, various maternal health problems (e.g., high blood pressure, diabetes), and maternal intake of alcohol, nicotine, or drugs [78]. The conclusions of a study conducted by the University of Alabama at Birmingham School of Dentistry led researchers to report that "poor periodontal health of the mother is a potential independent risk factor" for low-birthweight infants [79]. This finding has also been reported by other researchers [78; 80].

Treatment of periodontal disease in pregnant women, and in all women of childbearing age, could have a positive effect upon the incidence of preterm births, although evidence of this benefit is still scarce. Intervention studies have begun at several universities that should shed greater light on the interrelationship and how it may be favorably influenced [61]. The Columbia University researchers cited above found that 19.9% of women who did not receive periodontal intervention gave birth to PLBW infants, compared to 13.5% of women who did receive the therapy [74]. One study that included 586 women (148 PLBW infants, 438 full-term infants) found that the extent and severity of periodontal disease appears to be associated with increased risk of PLBW delivery [81].

# HYPEREMESIS GRAVIDARUM

Commonly known as severe "morning sickness," hyperemesis gravidarum is thought to be caused by hormones released by the placenta and is characterized by severe nausea and vomiting during pregnancy, which repeatedly exposes tooth enamel to gastric acid [82; 83]. Later in pregnancy, the enlarged uterus can exert pressure on the stomach and exacerbate acid reflux. Patients with hyperemesis may have enamel erosions.

Strategies to avoiding nausea, vomiting, and therefore oral acid exposure during pregnancy include dietary and lifestyle changes, such as reduction of exposure to hot showers; strong smells or flavors; bright or blinking lights; motion, such as riding in a car; and pressure on the stomach from tight clothing [82]. Antiemetics and/or antacids may also be prescribed.

A rinse made with one teaspoon of baking soda dissolved in 8 ounces of water should be used to neutralize acid in the oral cavity after vomiting. Tooth brushing should be delayed for several hours to protect the softened enamel. A soft-bristled toothbrush should be used to reduce damage to the enamel as long as the condition continues [83].

# WOMEN'S CANCERS

No woman is immune from contracting cancer. In the United States, women have a one in four lifetime risk of developing cancer [84]. Although some types of cancer (e.g., lung cancer, colorectal cancer) strike both sexes in large numbers, others affect women exclusively (or, in the case of breast cancer, almost exclusively).

## CERVICAL CANCER

Although the exact cause of cervical cancer is unknown, cervical cell changes may be the result of an "insult" from viruses and multiple sexual partners. Women with cervical cancer often report a history of cervical infections. The infections most frequently linked to cervical carcinoma are caused by herpes simplex virus type 2 (HSV-2); human papillomavirus (HPV) types 16, 18, 45, and 58; human immunodeficiency syndrome (HIV); and perhaps cytomegalovirus. However, HPV infection is almost always the cause of cervical cancer. These viruses alter the DNA in the nuclei of immature cervical cells [85; 86; 87; 88].

The Papanicolaou (Pap) test, or smear, safely and inexpensively detects cervical cancer at an early stage. Dr. George Papanicolaou, a Greek physician, developed the Pap test in the 1940s, and it became a regular component of gynecologic examinations during the 1950s. Since then, the incidence of invasive cervical cancer and the death rate from cervical cancer have declined. The number of women with cervical intraepithelial neoplasia (CIN) had been increasing, but more recent reports indicate declining trends following introduction of HPV vaccination [89; 90; 91]. As part of general health education, dental health professionals can help ensure that women understand the importance of Pap smears.

Recommendations regarding how frequently average-risk women should have Pap tests have changed significantly as of 2012. National health organizations, such as the National Cancer Institute (NCI) and the American Medical Association

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SUMMARY OF CERVICAL CANCER SCREENING RECOMMENDATIONS		
American Cancer Society		
<ul> <li>Initiate screening at 25 years of age</li> <li>Age 25 to 65 years: HPV testing every five years (preferred); co-testing (cytology + HPV) if HPV unavailable</li> <li>65 years and older: No testing with adequate negative screening history</li> </ul>		
J.S. Preventive Services Task Force/American College of Obstetricians and Gynecologists <sup>a</sup>		
<ul> <li>Younger than 21 years: No screening</li> <li>Age 21 to 29 years: Cytology alone every three years</li> <li>Age 30 to 65 years: Cytology alone every three years OR high-risk HPV alone every five years OR high-risk HPV with cytology every five years</li> <li>65 years and older: No screening</li> <li>Hysterectomy with cervix removal and no history of CIN grade 2 or 3: No screening</li> </ul>		
ACOG adopted USPSTF guidelines in 2021. HPV=human papillomavirus; CIN=cervical intraepithelial neoplasia.		
Source: [92; 93; 94] Table		

(AMA), have adopted consensus recommendations. Other organizations, such as the American Cancer Society (ACS), the American College of Obstetricians and Gynecologists (ACOG), and the U.S. Preventive Services Task Force (USP-STF), have developed updated guidelines for cervical cancer screening. Guidelines from the ACS, the USPSTF, and the ACOG are summarized in Table 1 [92; 93; 94]. Management of abnormal cervical cancer screening results should follow current guidelines [95].

In 2006, the U.S. Food and Drug Administration (FDA) approved a quadrivalent HPV (types 6, 11, 16, 18) recombinant vaccine, Gardasil, to prevent vulvar and vaginal precancerous lesions and cervical cancer caused by these strains of HPV. The vaccine is approved for administration in children and adults 9 to 26 years of age [96; 97]. This vaccine was the first of its kind to be made available. In 2009, a second HPV vaccine, Cervarix, was approved by the FDA for use in girls and women 10 to 25 years of age [98]. Cervarix protects against HPV strains 16 and 18 and contains a proprietary immune response boosting adjuvant that results in significantly higher serum neutralizing antibody titers compared to Gardasil [99]. In 2014, a 9-valent HPV recombinant vaccine (Gardasil 9) that adds protection to HPV types 31, 33, 45, 52, and 58 in addition to those types covered by the original Gardasil [100]. With this increased coverage, the 9-valent vaccine has the potential to prevent up to 90% of cervical, vulvar, vaginal, and anal cancers. Gardasil 9 is approved for girls and women 9 to 26 years of age and boys 9 to 15 years of age [100]. In 2018, the FDA expanded use of Gardasil 9 to include women and men 27 to 45 years of age [101]. Several other HPV vaccines are in development or clinical trials.

There is hope that HPV vaccination will have a significant positive impact on public health. As discussed, it is uncertain whether vaccination reduces the need for cervical cancer screening, and because neither vaccine provides protection against all HPV strains, both vaccine manufacturers and the

Centers for Disease Control and Prevention (CDC) recommend continuation of routine cervical cancer screening [102; 103].

It is critical to emphasize to the professional and the public that healthcare appointments are needed for women to be assessed for sexual questions, risk factors, presence of sexually transmitted infections, contraceptive needs, blood pressure, weight control, clinical breast exam, and any other issues of concern.

#### UTERINE CANCER

The most common type of gynecologic cancer is cancer of the uterus, and approximately 66,200 women will be diagnosed with uterine cancer in 2023 [104]. The three layers that comprise the uterus are the inner layer or lining, which is called the endometrium, the middle muscular layer, which is called the myometrium, and the layer of tissue that coats the outside of the uterus, which is known as the serosa. Most uterine cancers begin in the endometrium. Endometrial cancer occurs around 60 years of age on average. Uterine cancer is uncommon in women younger than 45 years of age [104].

Endometrial cancer is familial, and research is underway to identify genetic markers. Research has indicated that a relationship of mismatch repair (MMR) gene mutations to endometrial cancer may be present [105]. MMR genetic abnormalities are also considered causal in hereditary nonpolyposis colorectal cancer (HNPCC), which may be a risk factor for endometrial cancer. Another gene called PTEN, this one responsible for suppressing tumor growth, is often anomalous in women with endometrial cancers [104]. More research is necessary to fully understand the genetics involved in the development of HNPCC-associated uterine cancers.

Risk factors for endometrial cancer include advancing age, hormone imbalance, estrogen therapy, use of birth control pills, intrauterine device use, breast or ovarian cancer, early menarche (before age 12), infertility or no pregnancies, obesity, high-fat diet, diabetes, Lynch syndrome, polycystic ovarian syndrome, and family history [85; 104]. The only sign of endometrial cancer, especially in postmenopausal women, is abnormal vaginal bleeding. Women should be instructed to seek treatment when any vaginal bleeding occurs. A pelvic examination with an endometrial biopsy should be performed. If the result of the biopsy is positive, a total abdominal hysterectomy and bilateral salpingo-oophorectomy are performed. Other treatments, depending on the stage of the cancer, include radiation and chemotherapy. These tumors tend to be well differentiated and localized. If the tumors are detected and treated early, women with endometrial cancer have a high survival rate [104; 106].

## OVARIAN CANCER

Ovarian cancer is the deadliest of all female reproductive system cancers because it is difficult to detect and diagnose at an early stage [107]. Frequently, by the time it is diagnosed, the cancer has already spread throughout the pelvis. Screening for early ovarian cancer remains a scientific challenge, and new methods are being researched.

Ovarian cancer occurs most frequently between 40 and 70 years of age. The exact cause is unknown; however, evidence suggests a link to endocrine function. Factors preventing ovarian cancer include those that decrease the number of times a woman ovulates. Thus, protection is provided in women who conceive before 25 years of age, experience early menopause, and/or use oral contraceptives for years. Ovarian cancer is familial; if a woman's mother or sister had ovarian cancer, the woman herself is as much as 50% more likely to develop it. Environmental risk factors include talc and asbestos exposure, as well as a high-fat diet. The alarming factor with ovarian cancer is its elusive lack of symptoms. The most common sign is an enlargement of the abdomen [107]. Women may complain of an inability to fasten their pants and skirts. Other symptoms may include vague abdominal fullness or discomfort, pelvic pain, and ascites. Treatment options include surgery, radiation, and chemotherapy. Paclitaxel (Taxol), a newer anticancer medication, has successfully treated progressive ovarian cancer, especially when used in combination with carboplatin (Paraplatin). Another successfully used combination therapy includes cisplatin, etoposide, and bleomycin [108; 109]. Target drug therapy with bevacizumab has been shown to shrink or slow the growth of advanced epithelial ovarian cancers. The drug appears to be most effective when used in conjunction with chemotherapy [107].

#### BREAST CANCER

Breast cancer is the most common cancer in women, but it is also one of the most treatable if detected early. The risk to American women of developing breast cancer in their lifetime is reported as one in eight [110]. Nodal involvement remains the best prognostic indicator for long-term survival. The ACS has reported the five-year survival rate as 99% for localized, 86% for regional, and 29% for distal [111]. These survival rates underscore the importance of rigorous, consistent screening for all women.

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The most widely accepted risk factors for breast cancer are age, gender, and personal and family history of breast cancer. The identification of genes associated with familial breast cancer has been a remarkable step forward in identifying risk factors for prevention. However, *BRCA1* and *BRCA2*, the predominant breast cancer genes, only account for 5% to 10% of the breast cancer cases in the United States [112].

#### Screening

The following breast cancer screening information is based on guidelines from the ACS, the NCI, and the ACOG [113; 114; 115].

#### **Breast Awareness**

Women should be aware of changes in their own breast tissue, including lumps or swelling, skin irritation or dimpling, nipple pain or retraction (turning inward), redness or scaliness of the nipple or breast skin, or a discharge other than breast milk [114]. Although breast self-examination (BSE) has been recommended in the past, the NCI states that the harms of BSE may outweigh the benefits [113]. According to the NCI, BSE does not reduce mortality and leads to a greater number of biopsies and diagnosis of benign lesions.

The ACS and the ACOG recommend that women older than 20 years of age become familiar with the feel and appearance of their healthy breasts in order to recognize any significant changes [114; 115]. The best time to examine the breasts is a few days after the menstrual period ends, when the breasts are least affected by hormonal changes, swelling, and fibrocystic changes. The examination is also most comfortable after the menstrual period because the breasts are less tender. In women who are menopausal, or who do not have regular periods, the BSE should be done on the same day every month, such as the first day of the month.

#### Clinical Breast Exam

The clinical breast examination (CBE) as part of breast cancer detection is another questionable practice; this is partially due to the lack of efficacy data from randomized controlled trials [113]. At this time, it is not known if CBE reduces a woman's risk of dying from breast cancer. Although the experienced professional may find an irregularity that the woman has missed, according to the NCI the potential harms may outweigh the benefits. CBE is associated with a false positive rate as high as 12%; additionally, cancerous lesions are not found in up to 43% of women using CBE alone [113].

The ACS does not recommend CBE for average-risk women [114]. The ACOG recommends CBE every one to three years in women 20 to 39 years of age and every year in older women; however, this is a C-level recommendation (i.e., based on consensus and opinion rather than consistent scientific evidence) [115].

#### Mammography

A mammogram is a special x-ray that compresses the breast tissue between two plates. It identifies suspicious or malignant

tissue, measures the size, and locates any spread of cancer in the breast. Most breast lesions are present for several years before they can be palpated, and thus mammography can detect lumps and breast cancer much earlier than manual breast examination, at the earliest stage of development. When detected early, the five-year survival rate for women with in situ breast cancer is 99.1% [116].

In general, women 40 to 44 years of age should have the option to start screening with mammography every year. Women 45 to 54 years of age should have annual mammograms. Women 55 years of age and older may opt to have a mammogram every other year or may choose to continue with annual mammograms. Screening should continue as long as a woman is in good health and is expected to live at least another 10 years [114]. The benefits of annual mammography are based on consistent evidence; there is a 15% to 20% relative reduction of mortality in women 40 to 79 years of age [113]. However, the harms associated with mammography are also based on solid evidence that cannot be ignored. These include overdiagnosis and the resulting treatment of insignificant cancers (up to 54%); false-positives with additional testing and anxiety; and false-negatives with a delay in treatment (between 6% and 46% of women with invasive cancer will have a false-negative result). Below are the general screening guidelines for the techniques discussed [113; 114; 115]:

#### **Breast Awareness:**

Any changes in one's breasts should be reported to a physician.

#### **Clinical Breast Examination:**

Every three years for those 20 to 40 years of age Yearly after 35 years of age, if at risk Yearly after 40 years of age

#### Mammography:

Yearly for those 40 to 45 years of age and older If at higher than average risk, discuss starting earlier

#### **Treatment Choices**

A diagnosis of breast cancer threatens a woman's life, but it also can alter her self-image and change her roles, support systems, and family relationships. The varied choices of breast cancer treatment contribute to the complexity and confusion that the diagnosis can bring to a woman and her family and friends.

Not long ago, a diagnosis of breast cancer was usually followed by a radical mastectomy. Although surgery remains a primary component of treatment, now more breast tissue may be conserved, and surgery is typically combined with adjuvant therapies (i.e., chemotherapy, hormone therapy, radiation therapy). If the woman has carcinoma in situ (i.e., noninvasive breast cancer), the surgical procedure might be the modified mastectomy or lumpectomy; these surgeries remove the breast tissue and axillary lymph nodes but leave the pectoralis muscle intact [117]. Women with small tumors (less than 4 cm) and in an early stage of cancer (Stage I or II) are often good candidates for lumpectomy. In these women, lumpectomy with radiation has demonstrated the same survival rate as other surgical techniques, while preserving breast tissue [24]. For many women, breast cancer is a hormonally influenced malignancy. Cancer cells are tested following surgical removal, and hormone therapy is used when the cancer is sensitive to estrogen (i.e., estrogen receptor positive).

Women with locally advanced breast cancer (stage III) generally require neoadjuvant chemotherapy and/or radiation prior to any surgery to promote tumor shrinkage and allow for a more manageable surgical procedure [118; 119]. Many of the chemotherapeutic agents prescribed for women's cancers have a pronounced effect on the oral mucosa. Multiple, painful ulcerations may be present, which may present a substantial therapeutic challenge to treat and ameliorate. Weight loss often takes place at a time when the patient could use all of the nutritional support she can get. Clinicians have prescribed oral rinses of local anesthetic agents, to be used at mealtimes or in combination with antibiotics to decrease the incidence of secondary infection, and antihistamines to reduce the inflammatory component. Antimicrobial oral rinses containing chlorhexidine gluconate have also been prescribed. Clinicians have also employed agents that coat the surface of the mucosa and cover the ulcerations. Such agents have a transient effect at best. There is no good solution for this problem. The National Cancer Institute recommends oral evaluation and management of patients prior to initiation of chemotherapy. Communication between the oncology team and the dental team as to the patient's medical status and treatment plans can help to maximize outcomes [120].

# MENOPAUSE

The simplest definition of menopause is the end of menstruation. Although menopause literally means cessation of menses, menopause is actually a process rather than a discrete, single occurrence. It is defined as a transition of biologic and cultural events over a period of months to years. An average life expectancy of 78 years means that the "average" woman will live one-third of her life after her last menstrual period [23; 121; 122; 123].

Perimenopause refers to the stages of regression of ovarian function, which can be as long as 7 to 10 years. It culminates in the last menstrual cycle and extends at least one year after menopause. Menstrual periods stop when the ovaries no longer produce female hormones. This deficiency may cause symptoms such as hot flashes, vaginal dryness, emotional changes, and weight gain. Some women, however, are asymptomatic [23; 24; 122].

# MENOPAUSE AND ORAL HEALTH

In the menopausal and postmenopausal periods, many women experience symptoms in their oral cavity, including dryness of the mouth, pain, burning sensations of the tongue, and changes in taste sensations [18; 121; 124; 125; 126; 127]. There may be alterations in the oral mucosa as well, including thinning of the epithelial lining. A condition called menopausal gingivostomatitis has been identified, in which the gingiva becomes dry, bleeds easily, and may experience changes in color (from pale to very red) [18; 128].

Before menopause, periodontal disease is more common in men than women. But in the postmenopausal years, women surpass men in the incidence of periodontal disease, except women who are on hormone replacement therapy (HRT) (also known as menopausal hormone therapy [MHT]) [129]. When informed that patients have discontinued an HRT regimen, typically because of concerns over the safety of the therapy, dental health professionals should show increased vigilance in detecting and treating periodontal symptoms.

#### PREVENTIVE HEALTH FOR PERIMENOPAUSAL WOMEN

To ease the transition into perimenopause, women should consider the following strategies [130; 131; 132; 133; 134; 135]:

- Exercise: Perimenopausal women should perform a program of moderate-intensity aerobic, weight-bearing exercise for at least 150 minutes per week. It is recommended that workouts last at least 10 to 15 minutes per session (30 minutes five days per week is ideal), in order to maintain an elevated heart rate for a prolonged period of time. Alternately, 25 minutes of vigorousintensity exercise three days each week (a total of 75 minutes per week), or a combination of both, is recommended. If women need to achieve a healthy weight, one hour of moderate-intensity aerobic physical activity per day is recommended. Moderate-to-vigorous-intensity muscle strengthening activity performed two or more days per week is recommended for additional health benefits. Exercise has been shown to reduce bone loss, prevent weight gain, and improve overall well-being.
- Diet: The American Heart Association recommends eating a balanced diet, such as the DASH diet, that consists of six daily servings of grains (at least 50% whole grains); two to three servings per day of vegetables (variety of colors); two servings per day of fruits (variety of colors); three servings per day of dairy products; five or less servings of protein per day (e.g., legumes, nuts, fish, seafood, lean meats, poultry); three one-tablespoon servings per day of fats or oils (unsaturated); and no servings per week of added sugar or sweets.
- Health screenings: Perimenopausal women should be screened routinely for early detection of women's health problems, as discussed. Additionally, a lipid profile, colorectal cancer screening, and blood pressure checks should be performed at recommended intervals. Women should get a dental exam every 6 to 12 months.
- HRT: Although not without risk, HRT is an option for the treatment of both the physical and emotional effects of menopause. It is optimal to use HRT at the lowest dose and for less than five years.

#### Hormone Replacement Therapy

Treatment for perimenopausal/menopausal symptoms and for the prevention of long-term risk factors associated with postmenopausal women has generated clinical discussion and research studies on HRT. Although HRT may help some women, the availability of these medications does not imply that all women should take them. In fact, research called into question the advisability of the long-term use of HRT, leading many physicians to re-evaluate the criteria they use for determining candidates for this drug therapy [133].

A study conducted to investigate the association between HRT and mortality both prior to and after publication of the Women's Health Initiative (WHI) trials results found that users of systemic hormone therapy, who had switched to local hormone therapy by 2005, had a substantially lower mortality than nonusers [136]. It appears that the healthiest users decided either to drop systemic hormone therapy altogether or switched to local hormone therapy, per the changed recommendations following publication of the WHI results [136]. Re-analyses and follow-up studies from the WHI trials and data from other studies suggest that the risk-benefit profiles of HRT are affected by a variety of factors, including the timing of use in relation to menopause and chronological age and the type of hormone regimen [137].

#### HRT and Cardiovascular Disease

The incidence of cardiovascular disease in women rises markedly after menopause. Research has shown that both natural and surgically induced menopause are associated with changes in serum lipid profiles, a decline in high density lipoproteins (HDL), and an increase in low density lipoproteins (LDL) [138]. These cholesterol changes may increase the risk of developing postmenopausal heart disease.

For years, many women were placed on HRT based on research such as the Nurses' Health Study, which reported that postmenopausal estrogen users had a reduced risk of coronary artery disease and fatal strokes compared with women who had never used estrogen [139]. Other studies suggested that postmenopausal estrogen had an independent, protective effect against cardiovascular disease.

But in 2002, surprising results from a major clinical trial, the Women's Health Initiative (WHI), were published in the *Journal of the American Medical Association* [134]. The study was designed to evaluate the health benefits and risks of the most commonly used estrogen-plus-progestin hormone preparation in more than 16,000 menopausal women. The trial was halted after a mean follow-up of 5.2 years because of the apparent increased risks of coronary heart disease, stroke, pulmonary emboli, and invasive breast cancer associated with HRT. The authors of the study reported that the rate of women experiencing coronary heart disease events rose 29% in women taking HRT, compared to placebo. Stroke rates were 41% higher in the HRT group, while the rate of venous thrombo-embolism was about double in the drug cohort [133; 134]. A 2005 Cochrane review of the data from ten clinical trials (two

involving healthy women; eight involving women with heart disease) reported similar findings [140]. A 2015 Cochrane review of data from additional new trials concurred with these previous findings [141].

However, a review published in 2018 found that the absolute risks of adverse cardiovascular events for HRT initiated in women close to menopause are low, and that all-cause mortality effects are neutral or even favorable for younger menopausal women. For women in early menopause and without contraindications to treatment, the benefits of HRT are likely to outweigh the risks when used for menopausal symptom management [142]. According to the National Institute for Health and Care Excellence, HRT does not increase cardiovascular disease risk when started in women younger than 60 years of age and it does not affect the risk of dying from cardiovascular disease [143].

For HRT use in cardiovascular disease prevention, questions regarding benefits versus risks remain [144; 145]. The International Menopause Society does not recommend initiation of HRT in women older than 60 years of age for the primary prevention of cardiovascular disease [146].

# HRT and Osteoporosis

Osteoporosis is one of the most serious long-term concerns of perimenopausal and postmenopausal women, affecting approximately one in four women [132]. The loss of bone mass accelerates after menopause and causes bones to become brittle and at increased risk of fractures. Hip fractures among elderly women are not only costly and debilitating, but women often die from subsequent complications within a year. Studies have shown that long-term estrogen use protects women from postmenopausal bone loss and osteoporosis [122]. Estrogen therapy slows the demineralization process, but it cannot restore bone that has already been lost. In addition, once estrogen replacement stops, bone loss resumes. The WHI trial did show that women taking the estrogen-plus-progestin formulation experienced a one-third reduction in hip fractures and a 24% decline in total fractures [133].

Although HRT prevents fractures at any age after menopause, the age at initiation is important. A 2016 consensus statement published by several international societies and foundations states that menopausal hormone therapy is effective and appropriate for the prevention of osteoporosis-related fractures in at-risk women before 60 years or age or within 10 years after menopause. HRT can be considered first-line therapy for women 50 to 60 years of age or within 10 years after menopause [146]. Initiation of hormone therapy in those 60 to 70 years of age is considered second-line therapy and requires individually calculated benefit/risk, compared to other approved drugs. HRT should not be initiated after 70 years of age [146]. If HRT is elected, the lowest effective dose should be used [146; 147].

# HRT and Cancer

During the 1970s, unopposed estrogen therapy was routinely given to menopausal women with an intact uterus, which resulted in an increased risk of endometrial hyperplasia and cancer. Adding progesterone to estrogen, however, greatly decreased the risk of endometrial cancer. HRT advocates argued that the risks of endometrial cancer were low and rare compared with the reported cardiovascular and osteoporotic benefits. For years, the link between breast cancer and HRT remained controversial. Some studies suggested that lower doses of estrogen did not increase the risk of breast cancer while others suggested the opposite. Comparison of existing studies was difficult due to selection biases and other methodologic differences.

But the WHI trial strongly fell on the side of increased breast cancer risks associated with HRT. The trial found that invasive breast cancer rates increased by 26% in women taking hormone therapy. At the same time, HRT users showed a 37% reduction in colorectal cancer rates [133; 148]. Although the degree of association between HRT and breast cancer remains controversial, HRT is generally contraindicated in breast cancer [146; 149].

## HRT and Alzheimer Disease

Observational studies have indicated that long-term estrogen deficiency seems to be related to a higher risk of developing Alzheimer disease, but the reason why remains unknown [150; 151]. Among the 6.5 million people 65 years of age and older in the United States with Alzheimer disease, 4 million are women and 2.5 million are men [152]. Women also suffer more severe cognitive impairment [153]. The finding that women with Alzheimer disease have lower levels of estrogen than do those without Alzheimer disease seems to indicate that there is a relationship that bears further investigation; however, HRT is not recommended for cognitive improvement or maintenance in women with Alzheimer disease [151; 154; 155; 156].

# The Future of HRT

Previously, women taking HRT needed to follow a schedule of two tablets, which was both confusing and inconvenient. Regular menstrual-like flow occurred at the end of the 28-day cycle of medications. In 1995, combined estrogen/progesterone tablets became available in two different HRT regimens; a continuous therapy regimen and a cyclic regimen. This increased the convenience for women on HRT who have an intact uterus. However, in light of the findings of the WHI trial, many women have been or will be removed from HRT therapy, while others are taking it only for short-term management of symptoms [133]. The USPSTF recommends against the use of combined estrogen and progestin for the prevention of chronic conditions in postmenopausal women and women who have had a hysterectomy [157]. As a result of research indicating the potential harms of HRT, many women are looking to nondrug approaches to manage their menopausal and postmenopausal symptoms, including dietary modification, exercise, and calcium supplementation for osteoporosis prevention.

# OSTEOPOROSIS

Of all skeletal disorders, osteoporosis is the most common. It results from decreased density, or thinning, of the bone related to the aging process. Osteoporotic bone is more porous and is weaker than normal bone; thus, it fractures more easily. This condition is the leading cause of bone fractures in postmenopausal women and is associated with long-term disability, frailty, and enormous expense. Common sites for fractures are the spine, wrists, forearms, and hips. With the exception of arthritis, osteoporosis is the leading cause of musculoskeletal disturbances in the elderly [158].

#### PERIODONTAL DISEASE, TOOTH LOSS, AND OSTEOPOROSIS

Research seems to indicate that the loss of bone mass associated with osteoporosis may be associated with the incidence and severity of periodontitis. However, some of these clinical trials have evaluated small numbers of patients, and the control of potentially confounding factors has been inconsistent; the criteria used to define osteoporosis and to assess systemic bone density has also varied [159]. Nonetheless, a 2013 literature review found that 4 of 5 longitudinal studies, 20 of the 25 cross-sectional studies, and all 3 of the case-control studies reviewed showed an association between osteoporosis and periodontal disease [160].

Studies also support a relationship between osteoporosis and clinical attachment loss. While conclusions of the existing trials conflict with one another at times, the general consensus seems to be that an association may exist [159]. A 2022 survey of literature published in the last 25 years indicates that systemic low BMD is associated with alveolar bone loss, while evidence also suggests an association between clinical attachment loss and other parameters of periodontitis [161]. A 2021 study found that patients with osteoporosis and periodontal disease had higher indices of periodontal disease, including tooth mobility and tooth loss, than did patients with periodontal disease only [162]. Women who had experienced osteoporotic fractures also seemed to have an increased risk of loss of periodontal attachment [162].

One study compared the severity of periodontitis in postmenopausal women whose Fracture Risk Assessment Tool (FRAX) scores indicated a major risk for osteoporotic fracture versus controls [163]. Selection criteria for participants included: age 51 to 80 years; menopause for more than 1 year but less than 10 years; nonsmoker; hemoglobin A1c less than 7; and no pharmacologic treatment for osteoporosis within 5 years. FRAX scores were calculated and the participants were divided into two groups. Group 1 included 90 women with FRAX scores >20% (indicating major osteoporotic fracture risk); group 2 included 98 controls. The women in group 1 had significantly more severe periodontitis endpoints (e.g., clinical attachment loss, alveolar bone height, tooth loss) than controls. Plaque scores and bleeding on probe did not differ between the two groups [163]. The use of HRT appears to decrease the incidence of tooth loss in older women. In the Nurses' Health Study, which evaluated more than 42,000 postmenopausal women prospectively, the risk of tooth loss was lower in women taking HRT, after controlling for age and smoking [164]. A study of women in a California retirement community found that after adjusting for age, the use of estrogen replacement significantly decreased tooth loss and rates of edentia by 36%; the proportion of women with edentia declined with lengthier use of HRT [165].

Bisphosphonate drugs, such as alendronate, may retard the progression of alveolar bone loss associated with periodontitis. In one double-blind, placebo-controlled clinical study, alendronate lowered the risk of progressive loss of alveolar bone loss; during the nine-month trial, the relative risk of the loss of bone height and density was reduced to 0.45 in the alendronate group [166]. A study from 2019 found no improvement in maintaining alveolar bone level with the use of bisphosphonates but did suggest that its use may be promising as an adjunctive local delivery medication for management of periodontal diseases [167]. Two other studies support the assertion that bisphosphonates may be useful for periodontal treatment; however, existing information on this potential is limited [168; 169; 170]. However, bisphosphonate drugs are known to cause medication-related osteonecrosis of the jaw (MRONI) in some patients, particularly those who underwent IV bisphosphonate therapy, who were taking bisphosphonates for extended periods of time, and/or who underwent dental procedures while taking bisphosphonate drugs [171; 172].

#### DIAGNOSIS AND TREATMENT OF OSTEOPOROSIS

According to the Bone Health and Osteoporosis Foundation (formerly the National Osteoporosis Foundation), an estimated 12.3 million Americans have osteoporosis and an additional 43.4 million have low bone density [173]. The 2 million new cases of osteoporotic fracture each year exceeds the annual number of new cases of myocardial infarction, breast, cancer, and prostate cancer combined. Annual fracture incidence is expected to increase 68%, to 3.2 million, by 2040 [173]. Diagnosis of this disease in an aging population is challenging, even though impressive progress has been made. Bone densitometry is the procedure that measures bone mineral density. Dual-energy x-ray absorptiometry (DEXA or DXA) has become the routine method for bone density measurement. It is very precise and has the advantage over other, older diagnostic methods of a much shortened examination time (i.e., 2 minutes versus 20 to 40 minutes) [174]. DEXA is of particular advantage in measuring the lumbar spine and proximal femur areas and has become the gold standard for bone densitometry [173].

Various drug therapies exist for osteoporosis, and research findings suggest the possibility of newer treatments on the horizon. One of the most commonly prescribed drugs for women with osteoporosis is alendronate sodium, a bone resorption inhibitor. Alendronate has proven effectiveness in preserving bone tissue and decreasing bone loss. Calcitonin

is a bone metabolism regulator that slows the rate of bone turnover and seems to increase normal bone formation. It is indicated for the treatment of osteoporosis in women: who have been postmenopausal for at least five years; who have low bone density; who refuse or cannot tolerate estrogens; or in women for whom estrogens are contraindicated. It has not been recommended as a first-line treatment [175]. Calcitonin decreases bone resorption by inhibiting the activity of osteoclasts. Increases in bone mass of 1.5% to 13% have been reported, with the best responses noted in individuals with the highest bone turnover [176; 177].

In 2011, the FDA approved denosumab for treatment of osteoporosis in postmenopausal women who are at high risk of fracture [177; 178; 179]. Denosumab acts by binding to and inhibiting receptor activator of nuclear factor kappaB ligand (RANKL). RANKL controls the differentiation, proliferation, and survival of osteoclasts. Inhibition of RANKL provides a lengthened period of absorption and inhibition of bone resorption [177; 180].

In 2019, the FDA approved romosozumab for the treatment of osteoporosis in postmenopausal women who are at high risk of fracture. Romosozumab is a monoclonal antibody that inhibits sclerostin and improves bone mineral density [177; 181].

## PREVENTION OF OSTEOPOROSIS

Because most postmenopausal women have some degree of osteoporosis, they should take steps to prevent further bone loss. The best preventive measures are early education to encourage positive lifestyle habits before the disorder develops (ideally, well before menopause). The following methods have been identified as being helpful to prevent bone loss [158; 173; 182; 183]:

- Consume up to 1,200 mg per day of calcium.
- Raise vitamin D intake to 600 800 IU daily.
- Stop smoking.
- Limit the intake of alcohol, coffee, and soft drinks.
- Perform at least one to three hours of weight-bearing exercise per week.
- Engage in fall-prevention strategies by eliminating fall hazards in the home and work environment

Dairy products provide approximately 75% of the calcium in the average American's diet. However, the average daily calcium intake for women from dietary sources is only about half of the recommended amount. Women should be advised that it takes only three 10-ounce glasses of milk to supply 1,000 mg of calcium. Those who require more dietary calcium may choose to take supplements.

# CARDIAC HEALTH

Coronary heart disease (CHD) is still generally thought of as a man's disease. Yet, according to the American Heart Association, of the 126.9 million Americans with one or more types of cardiovascular disease (CVD), men have a slightly higher prevalence of CVD (66.1 million) compared with women (60.8 million), as well as a slightly higher mortality rate (51.9% vs. 48.1%) [184]. However, heart disease is the leading killer of women in the United States [185].

Women tend to show signs of cardiovascular disease later in life than men. Between 20 and 59 years of age, men have a higher prevalence of CVD than women [184]. Although menopause decreases a woman's protection from heart disease, her biologic advantage persists until 65 to 70 years of age. Older women who have heart attacks, however, are twice as likely to die within a few weeks as men [106; 186; 187]. Dentists, dental hygienists, and dental assistants can play a key role in educating patients about heart disease in women, which is particularly important because of the research linking periodontal disease to cardiovascular disease.

## SIGNS AND SYMPTOMS: GENDER DIFFERENCES

CHD signs and symptoms differ significantly between men and women. Women tend to have angina pectoris as the first symptom of heart disease; men initially have a myocardial infarction. Women rarely experience myocardial infarction as the initial manifestation of heart disease [85; 188]. Diagnosis of coronary disease in women is difficult. Women may have unspecified, misleading pain, which often results in a search for other causes. In the past, women have not been included in major cardiovascular research and treatment. This has greatly compromised the discovery of facts concerning the early identification and treatment of heart disease in women and is only now being rectified.

#### RISK FACTORS AND PREVENTIVE HEALTH BEHAVIORS

Women may have combinations of negative social, psychologic, cultural, physical, and addictive behaviors that increase their CHD risk. The major modifiable risk factors are cigarette smoking, high blood cholesterol, high blood pressure, diabetes, physical inactivity, excessive alcohol consumption, stress, and excessive weight gain. Women who smoke and also have high blood pressure and high blood cholesterol levels are eight times more likely to develop heart disease than those who do not. Women who have diabetes are four to six times more likely to die from CHD than women without diabetes [85].

Dental health professionals should make sure patients understand that heart disease is not an inevitable consequence of aging; rather, it is a disease process that can be greatly influenced by lifestyle modification. Factors such as diet, exercise, not smoking, maintaining normal weight, monitoring blood pressure and cholesterol, and taking HRT (when appropriate) are all beneficial health behaviors.

#### DENTAL HEALTH ISSUES

There is some evidence linking poor dental health with heart disease, particularly in studies that have shown a link between periodontitis and CHD. For example, a study by Helsinki University Central Hospital evaluated 100 patients with acute myocardial infarctions and 102 controls and graded their dental health. The researchers found that dental health was significantly worse in the patients who had experienced a heart attack, compared to the controls, even after adjusting for factors such as age, socioeconomic class, cholesterol (total, HDL) and triglyceride levels, C-peptide levels, diabetes mellitus, and smoking [189]. A separate study by the same researchers in Finland concluded that dental infections were associated with the pathogenesis of atherosclerosis, which is the only characteristic other than traditional coronary risk factors that showed an independent association [190]. Subsequent studies have confirmed an association between chronic oral infections and slightly increased risk of myocardial infarction [191; 192; 193; 194; 195].

The National Health and Nutrition Examination Study (NHANES I) evaluated more than 9,000 people for a median of 14 years and found that individuals with periodontitis had a 25% greater likelihood of developing CHD (an association found to be statistically significant). Poor dental hygiene characterized by extensive dental debris and calculus also increased the risk of CAD [196]. A 2021 literature review found that the prevalence of heart disease is more common among individuals with periodontitis [197]. A systematic review published in 2022 concluded that periodontal disease may be an important nontraditional risk factor for acute coronary syndrome [198].

One hypothesis explaining the possible mechanism responsible for the link between CVD and periodontitis centers on bacterial products, such as lipopolysaccharides (LPS), that can enter the bloodstream and affect the cardiovascular system. Several studies have reported the presence of periodontal bacteria in cardiovascular specimens [199]. It has also been postulated that micro-organisms normally present in the oral cavity, including P. gingivalis and Streptococcus sanguis, enter the bloodstream through local action that induce bacteremias, grow within the vascular plaques, and have the potential to induce platelet aggregation [200]. A study of carotid atheromas using polymerase chain reaction found that 42% of atheromas contained at least one of the periodontal micro-organisms studied and 72% contained the bacterial DNA of one of these micro-organisms [201]. Although periodontal treatment as a means to prevent CVD is not recommended, the emergence of periodontal infection as a risk factor for CVD should lead dental and healthcare professionals to recognize that patients cannot be healthy without good oral health [14; 202].

# SEXUALLY TRANSMITTED INFECTIONS

Environmental factors and lifestyle choices have an enormous influence on public health. This is particularly true for sexually transmitted infections (STIs). Although the organisms, modes of transmission, and complications resulting from STIs are well known, healthcare professionals have not been able to control these diseases, and their prevalence has increased over the last few decades. An estimated 1 in 5 people in the United States have an STI; half of these were among youth 15 to 24 years of age [203].

Dental health professionals may encounter these infections in patients who have oral manifestations of STIs, which are most often contracted via oral-genital contact. For this reason, dentists and hygienists should be able to recognize unusual lesions, determine a diagnosis, and refer the patient to a physician for appropriate treatment. When discussing STIs with patients, the dental health professional should display a nonjudgmental attitude. Good communication is a hallmark of the relationship between the dental professional and the patient, and this is all the more true regarding communication about sexuality. Many patients may not understand that STIs can be transmitted through oral sex. In explaining how an STI may have been contracted, the dentist or hygienist who uses clinical terms might be regarded by the patient as too "medical," and the patient might not understand the terminology. The patient might also find the topic to be embarrassing. A soft voice and touch, eye contact, active listening techniques, and body posture can all assist in communicating a caring and nonjudgmental attitude.

There is considerable variation in the symptoms of and treatment options for STIs. The following information is a general guide to the major STIs found in the United States. More detailed information is available from the CDC and local public health agencies.

#### GONORRHEA

Gonorrhea, which is caused by the bacteria *Neisseria gonor rhoeae*, was once the most prevalent STI in the United States. Gonorrhea is one of the most common infectious diseases, with an estimated 677,769 persons in the United States acquiring the disease in 2021, an increase of 45% from 2016 [203]. After a decline in the incidence of the disease from 1975 to 1997, the national rate for gonorrhea has been steadily increasing. This STI is transmitted vaginally, orally, or anally by sexual activity or from the mother to newborn during delivery. The majority of women are asymptomatic early in the disease. When symptoms do occur, they may include burning on urination and increased vaginal discharge. In the oral cavity, the disease manifests as a stomatitis and may exhibit a clinical appearance similar to the oral lesions of erythema multiforme, erosive lichen planus, or herpetic stomatitis [203; 204].

If the infection is in the oral cavity, diagnosis is made via bacteriologic evaluation of smears of the oral lesions. For infections in the genital area, gonorrhea is diagnosed in women with a culture of the cervical area. Both sexual partners should be tested and treated if either has a positive test for gonorrhea. Patients infected with gonorrhea are often co-infected with chlamydia and routinely treated with a regimen effective against both organisms. The recommended treatment of uncomplicated urogenital, anorectal, and pharyngeal N. gonorrhoeae infection in the United States is single-dose ceftriaxone 500 mg IM for persons weighing <150 kg. Administer 1 g ceftriaxone for persons weighing  $\geq$ 150 kg [205]. If ceftriaxone is unavailable, administer either gentamicin 240 mg IM in a single dose, or azithromycin 2 g orally in a single dose, or cefixime 800 mg orally in a single dose [205]. Women should be informed of the need for retesting to verify eradication of the infection.

## SYPHILIS

Syphilis is a bacterial STI caused by the spirochete *Treponema pallidum*. Like gonorrhea, syphilis is transmitted vaginally, orally, or anally through sexual activity, and via maternofetal transmission. In some cases, the disease has been acquired by dentists and hygienists providing dental treatment for a patient with syphilis during a contagious stage of the disease. Universal precautions apply, with the routine use of gloves, mask, and eye protection. Although syphilis is not as widespread as gonorrhea, its incidence is on the rise, which is especially ominous because of the harmful effects the untreated bacterium has on the heart, eyes, and central nervous system [203]. An estimated 133,945 cases of syphilis were reported in 2021, up 52% from 2016 [203].

In the first stage of syphilis, a painless, ulcerlike lesion called a chancre appears at the site of the infection, which may include the oral cavity and lips, on average about three weeks after contact with the infectious agent. On the lips, the chancre is often crusted and brownish, while intraoral lesions tend to be covered by a grayish, white membrane [204]. The chancre disappears within a few weeks, but if the syphilis is untreated, the bacteria continue to proliferate within the body. The untreated syphilis may progress through secondary and tertiary stages. During the secondary stage, there can be multiple oral lesions manifesting as painless, grayish-white plaques, most often found on the gingival, tongue, or buccal mucosa. They may have an irregular shape and are extremely contagious. These secondary signs and symptoms will resolve, with or without treatment; however, without treatment, the infection will progress. The tertiary lesions may not develop for a number of years, most frequently affecting the cardiovascular and central nervous systems. In the mouth, tertiary lesions are far more commonly observed than the primary or secondary lesions and are most often manifested by an interstitial or atrophic glossitis. There is a reported predilection for this luetic glossitis to undergo transformation to carcinoma [203; 204].

Darkfield examinations and molecular tests for detecting *T. pallidum* directly from lesion exudate or tissue are the definitive methods for diagnosing early syphilis and congenital syphilis [205]. Treatment includes antibiotics such as penicillin, doxy-cycline, tetracycline, or azithromycin. The preferred treatment for patients not allergic to penicillin is a single dose of penicillin G at 2.4 million units IM for adults and 50,000 units/kg body weight IM for infants and children [205]. Although syphilis can also be transmitted from an infected mother to her fetus (so-called congenital or prenatal syphilis), this form of the infection is very uncommon today due to routine blood tests conducted as part of prenatal care. In these cases, lesions may occur in any region of the oral cavity and tend to have a pink or red color [204].

#### HERPES SIMPLEX VIRUSES

Herpes is typically manifested either as a genital or oral viral infection. When it begins in the genital area, the infecting agent has historically been identified as HSV-2, but an increasing proportion of infections have been attributed to herpes simplex virus type 1 (HSV-1) [205]. Most infections are transmitted by persons unaware that they have the infection or who are asymptomatic when transmission occurs [205]. Similar to other STIs, HSV may be transmitted vaginally, orally, or anally through sexual activity and to a newborn during delivery. Herpes is most contagious during active outbreaks of the disease when lesions are present, but cells may be shed at other times. Latex condoms used during genital or oral sex are effective barriers to HSV [203]. Herpes is also commonly spread through kissing, using the same eating utensils, or sharing personal items with an individual infected with the herpes virus ("cold sores"). Parents, or other relatives, frequently infect their children in these ways, not knowing that "cold sores" are manifestations of the herpes virus.

HSV-1 is often found in the oral cavity and presents with signs and symptoms similar to HSV-2. A herpetic infection can be designated as primary in individuals not previously exposed, who have not yet developed antibodies to the virus, or recurrent in patients with previous exposure who have antibodies present. The primary infection often presents as a generalized stomatitis. Individual and discreet lesions typically appear after a prodromal sensation reported by many patients six to eight days after infection. Papules appear and develop into blisters that may become extremely painful ulcers. Although the clinical manifestation may heal and disappear, the virus is still present in the patient, often at a location remote to where the lesions occur [203]. Recurring outbreaks may be related to stress, hormonal changes, trauma, exposure to ultraviolet sunlight, or fatigue. Management of HSV should address the chronic nature of the infection rather than focusing solely on treating acute episodes of genital lesions [205].

Diagnosis of HSV-1 and HSV-2 can be difficult because the lesions classically associated with HSV are absent in many infected persons at the time of clinical evaluation [205].

Diagnosis is made by clinical inspection and culture of the sores. Prognosis and counseling depend on which HSV type is present. Type-specific serologic tests can be used to aid in the diagnosis of HSV infection in the absence of genital lesions [205]. Herpes does not have a cure, but antiviral drugs such as acyclovir, (Zovirax), famciclovir (Famvir), and valacyclovir (Valtrex) can help relieve pain, speed healing, and possibly decrease the incidence of outbreaks [21; 24; 177; 205].

#### CHLAMYDIA

An infection with Chlamydia trachomatis is the most common bacterial STI in the United States (with 1.6 million cases in 2020) [21; 85; 102; 203; 206]. Although many infected women are asymptomatic, any one of the following symptoms may occur one to three weeks after contact: frequent, uncomfortable urination; dyspareunia; cervicitis with scant cervical discharge; lower abdominal pain; and/or pelvic inflammatory disease (PID) [21]. The recommended treatment is doxycycline 100 mg orally twice daily for seven days. Alternative regimens include azithromycin 1 g orally in a single dose or levofloxacin 500 mg orally once daily for seven days [21; 177; 205]. Pregnant women should be treated with azithromycin or amoxicillin, as the members of the tetracycline family (e.g., doxycycline hyclate) should be avoided during the time of fetal tooth development due to the well-known possibility of permanent staining of the teeth.

#### HUMAN PAPILLOMAVIRUS (HPV)

Human papillomavirus (HPV) causes condyloma (i.e., genital warts). It is the most common viral STI and is highly prevalent among young, sexually active individuals. HPV is transmitted by skin-to-skin contact rather than via the exchange of bodily fluids [207]. More than 150 types of HPV have been identified, and more than 40 can infect the male and female genital tract [205]. High-risk HPV identified in genital cancers include types 6, 18, 45, and 58 [86]. A substantial proportion of cancers and anogenital warts are attributable to HPV in the United States. An estimated 34,800 new HPV-attributable cancers occurred every year during 2012–2016. Before the introduction of HPV vaccines, approximately 355,000 new cases of anogenital warts occurred every year [205].

Women are more susceptible to HPV infection than men because cells in the cervix divide swiftly, facilitating the spread of the virus. Most HPV infection is not visible to the naked eye, but genital warts that appear as small bumps or groups of bumps in the genital area are the most common recognized visible manifestation [86]. Diagnosis is made by inspection, colposcopy, biopsy, or cytology. There is no treatment for the virus, but there are treatments for the diseases that HPV can cause. Patient-applied and provider-applied treatments are available. Factors affecting the choice of treatment include wart size, number, location, morphology, cost, and convenience. Imiquimod 5% cream is used in the treatment of external genital warts. Cryotherapy with liquid nitrogen may also be used in treatment [86; 203; 205]. HPV is preventable by adopting safer sexual practices; women should limit the number of partners and use latex condoms. In addition, it is recommended that all girls and boys 11 to 26 years of age who have not completed the vaccine series receive the HPV vaccine [203; 205].

## HUMAN IMMUNODEFICIENCY VIRUS

HIV is the virus that causes acquired immunodeficiency syndrome (AIDS). Safer sexual practices to prevent HIV include limiting the number of partners, avoiding unprotected anal intercourse, and avoiding contact with the blood, semen, or vaginal secretions of others, including via the oral route. Women with HIV infection may experience remissions with medication regimens and improved supportive therapy that make it possible to regain high concentrations of T4/CD4 cells. However, some emerging HIV strains have proven to be resistant to current drug therapies [208].

Kaposi sarcoma, a malignancy that may affect the skin or oral cavity, is a common complication of late-stage AIDS. Oral lesions associated with Kaposi sarcoma most commonly appear on the palate but may manifest anywhere in the mouth [25].

# EATING DISORDERS

Eating disorders, such as anorexia nervosa and bulimia nervosa, can significantly impact oral health through a lack of proper nutrition and the effects of repetitive vomiting [209]. Although eating disorders occur more often in women/girls (3% to 4% lifetime prevalence) than men/boys (0.3% to 1.0% lifetime prevalence), they do occur in males in all age groups and in non-Western countries and are a particular concern for oral health [210]. Both anorexia nervosa and bulimia nervosa may carry a five or more times increased risk of mortality [210].

The frequent, self-induced vomiting in conditions like bulimia, typically after periods of binge eating, can have a destructive effect on the teeth. The regurgitated gastric contents can cause decalcification, softening of the enamel, and loss of tooth structure. Most often, this erosion occurs on the maxillary anterior teeth—specifically, on their palatal surfaces. A loss of occlusal anatomy can be observed when the posterior teeth show evidence of damage [211; 212]. In one small study, the prevalence of severe malocclusion was high in women with anorexia and bulimia nervosa and resulted in a negative oral health-related quality of life [213]. Dental manifestations may not be immediately apparent, most often appearing after about two years of chronic vomiting.

The extent of erosion can vary from one patient to another and is often affected by the extent to which the low pH stomach contents are regurgitated. If these contents are regurgitated fully, the enamel erosion may be limited. Although treatment of the eating disorder is crucial, patients who continue to vomit can use interim measures to neutralize acids and thus reduce damage in the oral cavity (as with hyperemesis gravidarum) [211]. One measure includes postvomiting rinsing with a prepa-

ration made with 1 quart of water combined with 1 teaspoon of baking soda. Fluoride rinses may also help to prevent the incidence of caries secondary to the erosion.

Dentists and other dental health professionals may notice other signs of eating disorders. For example, there may be trauma to the pharynx and the oral mucosa membranes related to the rapid intake of food and the abrupt, forceful vomiting that follows. The soft palate can also be affected when fingers or objects like pens are used to trigger vomiting. The parotid glands and, to a lesser degree, the sublinguals tend to swell in the presence of repeated binging and purging, seemingly related to numerous vomiting episodes. When salivary gland swelling does occur, it may be associated with cholinergic stimulation of the glands that occurs during regurgitation [214; 215; 216; 217].

Dental care professionals often are the first to see the signs of eating disorders (e.g., dental erosion, traumatized oral mucosal membranes) that indicate appropriate referrals for medical or psychiatric care. Although the role of dental care professionals in this regard is well established, research has indicated that many lack knowledge about the oral and physical cues of anorexia and bulimia. A study of 576 dental care providers randomly selected from the American Dental Association and the American Dental Hygienists' Association indicated low scores concerning the providers' knowledge about the oral and physical cues of anorexia and bulimia [212]. A study that explored the beliefs, attitudes, and experiences of dentists regarding eating disorder-specific secondary prevention behaviors found that training, network, and dental professional contingencies were areas of potential influence for increasing the prevention capacity of dental professionals [217].

Early identification of eating disorders is critical because they can cause significant complications (e.g., dehydration, abnormal heart function, GI complications) and are potentially fatal. Early identification, referral, and treatment of eating disorders may also help reduce the likelihood that the disorders will become fully developed [212; 214; 218].

# DOMESTIC VIOLENCE

Unfortunately, domestic violence, including emotional, psychologic, and physical abuse, is common. Dental health professionals may be the first healthcare providers that a victim encounters. Therefore, they may play a critical role in identifying a battered woman. For this reason, they should be aware of the signs and symptoms associated with domestic violence.

The obvious signs are the physical ones, including the loss of or injury to teeth. Injuries may also range from bruises, cuts, black eyes, concussions, broken bones, and miscarriages, to permanent injuries, such as damage to joints, partial loss of hearing or vision, and scars from burns, bites, or knife wounds. Typical injury patterns include contusions or minor lacerations to the head, face, neck, breast, or abdomen. These are often distinguishable from accidental injuries, which are more likely to involve the periphery of the body. In one hospital-based study, domestic violence victims were thirteen times more likely to sustain injury to the breast, chest, or abdomen than accident victims. Abused women are also more likely to have multiple injuries than accident victims. When this pattern of injuries is seen in a woman, particularly in combination with evidence of an old injury, physical abuse should be suspected [219; 220; 221].

In addition to physical signs and symptoms, battered women also exhibit psychologic clues that resemble an agitated depression. As a result of prolonged stress, these women often manifest various psychosomatic symptoms that generally lack an organic basis. For example, they may complain of backaches, headaches, and digestive problems. They often describe fatigue, restlessness, insomnia, or loss of appetite. Anxiety, guilt, depression, post-traumatic stress, or dysphoria are also typical [222; 223; 224; 225].

As difficult as it may be to ask patients about domestic violence, as many as 30% of female trauma patients will report that they have been battered when asked directly about how an injury occurred [226]. Obviously, some women will not admit to a history of being battered. However, any trauma that seems incompatible with a history of the injury is suggestive of battering and indicative of the need for gentle questioning about how things are at home.

After identifying a victim, dentists and other healthcare professionals should immediately implement a plan of action that may include providing a referral to a local domestic violence shelter to assist the victim and the victim's family. The acute situation should be referred immediately to local law enforcement officials. Other resources in an acute situation include crisis hotlines and rape relief centers. After a victim is introduced into the system, counseling and follow-up are generally available with counselors who specialize in the care of battered women and their spouses and children. These counselors may include social workers, psychologists, psychiatrists, other mental health workers, and community mental health services. The goals are to make the resources accessible and safe and to enhance support for women who are unsure of their options [225; 227].

# CONCLUSION

Although dentists, dental hygienists, and dental assistants are concerned primarily about oral health, they can also play an important advisory role in the overall health of their female patients. The oral health of women (as well as men) cannot be separated from their total health, and by offering information, support, and community resources, the dental professional can and should be an integral part of the healthcare team.

This course has reviewed many of the key health concerns that female patients may be encountering. By taking a leadership role in promoting primary prevention, healthy lifestyles, and prompt and appropriate treatment, both in and out of the dentist's chair, your patients may lead longer, higher quality lives. You can make a difference in making progress toward improving women's health.

# RESOURCES

American Cancer Society https://www.cancer.org

American Congress of Obstetricians and Gynecologists https://www.acog.org

American Dental Association https://www.ada.org

American Dental Hygienists' Association https://www.adha.org

American Heart Association https://www.heart.org

Centers for Disease Control and Prevention https://www.cdc.gov

National Cancer Institute https://www.cancer.gov

Bone Health and Osteoporosis Foundation https://www.bonehealthandosteoporosis.org

Office on Women's Health https://www.womenshealth.gov

Women's Health Initiative https://www.whi.org

# SELECTED GLOSSARY OF TERMS

**Bone densitometry**: Bone densitometry gives a quantitative measure of the bone mass by calculating a mean value with a standard deviation. This diagnostic test allows the clinicians to estimate the client's risk of fractures and determine whether treatment is needed to prevent further osteoporosis and risk of fractures.

**Dietary calcium**: Dairy products are the most common source of calcium in the American diet. Skim milk, 1 cup, has 302 mg of calcium; yogurt, low-fat, 8 ounces, has 415 mg of calcium; and cheddar cheese, 1½ ounces, has 306 mg of calcium.

**Dysmenorrhea**: Severe uterine pain usually occurring at or one day prior to the onset of menstruation and decreasing during the menstrual cycle.

**Endometriosis:** A condition in which endometrial cells implant on other parts of the body (e.g., bladder, rectum, ovaries, outside surface of the uterus), causing symptoms that include pain and pelvic heaviness.

Hormone replacement therapy (HRT): Combined estrogen and progesterone treatment for women who have reached or passed menopause.

Human immunodeficiency virus (HIV): The virus that causes AIDS.

Mammography: An x-ray of the breast used to identify suspicious or malignant tissue and locate the spread of cancer.

Menarche: The first menstrual period.

**Menopause:** The cessation of menstruation resulting from depletion of ovarian follicles and declining estrogen levels.

**Oral contraceptives (OC):** Birth control pills that provide supplemental hormone therapy and contraceptive benefit until a woman is postmenopausal.

**Osteoporosis**: Decreased density or thinning of the bone over time.

Papanicolaou (Pap) test: A test for the early detection of cervical cancer cells.

**Perimenopause:** The years preceding menopause when a woman can experience significant physical and emotional changes as she goes from a reproductive state to a postreproductive state. Perimenopause begins with the onset of menopausal symptoms and ends one year after the permanent cessation of menses. The terms female climacteric and "change of life" often are used to describe this time.

**Postmenopause:** The period of time after 12 consecutive months without any menstrual bleeding.

**Premenstrual syndrome (PMS):** A cluster of symptoms that occurs two to three days before the onset of menstruation and lasting for the first few days of the menstrual period.

Sexually transmitted infection (STI): An infection acquired during sexual activity, usually during sexual intercourse with an infected individual.

**Unopposed estrogen:** This is a term applied to the administration of estrogen alone. Unopposed estrogen therapy should be used only in women who do not have a uterus. For women who have a uterus, unopposed estrogen therapy may cause endometrial hyperplasia, which can lead to endometrial cancer.

Customer Information/Answer Sheet/Evaluation insert located between pages 68-69.

# COURSE TEST - #53384 WOMEN'S HEALTH FOR DENTAL PROFESSIONALS

This is an open book test. Please record your responses on the Answer Sheet. A passing grade of at least 70% must be achieved in order to receive credit for this course.

# This 5 CE Credit Hour activity must be completed by January 31, 2026.

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AGD Subject Code: 149. This course meets the Dental Board of California's requirements for 5 units of continuing education.

Dental Board of California course #05-3841-00382.

# 1. Which of the following has the Office of Research on Women's Health identified as a research priority?

- A) The health of girls and women across the life span
- B) The advancement of women in biomedical research careers
- C) Sex/gender, behavioral, psychosocial, socioeconomic, and geographic factors
- D) All of the above

2. Which of the following clinical findings is NOT associated with menstruation?

- A) Gingivitis
- B) Increase in tooth mobility
- C) Nodular hyperplastic reactions
- D) Increased incidence of dental caries

# 3. Which of the following statements is NOT true regarding the use of oral contraceptives?

- A) Gingival inflammation is a rare side effect of birth control pills.
- B) Changes in the bacterial flora include rises in the prevalence of Prevotella.
- C) There is an increased risk of several potential serious conditions, including thromboembolism.
- D) Tooth extractions should be performed on day
   23 to 28 of the pill cycle to reduce the risk of postextraction osteitis.

#### 4. "Pregnancy tumors" are

- A) usually present in clusters.
- B) best removed in the postpartum period.
- C) often found associated with salivary glands.
- D) easily distinguished from pyogenic granuloma based on appearance.

- 5. Periodontal disease is a statistically significant risk factor for preterm low birth weight, with an adjusted odds ratio of
  - A) 2.3.
  - B) 4.2.
  - C) 5.6.
  - D) 7.9.
- 6. The most common type of gynecologic cancer is
  - A) uterine.
  - B) ovarian.
  - C) cervical.
  - D) colorectal.
- 7. The risk to American women of developing breast cancer in their lifetime is reported as
  - A) 1 in 8.
  - B) 1 in 20.
  - C) 1 in 30.
  - D) 1 in 42.
- 8. The Women's Health Initiative clinical trial was halted after a mean follow-up of 5.2 years because of the apparent HRT-associated increased risks of *A*) stroke.
  - A) stroke.
  - B) osteoporosis.
  - C) cervical cancer.
  - D) periodontal disease.

- 9. Studies have shown that long-term estrogen use has all of the following effects on bone health in women, EXCEPT:
  - A) Slows demineralization
  - B) Protects against osteoporosis
  - C) Restores bone that has been lost
  - D) Reduces the incidence of hip and total fractures
- 10. Of the 6.5 million Americans 65 years of age and older with Alzheimer disease, how many are women?
  - A) 1 million
  - B) 2 million
  - C) 3 million
  - D) 4 million
- 11. In addressing alveolar bone loss associated with periodontitis, bisphosphonate drugs, such as alendronate,
  - A) are not useful treatments.
  - B) are not associated with MRONJ.
  - C) may retard progression of bone loss but also may cause MRONJ.
  - D) None of the above
- 12. Which of the following methods has NOT been identified as being helpful to prevent bone loss in postmenopausal women?
  - A) Stopping smoking
  - B) Limiting vitamin D intake
  - C) Consuming up to 1,200 mg per day of calcium
  - D) Performing at least one to three hours of weightbearing exercise per week
- 13. Data from the National Health and Nutrition Examination Study (NHANES I) showed that individuals with periodontitis had a
  - A) 10% greater likelihood of developing CHD.
  - B) 25% greater likelihood of developing CHD.
  - C) 45% greater likelihood of developing CHD.
  - D) 60% greater likelihood of developing CHD.
- 14. A study of carotid atheromas using polymerase chain reaction found that what percentage of atheromas contained at least one of the periodontal micro-organisms studied?
  - A) 5%
  - B) 18%
  - C) 42%
  - D) 60%

- 15. In the oral cavity, which sexually transmitted infection (STI) may manifest as a stomatitis and exhibit a clinical appearance similar to the oral lesions of erythema multiforme, erosive lichen planus, or herpetic stomatitis?A) HIV
  - B) Chlamydia
  - C) Gonorrhea
  - D) Condyloma

# 16. Which of the following STIs is NOT viral in origin?

- A) HIV
- B) Herpes
- C) Syphilis
- D) Condyloma
- 17. All of the following statements are TRUE, EXCEPT:
  - A) Anorexia nervosa and bulimia nervosa can significantly impact oral health.
  - Both anorexia nervosa and bulimia nervosa may carry a five or more times increased risk of mortality.
  - C) The frequent, self-induced vomiting in conditions like bulimia can have a destructive effect on teeth.
  - D) Anorexia nervosa and bulimia nervosa occur only in adolescent girls.

# 18. A dental manifestation of purge-type eating disorders is

- A) decalcification.
- B) softening of the enamel.
- C) loss of occlusal anatomy.
- D) All of the above
- 19. Victims of domestic violence are more likely than accident victims to sustain injury to all of the following areas, EXCEPT:
  - A) The head
  - B) The chest
  - C) The breast
  - D) The abdomen
- 20. After identifying a victim of domestic violence, the dental professional should
  - A) encourage the patient to call a crisis hotline.
  - B) provide a referral to a local domestic violence shelter.
  - C) refer the patient to local law enforcement officials if the situation is acute.
  - D) All of the above

Be sure to transfer your answers to the Answer Sheet located on the envelope insert located between pages 68–69. DO NOT send these test pages to NetCE. Retain them for your records.

PLEASE NOTE: Your postmark or facsimile date will be used as your test completion date.

# Botulinum Toxin and Dermal Fillers for Facial Aging

#### Audience

This course is designed for dental professionals who may administer or care for patients who have undergone aesthetic procedures.

#### **Course Objective**

The purpose of this course is to provide clinicians with the knowledge necessary to provide minimally invasive aesthetic procedures and to care for patients who have undergone these procedures.

#### Learning Objectives

Upon completion of this course, you should be able to:

- 1. Outline the background of aesthetic medicine and botulinum toxin/filler use.
- 2. Describe the process of usual facial aging.
- 3. Discuss the mechanism of action and clinical use of botulinum toxin for the treatment of facial aging.
- 4. Compare and contrast the classes of dermal filling agents available.
- 5. Analyze components that affect the appropriate selection of dermal filling agent.
- 6. Describe key aspects of individualized assessment of patients seeking aesthetic treatments for facial aging.
- 7. Outline the minimally invasive approach to the treatment of facial aging.
- 8. Evaluate patient-related factors affecting suitability for various aesthetic treatments.
- 9. Identify acute and potentially severe side effects of botulinum toxin/filler use.
- 10. Discuss the role of biofilm infections in delayed reactions to dermal fillers.

#### Faculty

Mark Rose, BS, MA, LP, is a licensed psychologist in the State of Minnesota with a private consulting practice and a medical research analyst with a biomedical communications firm. Earlier healthcare technology assessment work led to medical device and pharmaceutical sector experience in new product development involving cancer ablative devices and pain therapeutics. Along with substantial experience in addiction research, Mr. Rose has contributed to the authorship of numerous papers on CNS, oncology, and other medical disorders. He is the lead author of papers published in peerreviewed addiction, psychiatry, and pain medicine journals and has written books on prescription opioids and alcoholism published by the Hazelden Foundation. He also serves as an Expert Advisor and Expert Witness to law firms that represent disability claimants or criminal defendants on cases related to chronic pain, psychiatric/substance use disorders, and acute pharmacologic/toxicologic effects. Mr. Rose is on the Board of Directors of the Minneapolis-based International Institute of Anti-Aging Medicine and is a member of several professional organizations.

#### Faculty Disclosure

Contributing faculty, Mark Rose, BS, MA, LP, has disclosed no relevant financial relationship with any product manufacturer or service provider mentioned.

#### Division Planner

Mark J. Szarejko, DDS, FAGD

**Senior Director of Development and Academic Affairs** Sarah Campbell

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#### **Designations of Credit**

NetCE designates this activity for 10 continuing education credits.

AGD Subject Code 780.

This course meets the Dental Board of California's requirements for 10 units of continuing education.

Dental Board of California course #10-3841-00415.

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# INTRODUCTION

Visibly apparent aging and loss of youthful appearance are frequent concerns of patients seeking cosmetic treatment. Botulinum toxin and dermal (soft tissue) fillers are minimally invasive (i.e., injection-delivered) therapies that, along with knowledge advances, have revolutionized cosmetic treatment of aging features.

The clinical features of aging are the result of bone resorption; ligament laxity; redistribution, volume loss, and descent of facial soft tissue; and formation of lines and folds in inelastic, sagging skin. This complexity is not amenable to single-modality treatment; current practice combines botulinum toxin and fillers as the core approach, with other therapies added. Filling isolated lines or creases is de-emphasized.

In carefully selected patients with strict adherence to safety standards, desired results can be achieved with a low risk to safety. With increasing consumer demand, injector backgrounds and settings have expanded beyond oversight. Rises in catastrophic complications are largely unknown, as the "risk-free" perception of botulinum toxin and fillers continues. Clinicians and patients may be unaware of the range of U.S. Food and Drug Administration (FDA)-approved minimally invasive options, advances in the understanding and addressing facial aging with these therapies, and the potential of serious complications with incorrect use. These areas are the focus of this course.

Beyond the scope of this course are cosmetic surgery (e.g., rhinoplasty, face-lift), reconstructive or rehabilitative surgery, cosmetic concerns of systemic origin (e.g., lipoatrophy from antiretroviral therapy), and nonfacial cosmetic concerns. Laser, energy, and topical therapies are noninvasive interventions for sun-damaged, aged skin and acne scars, but they will not be the focus of this course. Cosmetic medicine is a point of convergence for diverse psychological, social, cultural, and racial factors, all of which should be considered for each patient. The properties of products discussed in this course are unique. This requires reference by commercial brand, but should not be construed as endorsement of any commercial product.

# TERMINOLOGY

Plastic surgery includes subfields of reconstructive or rehabilitative surgery for congenital malformations or acquired disfigurements, and cosmetic surgery for correction, restoration, or enhancement of appearance [1]. "Aesthetic medicine" was coined to replace "cosmetic medicine/surgery," but the terms remain interchangeable [2].

The cosmetic medicine literature describes features with terms (e.g., defect, defective, deformity, deformation) that carry different meanings outside of this highly specialized professional audience. It is not the intent of this course to imply that normal aging of the face or skin is in any way a defect aside from the patient's perception or desires in terms of appearance. Beauty is a standard that varies by culture, time, age, and personal experiences, and there is no one standard for any facial feature or individual.

Therapeutic goals are variously described as volumizing, revolumizing, rejuvenation, restoration, harmonization, resurfacing, correction, and others, with little consistency. This course will not attempt to modify terminology used in the published literature, except to improve logical consistency.

# BACKGROUND

Until the 1990s, facial aging was attributed to gravitational effects that required surgical lifting and tightening to defy soft-tissue descent. Facial aging as a multi-tissue process of descent, volume loss, and resorption was first described in 1965 but remained obscure, and the focus on superficial tissue descent and correction persisted [3; 4; 5; 6].

Botulinum toxin and dermal fillers were introduced to correct cosmetic defects without the need for surgery. Earlier use to spot-correct isolated wrinkles and creases led to temporary but limited benefits, with no advantage over surgical facelift for persons with moderate or advanced aging features [4; 5; 6; 7].

Studies identified soft tissue volume loss and hard tissue resorption as causal to facial aging. This prompted filler injection into deep tissue for re-volumizing; new fillers designed for specific tissue placement; use of lower-dose botulinum toxin to improve outcomes; advances in lasers and energy devices for resurfacing or tightening with minimal recovery time; and evidence of synergistic efficacy and superior cosmetic outcomes with combined therapies [6; 7; 8]. These advances brought a paradigm shift from "wrinkle-chasing," with isolated clinical benefit, to recognition of facial aging as a complex interaction of extrinsic and intrinsic factors across multiple tissue planes requiring a three-dimensional, multilayered treatment approach [9; 10]. Surgical facelift requires patients to wait until visible aging is sufficient to warrant surgery, often with sudden, sometimes unnatural, changes in appearance. Minimally invasive therapy offers a more gradual, natural-looking harmonization preferred by many patients [7].

Botulinum toxin and dermal filler injection techniques are constantly evolving; what was considered state-of-the-art 5 to 10 years ago no longer represents a practice standard [11]. Every year, the American Society of Plastic Surgeons (ASPS) and the American Society for Dermatologic Surgery (ASDS) separately publish the number of procedures performed by their boardcertified members. In 2020, ASPS members performed 15.6 million cosmetic procedures—13.2 million nonsurgical (92% female)—at a total cost of \$16.7 billion. Among patients who received cosmetic procedures, 66% were White, 12% were Hispanic, 9% were Black/African American, 7% were Asian, and 6% were other [12]. The 4.4 million botulinum toxin and 3.4 million dermal filler procedures reported by ASPS in 2020 represent an increase of 459% compared with 2000 [12]. ASDS members in 2019 performed an additional 2.3 million botulinum toxin (88% female) and 1.6 million filler (90% female) procedures, a 60% and 78% increase from 2012, respectively [13]. The number of cosmetic procedures was down significantly in all categories in 2020 (compared with 2019), likely due to COVID-19.

Between 2012 and 2017, there was a 50% increase in cosmetic procedure requests by persons younger than 30 years of age (90% female), and in 2016, more than 229,000 cosmetic procedures were performed in patients 18 years of age or younger [14; 15]. The annual figures by ASPS/ASDS are considered the benchmark for cosmetic procedures, trends, and demand, but they significantly under-represent the actual number of minimally invasive procedures performed outside of their membership [16; 17; 18; 19; 20].

## INCREASING CONCERNS

As cosmetic treatment methods have evolved, provider backgrounds expanded from specialists in plastic surgery (traditional) to dermatology, ophthalmology, and otolaryngology, then to dentists and registered nurses, followed by licensed aestheticians, unsanctioned medical personnel (e.g., medical assistants), and lay practitioners [17]. As such, the experience and qualifications of injectors is increasingly questionable and unpredictable. A large and growing proportion is performed in medical spas, spas, hair salons, other commercial settings, and at "Botox and filler parties" in private homes by nonhealthcare professionals, sometimes without written informed consent [16; 17].

There is an increasing number of filler complications from intravascular injection, an immediate, severe event that can result in blindness, tissue necrosis, or stroke, and from bacterial biofilm infection, when filler injection seeds skin-surface bacteria into tissue with the filler product [19]. Biofilm infections may become disfiguring, are often antibiotic-resistant, and are potentially a methicillin-resistant *Staphylococcus aureus* (MRSA) infection [21]. The increasingly unregulated state of botulinum toxin and filler injection practice, the absence of a universal adverse event reporting mechanism, and potentially powerful financial incentives to conceal complications have prompted calls for greater regulation of providers and practice and for relabeling of filler injections as "dermal implants" to accurately reflect the risks inherent in placing an inanimate object into human tissue [16; 17; 18; 22; 23].

The face ages in a unique but relatively consistent manner, creating a distinct but recognizable "aged" appearance. As people age, many are left with the feeling that their physical appearance is no longer an accurate representation of their mental state. Some opt to pursue cosmetic procedures for "matching their outsides with their insides" [24]. In skilled hands with diligent execution of precautions, the results attainable without surgery can be impressive, with a good safety margin. Improper patient selection, preparation, or technique invites problems ranging

# #50201 Botulinum Toxin and Dermal Fillers for Facial Aging

from patient dissatisfaction and poor cosmetic outcomes to increased risks of serious and potentially catastrophic complications of intravascular injection or delayed bacterial infections. The idea that botulinum toxin and fillers are risk-free cosmetic treatments is thoroughly dispelled.

# THE PROCESSES OF FACIAL AGING

In the face, the process of aging that culminates in cosmetic concerns is complex. Changes of the facial skeleton, soft tissue, retaining ligaments, fat compartments, and the skin contribute to the features of facial aging in varying degrees, influenced by intrinsic (e.g., genetic) and extrinsic (e.g., sun exposure) factors [25]. To understand facial aging and appropriate interventions requires multidimensional knowledge of the normal anatomy and physiology of facial tissue layers, age-related changes in histology and morphology in each plane, and their multilevel interactions to form cosmetic features of aging.

Perceptual models used in cosmetic medicine can assist in conceptualizing these changes. Each model views facial aging from a different perspective. Presented in sequence, the models break down the complex, dynamic, multidimensional process into its dimensional components. The predominant models are [4; 26; 27; 28; 29; 30; 31; 32]:

- The two-dimensional (2-D) model: Organizes the surface anatomy and superficial cosmetic defects into horizontal zones that anchor morphologic features to familiar anatomic boundaries
- The three-dimensional (3-D) model: Delineates facial anatomy into its underlying tissue layers to describe normal and age-related changes in structure/function at each facial tissue level
- The integrative model: "Zooms out" from the 3-D model to describe how tissue-level changes interact to form the visible features of facial aging
- The aesthetic zones/units model: Describes cosmetic defects of facial aging as changes in underlying and surrounding tissue within anatomically compartmentalized units

All four models will be used later in this course to describe the cosmetic features of facial aging and recommended minimally invasive interventions.

#### THE TWO-DIMENSIONAL MODEL

To describe the anatomic locations of common cosmetic concerns widely referenced in this course (*Table 1*), the face is divided into three horizontal zones with defined anatomic boundaries [4; 30; 31; 32]:

• The upper face: Forehead, glabella (smooth area between eyebrows), periocular (lateral to the eyes) areas, and temples

- The midface: Between the glabella and tip of nose, lateral to the zygoma (cheekbone). The malar area is highly relevant, as the malar is the cheekbone prominence. The submalar is the bony area underneath the cheekbone.
- The lower face: The perioral area (lips), mandible, chin, and neck

# THE 3-D MODEL: NORMAL ANATOMY OF FACIAL TISSUE

The two-dimensional model is a good descriptive framework for cosmetic concerns but does not describe the aging processes of underlying facial tissue that inform their minimally invasive correction. This area is addressed by the three-dimensional model.

#### The Skin

The skin consists of the epidermis and dermis, mutually dependent layers that rest on the superficial fat layer [35].

#### Epidermis

The epidermis is the most superficial layer, composed of stratified squamous cells or keratinocytes (90%) and melanocytes (approximately 8%). The epidermis is directly exposed to the environment and its damaging effects. To replace damaged cells, new cells must constantly form and migrate to the surface over two to four weeks [35; 36].

Melanocytes produce melanin, which gives pigment to the skin and absorbs ultraviolet (UV) light to prevent DNA damage. Absolute numbers of melanocytes are constant across races. The amount of melanin produced, size of melanosomes, and extent of aggregation account for differences in pigmentation. Epidermal melanocyte density declines with aging [35; 36; 37].

#### Dermis

The superficial papillary dermis (20% of the dermis) is loose connective tissue with capillaries, reticular fibers, and some collagen. Small projections (dermal papillae) into the epidermis maintain adhesion between the layers and nourish the epidermis [35; 36].

The deeper reticular dermis is dense connective tissue, and the deepest level borders the superficial fat layer. Collagen makes up most of the dermis (75% is collagen type I), providing strength and structure to the skin. Elastin fibers, synthesized by fibroblasts and keratinocytes, give elasticity and resilience. Fibroblasts, the major cell type of the dermis, produce procollagen and elastin fibers [35].

Filling the spaces between collagen and elastin fibers is an extracellular matrix of glycosaminoglycans (hyaluronic acid), chondroitin sulfates, and glycoproteins (carbohydrates or amino sugars linked to a protein) [35; 36; 38].

#### The Superficial Fat Layer

The superficial fat layer, consisting of adipose tissue and collagen network, contributes to thermoregulation, shock absorp-

FACIAL AGING FEATURES			
Zone	Cosmetic feature	Description	
Upper face	Glabellar rhytides	Vertical lines between the eyebrows	
	Horizontal forehead rhytides	Horizontal creases on the forehead, exacerbated during brow elevation	
	Lateral canthal rhytides ("crow's feet")	Multiple periocular lines and wrinkles that radiate lateral to the eye, more prominent when smiling	
	Brow ptosis (drooping)	Tissue descent that can mimic angry or scowling expressions	
	Temporal fossa wasting	Concavity of the temple area	
Midface	Nasojugal fold (tear trough depression)	Depression between the rim of the orbital bone and the nasal sidewall	
	"Bunny lines"	Wrinkles on the dorsal and lateral nose during contraction of the upper nasalis muscle	
	Nasolabial folds <sup>a</sup>	Creases extending from the lateral nasal alae to the lateral mouth	
Lower face	Perioral lip rhytides ("whistler's wrinkles")	Vertical wrinkles extending from the lip border	
	Mouth frown	A downward turn of the corners of the mouth	
	Melomental folds ("marionette lines")	Facial lines extending from the corners of the mouth to the mandible (jaw)	
	Mental crease	A horizontal groove present on the chin	
	Peau d'orange chin	Multiple dimples on the chin during contraction of the mentalis muscle	
	Masseteric hypertrophy	Square appearance to the jawline	
	Gingival (gummy) smile	Significant upper gum display during smiling <sup>b</sup>	
Neck <sup>c</sup>	Platysmal bands	Vertical linear bands present on the anterior neck	
	Horizontal neck lines	Horizontal bands present on the upper neck	
<sup>a</sup> Sometimes ass <sup>b</sup> Not necessaril <sup>c</sup> The neck is us	signed to the lower face. y age-related. sually included in the lower face for	three horizontal zones.	
Source: [10; 33; 34] Table 1			

tion, wound healing, and immune function. The adipocytes can transform into myofibroblasts to influence local collagen synthesis [39]. Fibrous partitions separate the superficial fat into perioral (around the lips), nasolabial, cheek, and periorbital (around the eye sockets) compartments [40].

In the midface, the malar fat is composed of superficial fat compartments that lie above the superficial fascia. From medial to lateral, they are [25; 41]:

- The nasolabial fat
- The superficial medial cheek, middle cheek, and lateral temporal cheek fat
- The inferior infraorbital fat, where under-eye "bags" appear, above the superficial medial cheek

# Superficial Musculo-Aponeurotic System

The soft tissue is complex, because active movement over and around the orbital and oral cavities requires a muscle layer within soft tissues that connects with the overlying skin [42]. The superficial musculo-aponeurotic system is an organized fibrous network comprised of the platysma muscle, parotid fascia, and fibromuscular layer covering the cheek. The superficial musculo-aponeurotic system divides the deep and superficial fat, connects the facial muscles to the dermis in a moveable continuous plane, and functions to transmit, distribute, and amplify the activity of all facial muscles [43; 44].

# Muscles and Ligaments

Muscles of facial expression and muscles that facilitate chewing, smiling, speaking, and blinking alter the tension in adjacent skin, unlike other muscles that attach to bones or tendons. Muscles of facial expression significantly impact facial aesthetics, as repeated contraction can form dynamic rhytids and static lines [44; 45; 46; 47].

# The Deep Fat Layer

The deep fat layer is separated from superficial fat by the superficial musculo-aponeurotic system in the midface, platysma in the neck, and superficial temporal fascia in the temples, forming deep fat pads with fibrous ligament partitions [39; 40]. Deep fat compartments in the midface are [25; 41]:
- The deep cheek fat, which divides into medial (deep and medial to nasolabial fat) and lateral (deep to superficial medial cheek fat) parts. The deep medial cheek extends medially almost to the lateral incisor tooth.
- Medial portion of the buccal fat pad, just lateral to the deep lateral cheek
- The medial and lateral suborbicularis oculi fat, deep to the orbicularis oculi muscle of the lower eyelid

#### The Deep Fascia

The deep fascia layers are interconnected and secured to the facial skeleton in specific areas by a network of retaining ligaments, perpendicular to the layers and connect all layers to the deep fascia. The deep fascia provides the attachment for ligament origins and is formed by the periosteum on the facial skeleton and by deep muscle fascia where the skeleton is overlain by the masticatory structures [42].

#### The Facial Skeleton

The facial skeleton forms the scaffold on which soft tissues are draped and has a substantial effect on appearance. The primary bones of the facial skeleton by horizontal zone are [31; 46; 48]:

- Upper face: The frontal bone (forehead), bordered below by the glabella (smooth area between eyebrows) and frontonasal groove, and laterally by the supraorbital (above-eye) ridges.
- Midface: Medial and middle thirds of the midface skeleton formed by the maxilla (houses roof of the mouth, extends upward to orbital floor). The lateral third is formed by the zygoma (cheekbone) body and arch.
- Lower face: The mandible (jaw bone) is the primary bone.

#### The 3-D Model: Age-Related Alteration

Age-related physiologic processes lead to morphologic changes of the facial skeleton, soft tissue, retaining ligaments, fat compartments, and skin. The three-dimensional alterations of facial aging require accurate evaluation to provide patients the optimal aesthetic strategy [25; 30; 42].

#### The Facial Skeleton

From prominent bone formation in youth, age-related changes in the relative dynamics of bone expansion and bone loss lead to predominant bone resorption in the aging craniofacial skeleton, an important contributor to facial aging [42; 49]. Skeletal resorption and atrophy is uneven, and bone reduction is greatest in facial areas where prominent aging stigmata appear [4; 25; 31; 42; 50]. The maxilla has the greatest resorption; substantial reduction in its anterior projection largely contributes to aged appearance. The periorbital bones and anterior and inferior mandible (prejowl area) resorb extensively; the chin becomes shorter. The posterior and superior mandible undergo bone formation, increasing the mandible angle from 97° in younger skulls to 135° in older skulls. Maxilla and mandible resorption appreciably reduces the facial height. The midface recedes, but the forehead continuously expands.

Local changes in soft tissue and mechanical needs can also induce bone remodeling [50]. Mechano-transduction transforms mechanical energy into electro-chemical signaling to tissues or cells. Through this process, chronic facial muscle tension or overuse contributes to skeletal changes by impacting molecular signaling pathways, which alters bone remodeling patterns [51].

Reduction of anterior projection in the aging facial skeleton occurs immediately beneath the periosteum attached to the bone surface. The periosteum recedes with the bone; ligament origins recede with the periosteum [42].

#### Facial Fat

Superficial and deep facial fat is highly compartmentalized. Aging significantly alters the volume, structure, and position of facial fat compartments. Typically, deep fat atrophies and superficial fat may be unchanged or hypertrophy. Assessment of the fat depletion pattern is crucial for volumetric restoration. With attention to ligament involvement, the pattern is fairly predictable [8; 25; 30; 41; 42; 50; 52]. It occurs first in the periorbital and malar fat. The most extensive loss of deep fat occurs in the lateral and medial orbital fat and medial cheek fat. Likewise, the most extensive loss of superficial fat occurs with lateral temporal and preauricular fat.

#### Ligaments

Ligaments confine the fat areas; retaining ligaments anchor and stabilize the skin and facial fascia. With aging, medial ligaments of the center face keep their strength with strong fixation points, but lateral ligaments weaken and lose ability to prevent movement of fat compartments (though they may retain the borders). With loss of lateral fat volume and ligament support, the malar fat moves inferomedially and the superficial nasolabial and superior/inferior jowl fat move medially.

#### Superficial Musculo-Aponeurotic System and Muscles

The ligaments also transmit the effect of skeleton resorption by strongly connecting the skeleton with the superficial musculoaponeurotic system. Glabella and masseter muscles can become hypo- or hypertonic. Chronic muscle use in facial expressions can aggravate some features of aging. Atrophy is prominent in masticatory muscles.

#### Epidermis and Dermis

Aging substantially alters the skin. Dermal collagen content declines by roughly 1% every year starting at around 40 years of age in women and 50 years of age in men. The remaining collagen fibers become disorganized, compact, and fragmented. Elastic fibers decrease in number and diameter. Epidermal thinning, collagen loss, and dermal elastosis contribute to fine rhytids of the aging face. Loss of muscle tone, skin elasticity, and thickness leads to sagging [41; 49].

These dermal changes trigger a cascade of secondary events that greatly influence surrounding tissues. Wrinkles and furrows, a main focus of patients seeking cosmetic treatment for aging, develop from a slow, progressive alteration of all facial structures [49]. UV radiation from sun exposure substantially contributes to skin changes in aging.

## THE INTEGRATIVE AND AESTHETIC UNITS PERSPECTIVES

The two- and three-dimensional models describe age-related changes within facial tissue layers. However, the integrative and aesthetic units models describe how these changes interact and combine into the cosmetic features of facial aging [4; 25; 30; 41; 42; 53].

As noted, bone resorption is extensive in orbital and periorbital, malar, submalar, and mandibular areas. Soft tissue loss occurs in periorbital, forehead, glabellar, temporal, malar, perioral, mandibular, and mental areas. Retaining ligaments of fat compartments weaken; facial fat and soft tissue descent forms malar bags, folds, and sagging in nasolabial, jowl, and submental areas.

Increased orbit size and posterior maxillary resorption promote inferior displacement of the malar fat, accentuation of nasolabial folds, a blunted midface, and loss of support for periorbital tissues that contributes to perioral lines. Infraorbital volume loss exposes the inferior border of the orbicularis oculi muscle that helps form a malar crescent over the zygomatic eminence (lateral) and the nasojugal fold (medial); formerly concealed infraorbital fat pads ("palpebral bags") emerge.

Periorbital and perioral skin wrinkling from repeated muscle action progress from dynamic rhytids to static rhytids as the skin changes become permanent. Volume loss, distributional changes, and sagging disrupt the defining arcs and convexities of youth and contribute to the distinct morphology of the aging face.

#### Youthful Appearance and Aging

Loss of youthful features and development of aging features are frequent cosmetic concerns of patients. Expert plastic surgeons and cosmetic dermatologists are broadly uniform in characterizing youthful features and age-related changes. The following section specifically describes female features; male features will discussed later in the course [4; 29; 32; 49; 54; 55; 56; 57; 58].

The youthful face has a diffuse, balanced distribution of superficial and deep fat, conferring a smooth, three-dimensional topography delineated by a series of arcs and convexities, without clear distinction between temple, eyelid, and malar areas. On frontal view, the primary arc of the jawline, convexities of the temples, and multiple smaller secondary arcs of the lips are evident. In profile, the definitive features of youth are the lateral cheek projection, extending as an unbroken convex line from the lower eyelid to the cheek (the "ogee" curve). Youthful features converge on the malar area. Prominent malar eminences are a hallmark of beauty in many cultures, and malar area convexity (roundness) is a defining feature of a youthful face. With aging, the malar fat position over the zygoma and orbital rim diminishes and descends. Ptotic cheek fat, and descent of malar soft tissue, produces sunken cheeks and shadows, leaving behind a cheek concavity accentuated by depletion of malar fullness.

From the front, the jawline appears scalloped; the temporal, buccal, and suborbital areas hollow; and the lips straight and angular. In profile, the primary arc of the cheek is broken, the mandibular arc replaced by a jowl line, and the forehead and brow lose their anterior projection.

Youthful features and age-related changes have agreement, but the extent of cosmetic correction is debated. A multinational panel of cosmetic medicine experts recommended an age-appropriate approach as the criterion standard, with a conservative approach preferable [52].

#### The Facial Aesthetic Units Perspective

The aesthetic units perspective informs how some visibly apparent aging features develop and directs cosmetic intervention. The surface and subsurface structural changes in skin thickness, composition of subcutaneous tissue, contour of the facial skeleton, and location and integrity of retaining ligaments contribute to variability of bony landmarks, formation of lines and wrinkles, variable skin pigmentation, and overall discontinuity of the facial region, termed "facial aesthetic units" [28].

In younger persons, facial aesthetic units flow together, appearing as a smoothly contoured, single dynamic structure without perceptible division. With aging, the redistribution of facial fat, loss of tissue volume, and retention of ligament borders induce a demarcation of the underlying facial structures. The compartmentalized aesthetic units become distinct as changes within and between distinct aesthetic units collectively contribute to an overall aged facial appearance [4; 28].

A strong correlation was found between observer judgment of age and visually obvious separation of facial aesthetic units, suggesting it may serve as a psychophysical cue fundamental to perception of facial aging. This finding also aligns with current practice. Facial rejuvenation can include creation of more homogeneous skin tones, texture, and facial symmetry, and smooth contours between anatomical regions by blending the transition of facial aesthetic units for a harmonious and youthful facial appearance [28].

#### BOTULINUM TOXIN

#### DISCOVERY AND DEVELOPMENT

Botulinum toxin is derived from neurotoxins produced by *Clostridium botulinum*, the gram-positive bacillus that causes botulism. Subsequent to the 1897 discovery of *C. botulinum* as etiologic agent of botulism, seven botulinum toxin serotypes

BOTULINUM TOXIN PRODUCTS AND FORMULATIONS					
Name, Serotype	Commercial Product	FDA-Approved Indications	Comments		
ONA type-A	Botox Botox Cosmetic Vistabel Vistabex Vacuum-dried powder (50 or 100 U/vial)	Glabellar, lateral canthal, and forehead lines	The original, most-studied formulation. Widely used off-label for treating other lines and facial contouring.		
ABO type-A	Dysport (300 or 500 U/vial)	Glabellar lines	First marketed in Europe		
INCO type-A	Bocouture or Xeomin (as lyophilized powder in 50 or 100 U)	Glabellar lines	Newer formulation. Free of complexing proteins. May reduce risks of sensitization and antibody formation.		
PRA type-A	Jeuveau (4 U [0.1 mL] IM in each of five sites)	Glabellar lines	Newer formulation. Similar in efficacy to ONA.		
RIMA type-B	Myobloc, in liquid (5,000 U/mL)	No cosmetic indications	Less studied than type-A. Used in off-label facial lines. Distributed in the United States and Canada.		
DAXI type-A	Daxxify (as lyophilized powder in 50 or 100 U)	Glabellar lines	New formulation (2022 FDA approval)		
ABO = abobotulinumtoxinA, INCO = incobotulinumtoxinA, ONA = onabotulinumtoxinA, PRA = prabotulinumtoxinA, RIMA = rimabotulinumtoxinB, DAXI = daxibotulinumtoxinA, U = units.					
Source: [59] Table 2					

(A, B, C1, D, E, F, and G) with differing pharmacologic properties have been identified. Only serotypes A and B are used clinically, with type A (botulinum toxin-A) the most widely used for both medical and aesthetic indications [59].

During the late 1960s and early 1970s, the clinical value of botulinum toxin became evident in the treatment of strabismus. This was followed by demonstrated benefit in blepharospasm, hemifacial spasm, cervical dystonia, and other disorders of muscle hyperactivity and spasticity. From the first report of botulinum toxin-A injection for a cosmetic indication (glabellar frown lines) in 1992, its use has expanded to become the most requested procedure in aesthetic medicine. One commercial brand of botulinum toxin-A, Botox, has become popularized as the generic reference for all cosmetic botulinum toxin [60; 61].

Botulinum toxin-A is the primary form used for cosmetic treatment. While less extensively studied for cosmetic indications, botulinum toxin-B also appears to be effective [59].

#### MECHANISM OF ACTION

Botulinum toxins block the release of acetylcholine from motor neurons at the neuromuscular junction. By inhibiting acetylcholine neurotransmission between peripheral nerve endings and muscle fibers, botulinum toxin weakens or paralyzes skeletal muscle and, in aesthetic medicine, weakens muscular contraction [10].

Botulinum toxin blocks presynaptic acetylcholine release, causing reduced or diminished muscle contraction. This results in temporary improvement in the appearance of the areas affected by lines and wrinkles, for facial contouring and improving the skin [62]. The inhibitory effect is temporary; recovery of muscular function is often evident by three months, but the cosmetic effect may persist longer [10; 33].

#### AVAILABLE PRODUCTS AND FORMULATIONS

Four botulinum toxin formulations are approved by the FDA for aesthetic use (*Table 2*). The FDA recommends using specific names (e.g., ONA or ABO, Botox or Dysport), instead of serotypes (e.g., botulinum toxin-A), to prevent confusion between products [59]. Discussion in this course is limited to the five serotype A botulinum toxin products approved for cosmetic use; the off-label use of RIMA will not be explored. Unless a specific product is described, botulinum toxin is used to broadly reference the use of FDA-approved botulinum toxin-A formulations.

ONA, ABO, PRA, INCO, and DAXI must be reconstituted before using, with sterile, non-preserved saline recommended by their respective makers. In practice, many clinicians reconstitute these products in saline containing benzyl alcohol to reduce injection-site pain [63]. Compelling evidence now suggests that reconstitution using preserved saline dramatically improves patient comfort without compromising efficacy [18].

The formulations (i.e., ONA, INCO, PRA, ABO, and DAXI) are not interchangeable. The products differ in units, chemical properties, biologic activities, weight, and manufacturing pro-

cess. Production process and conditions such as pH, temperature, formulation, and concentration are crucial; alterations in any can increase the likelihood of formation of inactivated toxoid proteins, which in turn may be immunogenic [62].

Dose conversions are not standardized. Dosing is not interchangeable, and the products and procedures should be selected and prescribed according to individual needs and aims of treatment [62].

#### CLINICAL USE OF BOTULINUM TOXIN

With aging, decreased skin elasticity and repeated muscle contraction cause hyper-functional facial lines, particularly in the glabellar and periorbital regions. Depressor muscles overpower the levators to result in ptosis of the brow and mid-cheek groove, and patients develop horizontal forehead rhytides, glabellar frown lines, or lateral canthal "crow's feet," indications for botulinum toxin use [64].

Botulinum toxin is also extensively used off-label for brow shaping, eyebrow lifting, opening the aperture of the eye, decreasing mouth frown, defining the jaw line, increasing lip show, decreasing gummy smile, reducing "bar-code" lines around the mouth, eliminating "golf ball" chin, reducing platysma bands, and softening a squared, masculine jaw [65].

Patients treated with botulinum toxin for aesthetic purposes can expect their results to last at least three months, but effects can persist four to five months depending on the area treated, dose, and formulation used. The results may last longer for some patients, especially after repeated treatment [62].

Long-term outcome data support practice trends in decreased dosing and increased botulinum toxin injection intervals. Patients treated for glabellar lines over an average of nine years reported high levels of satisfaction sustained by repeated treatment and greater reductions in their perceived age with increasingly longer treatment durations [6].

While botulinum toxin monotherapy of dynamic rhytides is effective, current practice favors botulinum toxin combined with fillers, lasers, and/or light- or energy-based devices for synergistic effects and superior and more durable improvements [10; 33; 59].

Dilution of FDA-approved botulinum toxin for off-label intradermal injection is used for reducing surface wrinkling by weakening superficial facial muscle activity but sparing deeper muscle function. This approach is also used for reducing upper face rhytides without affecting brow muscles [64; 66].

Safe and effective use of botulinum toxin requires the understanding of anatomy, movement of muscles in isolation and in relation to other muscles, the concept of compensatory strengthening, and observant evaluation of the patient at rest (static) and with normal and exaggerated animation (dynamic). Every patient is unique, and inter-patient differences can be vast [65].

#### Patient Selection

To help determine botulinum toxin suitability, assess facial muscle function and tone in static and dynamic states looking for signs of stronger contraction (e.g., greater dynamic movement, deeper lines, larger apparent mass during use) [67]. Observing dynamic movement of the skin can help identify areas of stronger or weaker muscle contraction, why certain wrinkles are formed, and which muscles are creating them. The findings assign patients to one of the following categories [67]:

- Kinetic: Regular muscle contraction and wrinkles during active expression, but not at rest. Botulinum toxin very likely effective.
- Hyperkinetic: More excessive muscle contraction. May require more frequent, higher-dose botulinum toxin to achieve the desired effect.
- Hypertonic: Inability to relax specific muscles, visible wrinkles at rest. Some benefits may be possible with botulinum toxin, but adding filler injections may be necessary.
- Deep static lines with loss of skin elasticity: Unsuitable for botulinum toxin injection.

#### Side Effects and Safety

Compared with dermal fillers, prevention of botulinum toxin adverse effects is more straight-forward [18; 33; 59; 62]. Common acute side effects include transient swelling, bruising, and headache. Ice or cooling is commonly used for post-injection comfort and to prevent bruising. Temperature seems to influence botulinum toxin uptake, suggesting that cooling the area might undermine efficacy.

Poor treatment response can result from insufficient or incorrect dosing, anatomical variation, or errors in drug handling during preparation, storage, or administration. Diffusion of toxin to untargeted areas from improper injection placement can result in excessive muscle weakness, cosmetic disfigurement, and/or functional deficits that persist for months.

#### Contraindications

Injection-site infection, known hypersensitivity to any product component, and allergy to cow milk proteins for ABO only are all contraindications to botulinum toxin treatment [59]. Perioral botulinum toxin injections in professional speaker, vocalist, or musician patients require discussion of the potential functional impact from weakened or impaired muscle tone, a possible contraindication.

#### SOFT TISSUE (DERMAL) FILLERS

A variety of injectable soft tissue (dermal) filling agents are available for correction of prominent skin lines, fat atrophy, volume lost, and other contour changes of facial soft tissue (*Table 3*) [68]. Fillers are classed on different variables that

FDA-APPROVED DERMAL FILLERS AND CLINICAL USE			
Product, Year Approved	Approved Indications		
Hyaluronic acid: Galderma Labs	3		
Restylane <sup>a</sup> , 2003	Correction of moderate-to-severe facial rhytides and/or folds		
Restylane-L, 2012	Lip augmentation		
Restylane Silk, 2014	Lip augmentation Correction of perioral rhytides		
Restylane Lyft, 2015	Correction of moderate-to-severe deep facial rhytides and folds		
Restylane Defyne, 2016	Correction of moderate-to-severe facial rhytides and folds with age-related volume loss		
Restylane Refyne, 2016	Correction of moderate-to-severe facial rhytides and folds		
Restylane Kysse, 2020	Lip augmentation Correction of perioral rhytides		
Restylane Contour, 2021	Cheek augmentation, correction of midface contour deficiencies Correction of perioral rhytides		
Hyaluronic acid: Allergan			
Juvéderm XC, 2006	Correction of moderate-to-severe facial rhytides and folds		
Juvéderm Ultra XC, 2006			
Juvéderm Ultra Plus XC, 2006			
Juvéderm Ultra Plus XC, 2015	Lip augmentation Correction of perioral rhytides		
Juvéderm Voluma XC, 2013	Correction of age-related volume deficit in the midface Cheek augmentation		
Juvéderm Volbella XC, 2016	Lip augmentation Correction of perioral rhytides		
Juvéderm Vollure XC, 2017	Injection into the mid-to-deep dermis for correction of moderate-to-severe facial wrinkles and folds (e.g., nasolabial folds)		
Hyaluronic acid: Merz Aesthetic	s		
Belotero Balance, 2011	Correction of facial rhytides and folds, especially around the nose and mouth		
Hyaluronic acid: Teoxane S.A.			
RHA 2 and RHA 3, 2017	Injection into the mid-to-deep dermis for correction of moderate-to-severe dynamic facial wrinkles and folds (e.g., nasolabial folds)		
RHA 4, 2017	Injection in deep dermis to superficial subcutaneous tissue for correction of moderate- to-severe dynamic facial wrinkles and folds (e.g., nasolabial folds)		
Hyaluronic acid: Prollenium Me	edical Technologies, Inc.		
Revanesse Versa, 2018	Injection in mid to deep dermis for correction of moderate-to-severe facial wrinkles and folds (e.g., nasolabial folds)		
Calcium hydroxylapatite (CaHA	): Merz Aesthetics		
Radiesse <sup>a</sup> , 2006	Correction of moderate-to-severe facial rhytides and folds		
Radiesse(+), 2015			
Poly-L-lactic acid (PLLA): Galde	rma Labs		
Sculptra Aesthetic, 2009	Correction of shallow-to-deep nasolabial fold contour deficiencies and other facial rhytides		
Polymethylmethacrylate (PMMA	A): Suneva Medical		
Bellafill, 2006	Correction of volume deficits around the mouth (e.g., nasolabial folds)		
Bellafill, 2015	Correction of acne scars		
<sup>a</sup> Does not contain lidocaine.			
Source: [72; 73]	Table 3		

inform appropriate selection and potential complications: biodegradability, longevity in the tissue, and histologic reaction [69; 70; 71].

The FDA designates fillers as either absorbable/temporary (e.g., hyaluronic acid, calcium hydroxyapatite [CaHA], poly-L-lactic acid [PLLA]) or non-absorbable/permanent (e.g., polymethyl-methacrylate [PMMA]) based on the agent's biodegradability. If an agent absorbs within 18 months, it is considered temporary; if it does not absorb within 24 months, it is considered permanent. Some agents combine absorbable material for immediate effect and carrier until a nonabsorbable material induces fibroblast stimulatory effects (in more than 18 months). These agents are considered semipermanent. Agents with minimal tissue response are considered volumizers, while those that induce a strong tissue reaction are considered stimulators.

Temporary fillers use FDA-approved biodegradable materials absorbed by the body over time. Permanent fillers persist indefinitely in tissue. Some FDA-approved fillers, such as collagen-based products or avian-derived hyaluronic acid (Hylaform), remain available but are largely replaced by hyaluronic acid fillers with superior clinical properties and/or negligible allergenic potential [68; 73; 74].

Most acute side effects and potential serious adverse effects of FDA-approved dermal fillers are common across fillers. All filler agents are contraindicated in patients with known hypersensitivity to any product component specific to the product. There are a variety of other contraindications to the use of various dermal fillers (*Table 4*).

With all fillers, treatment should undercorrect the defect and avoid overcorrection. All treatment sites should be massaged immediately after injection to facilitate an even distribution.

#### HYALURONIC ACID

Hyaluronic acid is a glycosaminoglycan disaccharide and natural constituent of the dermal extracellular matrix, cartilage, and connective tissue. Hyaluronic acid is highly hydrophilic, enabling dermal hyaluronic acid to hydrate and cushion the skin and fill empty spaces within the extracellular matrix. Dermal hyaluronic acid content declines with skin aging, which reduces water-binding capacity and elasticity, induces volume loss, and promotes the development of rhytids and other aging features [72; 73; 76; 77].

Unmodified hyaluronic acid readily dissolves in water to form a viscous gel, but injected into the dermis, it is quickly degraded by hyaluronidase and free radicals in the skin [76]. Most FDA-approved hyaluronic acid fillers use nonanimal stabilized hyaluronic acid synthesized from *Streptococcus equi* bacteria. Liquid nonanimal stabilized hyaluronic acid, as with native hyaluronic acid, is rapidly broken down [72; 77]. To increase stability and longevity, manufacturers use crosslinking agents to bind hyaluronic acid polymer chains to each other, resulting in a gel that resists enzymatic and free radical breakdown. Most fillers use 1,4-butanediol diglycidyl ether (BDDE) as a cross-linker [76; 77]. The hyaluronic acid modification process,

proprietary to each maker, allows a portfolio of hyaluronic acid filler consistencies with varied rheologic properties (e.g., viscosity, gel hardness, lifting ability, tissue integration) that determine optimal tissue placement depth and product longevity [19; 78; 79].

Hyaluronic acid can bind 1,000 times its volume in water. This water-binding and space-filling effect underlies the volumizing efficacy of hyaluronic acid fillers [76]. Efficacy has been observed to persist beyond a time frame explained by spacefilling effects alone. This led to research of other mechanisms, which identified induction of adipogenesis, neocollagenesis through mechanical tension on fibroblasts, and periosteal stem cell activation followed by new tissue formation with periosteal filler placement [52; 80; 81].

Hyaluronic acid fillers combined with botulinum toxin act synergistically to produce superior, more durable effects than either monotherapy. For example, the longevity of effects is improved when treating sites of dynamic wrinkles, such as glabellar lines. Reduced filler deformation due to botulinumtoxin induced local muscle relaxation at least partially accounts for this effect [68].

#### CALCIUM HYDROXYLAPATITE

Calcium hydroxylapatite (CaHA) is a mineral commonly found in human teeth and bones that functions as a scaffold for collagen ingrowth. CaHA filler contains CaHA microspheres as biodegradable particles suspended in an aqueous carboxymethylcellulose gel carrier. Once injected, the carrier gel gradually resorbs; the microspheres stimulate a fibroblastic response resulting in active physiologic remodeling of the extracellular matrix and long-term collagen deposition around the implant that promotes volumizing. The microspheres eventually degrade into calcium and phosphate ions and are excreted. The effects last around 18 months [10; 73; 79].

Radiesse (formerly Radiance) is the only FDA-approved CaHA filler, indicated for correcting moderate-to-severe soft-tissue defects, facial folds, and wrinkles, including nasolabial folds [72]. The viscoelastic filler is well suited for supraperiosteal and deep fat placement. When injected more superficially, it should be diluted 1:1 or 1:2 [10; 68]. Radiesse(+), formulated with 0.3% lidocaine, was approved in 2015 to reduce pain without needing to premix before injection [82].

Radiesse is contraindicated in patients with a history of anaphylaxis or multiple severe allergies [68]. Radiesse injection of the lips risks forming nodules and should be avoided. Radiesse is visible on x-ray and may obscure underlying features [73].

#### POLY-L-LACTIC ACID

Poly-L-lactic acid (PLLA) is a biodegradable, biocompatible, synthetic polymer used for decades in resorbable sutures, orthopedic plates, and urologic stents. First approved in 1999 as a dermal filler in Europe, PLLA received FDA approval in 2004 for the treatment of HIV-associated lipoatrophy (Sculptra) and in 2009 for aesthetic treatment in immunocompetent patients (Sculptra Aesthetic) [49; 72; 73].

CONTRAINDICATIONS TO DERMAL FILLERS			
Contraindication	Specific Conditions		
Relative and absolute contraindicatio	ns		
Allergic history	Multiple severe allergies Anaphylaxis Heightened immune responses to common inhaled and food allergens (atopy) Allergy to latex, hyaluronic acid products, streptococcal/other gram-positive bacterial proteins, or lidocaine Desensitization therapy during filler treatment		
Scar-related	History of hypertrophic scarring or keloid formation Scars at intended treatment site		
Bleeding-related	Current anticoagulant or antiplatelet therapy History of bleeding, clotting (hemophilia), or connective tissue disorders		
Active autoimmune disease	Systemic lupus erythematosus Rheumatoid arthritis Hashimoto thyroiditis		
Patient-related factors	Unattainable expectations Pregnancy Lactation		
Contraindications unless fully resolve	ed with treatment		
Inflammatory skin diseases	Atopic dermatitis Seborrheic dermatitis Acne Rosacea Psoriasis		
Skin infection or any unhealed facial wound	Impetigo Folliculitis <i>Propionibacterium</i> acnes Viral warts Perioral HPV Molluscum contagiosa Streptococci or staphylococci bacterial infections <i>Candida</i> (yeast) infections		
Local infection	ENT, oral cavity, or dental infections or abscess		
Remote infection	Intestinal tract, urinary tract, or bladder infection		
Inflammatory processes	Pimples Hives Rashes Cysts		
ENT = ear, nose, or throat, HPV = hu	man papillomavirus.		
Source: [19; 75]	Table 4		

PLLA induces a subclinical inflammatory response that stimulates fibroblast proliferation, neocollagenesis, and type I collagen formation, leading to a progressive increase in dermal volume [68; 72]. Each PLLA injection produces a gradual treatment effect with limited correction. Three injection sessions at six-week intervals are generally required, but improvements after the final injection can last up to two years. Patients should be counseled that final results can take months to achieve [83; 84]. Treatment should aim to undercorrect, because the results progressively improve over time. Injections should be spaced at least three weeks apart because transient post-injection edema can mimic a full correction [68].

Injections should be placed into the deep dermis or subcutaneous fat. The lip and periorbital region should be avoided due to risk for nodule formation. Subcutaneous papules are a common adverse effect [68].

#### POLYMETHYLMETHACRYLATE MICROSPHERES

Polymethylmethacrylate (PMMA) is a non-biodegradable, biocompatible, synthetic polymer used in medical devices such as bone cement and intraocular lenses. As a soft tissue filler, PMMA microspheres are tiny, round, smooth particles suspended in a gel-like solution containing lidocaine and bovine collagen [73].

The collagen gel gives an initial volume but is resorbed over one to three months. The microspheres stimulate a local inflammatory reaction, followed by deposition of granulation tissue that encapsulate the microspheres and mature into connective tissue. By three months post-injection, the microspheres are surrounded by newly formed collagen, accounting for the observed volume-filling effect [74; 79; 84]. Tissue encapsulation of PMMA microspheres makes the results irreversible.

The PMMA filler Bellafill is the only FDA-approved permanent filler. Treatment of nasolabial folds and facial acne scars are the only approved cosmetic indications, but Bellafill is used off-label to volumize other mid- and lower-face contour defects [74; 85].

The bovine collagen carries potential immunogenic issues. Clearance for Bellafill injection requires non-reactive response to skin-testing for bovine collagen hypersensitivity one month pre-procedure [74; 79].

Good PMMA candidates are patients with well-defined lines and furrows and minimal excess skin [74; 85]. PMMA use is not recommended in areas of thin skin (e.g., lower eyelid, neck), the lips, and in patients with generally thin, loose skin [74].

Bellafill is intended for deep tissue placement. A series of conservative injections can be required for optimal results, with touch-up injections performed one to three months after initial treatment [74]. Optimal results require 3 to 12 months for sufficient new collagen synthesis, and additional improvement beyond 12 months may occur [86].

#### FILLER SELECTION

#### Hyaluronic Acid Fillers

Unlike CaHA (Radiesse), PLLA (Sculptra), and PMMA (Bellafill) fillers, availability of numerous hyaluronic acid products requires judicious product selection based on rheologic properties. Each facial area and anatomic plane subjects filler to biomechanical stressors of compression, stretching, and lateral shearing from skin tension, muscle activity, and fat volume of varying intensity and frequency [78; 87].

Rheology studies the flow and deformation of filler material subjected to biomechanical stressors to understand their clinical properties and behavior. Manufacturers crosslink and modify hyaluronic acid products (e.g., Hylacross, Vycross) using methods that determine gel rheology. The rheologic properties leverage the distinct tissue distribution patterns and clinical behaviors of hyaluronic acid products [76; 77]. The clinical behavior of Radiesse is influenced by the same rheologic factors as hyaluronic acid fillers. Rheologic properties are unique to each hyaluronic acid and CaHA product, between filler families. The major rheologic properties are [9; 29; 53; 76; 78; 88; 89; 90]:

- Shearing: Force pushing one part of a body in one direction and another part in the opposite direction
- Elasticity: Ability to resist deformation by external forces
- Viscosity: Ability to resist shearing forces
- Cohesivity: Ability to resist vertical compression and stretching
- Hydrophilicity (water-binding ability): Capacity to attract water and expand
- Particle size: Contributes to overall lifting and filling power
- Particle concentration and crosslinking: Influences durability by resisting enzymatic degradation.

Clinically, the elasticity of filler reflects the gel's firmness. The level of viscosity will determine the pattern and extent of tissue integration. High-viscosity agents resist tissue spread and shearing. Low-viscosity agents are ideal for superficial placement to treat shallow folds and lines and are best used where spread and softness is more important than volume (e.g., the lips) [53; 76; 77; 78]. Conversely, high-elasticity and high-viscosity gels are best suited for deep placement to treat deep folds and restore volume loss by creating volume and lift in the mid- and lower face.

Cohesivity is spreading related to tissue depth and ability to hold form or shape under stress by overlying/underlying muscle and skin compression. Cohesivity increases with degree of cross-linking and hyaluronic acid concentration. Low-cohesivity gels are easier to mold and spread evenly in the skin, making them suited for correcting small rhytides. High-cohesivity gels are suited for revolumizing large areas of volume loss.

Restylane Lyft is an example of a high-elasticity, large-particle gel with greater filling power and resistance to degradation in deep-tissue volumizing. Juvéderm products use elasticity from highest to lowest in gels intended for deep (Voluma), midlevel (Vollure), and superficial (Volbella) tissue placement.

#### Calcium Hydroxylapatite

With a high lift capacity and results that last more than one year, Radiesse works well to fill volume loss in the midface and is placed in a manner similar to injection of hyaluronic acid products [84]. The use of Radiesse for melomental folds ("marionette lines") has been reported extensively, with effective and durable results [58].

Of note, Radiesse may be more likely than other fillers to result in intra-arterial complications, skin necrosis, and blindness. The increased propensity to cause vascular compromise could

be related to particle size, with larger particles resulting in more proximal vessel obstruction. Certain particles may also stimulate the clotting cascade, ultimately resulting in skin necrosis [16]. This seems to elevate precautions in using this product near vascular danger zones.

#### Poly-L-Lactic Acid (Sculptra)

PLLA volumizes soft tissue in a gradual, progressive, and predictable manner, providing natural-looking restoration of facial volume [91]. Although it is categorized as biodegradable by the FDA, the duration of action is 12 to 24 months and, with repeat treatment, several years. As noted, PLLA is more accurately classed as a semipermanent dermal filler [84; 92].

PLLA should be avoided in perioral and periocular areas; in the neck where thin skin requires superficial injection; and in mandibular ligament/platysma muscles [49; 58]. Superficial injection in the dermis is also inappropriate. PLAA injection is recommended for the supraperiosteal in the temples, lateral brow, zygomatic area, maxillary area, mandibular area, and mental area [93]. It may also be used in the subcutaneous fat in the mid-cheek regions and preauricular area. More specifically, recommended PLLA injection sites are [49; 58; 93]:

- Temporal fossa: Supraperiosteal at the temporal muscle origin
- Lateral brow: Supraperiosteal at the tail of the brow
- Medial malar region: Supraperiosteal on the zygomatic bone, maxilla, and pyriform fossa
- Submalar/mid-cheek: Deep subcutaneous plane where bony background is absent
- Lateral third of the mandible/mandibular angle and lower lateral cheek: Superficial subcutaneous fat above the parotid gland and masseter muscle
- Mandible/chin: Supraperiosteal over the menton and prejowl sulcus

Sculptra may provide global volume restoration in lean patients who are too depleted for space-occupying fillers, an alternative to deep volumizing hyaluronic acid fillers that could be too expensive and difficult to use as scaffolding [94].

#### Polymethylmethacrylate (Bellafill)

Used as a deep tissue filler for mid- and lower-face volume loss, Bellafill seems comparable to other filler types in efficacy [84]. This shifts the basis for Bellafill selection to patient preference and appropriateness [34; 74].

Persistent effects, possibly with a single treatment (or with minor touch-ups), can make Bellafill attractive, but treatment with permanent fillers requires careful screening. Patients who have histories of unsubstantiated dissatisfaction with cosmetic results, are unsure of their desired outcome, or are new to fillers are poor candidates for Bellafill [34; 74].

#### Other Considerations in Filler Selection

Clinician experience influences the choice of filler. Improper use can result in an unacceptably high risk for adverse effects, and clinicians not trained in using specific fillers should refrain from their use [34; 74]. Complications or unfavorable cosmetic results with permanent fillers may require surgical intervention and may be impossible to completely reverse.

The desired duration of effect should be considered. Fillers that eventually degrade in tissue (e.g., hyaluronic acid) offer the advantage of reversibility but require multiple subsequent treatments to maintain the desired effect. Adverse effects of products may not become apparent until post-market, making it prudent to select products with an established safety/adverse event profile from clinical use [95].

#### DEOXYCHOLIC ACID

Deoxycholic acid (Kybella) is FDA-approved for treatment of moderate-to-severe submental fullness/convexity ("double chin"). Injection into the subcutaneous fat below the chin area causes focal adipolysis and necrosis. This induces macrophages to clear cell membrane fragments, recruit fibroblasts, and stimulate neocollagenesis. Once destroyed, adipocytes cannot store or accumulate fat. Submental appearance is improved through subcutaneous fat reduction and tissue tightening [96; 97].

Kybella is an alternative to liposuction for achieving an aesthetically pleasing jawline by submental fat reduction, but comparisons in clinical trials are lacking. Kybella is given in 0.2-mL injections, spaced 1 cm apart, until all sites in the planned treatment area are injected. Up to 50 injections, or 10 mL, are allowed per session. Several sessions spaced at least four weeks apart are usually required. In phase 3 clinical trials, the drug was effective and safe, although a significant number of patients experienced pain, transient bruising, edema, and numbness [98; 99].

In the phase 3 trials, patients were injected with a mean 186 mg of drug as treatment. Cosmetic surgeons reported charging a mean \$691 per 20-mg vial of deoxycholic acid, which would have cost the average study participant \$6,426.35. In contrast, the average patient cost for submental liposuction is \$2,976.56. While Kybella is cost-effective only for patients with mild-to-moderate submental liposis who require fewer injections and treatments, the avoidance of surgery for some patients may outweigh the greater expense [99].

With a 13% decrease in procedures performed in 2020 (135,586) compared with 2019 (156,153), Kybella uptake into cosmetic practice seems limited following its 2015 FDA approval [12].

#### INDIVIDUALIZED ASSESSMENT AND TREATMENT PLANNING

#### **KEY ASSESSMENT ELEMENTS**

Optimal assessment of facial aging begins with a thorough patient history and examination that assesses anatomical

structure and age-related changes to the bone, fat, muscle, and skin. Specifically, this should include [10; 49]:

- Skeletal changes
- Degree and location of volume loss
- Muscle anatomy and movement
- Appearance of lines and wrinkles
- Skin quality
- General facial appearance, symmetry, or any imbalance in facial proportions

The use of photonumeric scales are recommended for the objective assessment of facial aging features. Photonumeric scales have the advantage of providing a consistent visual frame of reference that minimizes variability in perception and subjectivity [100].

With these scales, assessment of the upper, mid, and lower face is performed, with specific aging features rated using a 0–4 scale (0: absent; 4: advanced) [101; 102; 103]. The score helps inform the appropriate level of intervention [10]:

- Early intervention: Individuals with minimal evidence of facial aging (Levels 0–1)
- Restoration: Individuals with moderate to advanced signs of aging (Levels 2-4)

The assessment lays the foundation for a detailed, individualized treatment plan that balances clinical experience with patient desires and expectations [10]. In this initial period, it is important to discuss treatment goals and ensure the patient understands the progressive nature of the aging process. Costs should also be reviewed, and in patients with limited financial means, treatment should focus on areas that will have the greatest impact. When the individualized treatment plan is formulated, the extent and sequence of procedures and/or treatments should be discussed. Clinicians should ensure the patient understands the maintenance involved in any type of facial restoration and that overtreatment and unnatural results (and likewise undertreatment and suboptimal results) will be avoided.

#### ETHNIC CONSIDERATIONS

Fundamental to individualized patient assessment is careful consideration of racial/ethnic and gender variation in facial aging features. In this course, the terms used to reference ancestry are Caucasian (European, North African, southwest Asian/Middle Eastern), African (sub-Saharan Africa), Latino/ Hispanic (Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture), East Asian (China, Korea, Japan), Southeast Asian (Thailand, Singapore, Indonesia), and South Asian (the Indian subcontinent) [104].

People of all races have distinct ethnic features, yet cultural standards of beauty share remarkable similarity around the world, such as balance, proportion, and symmetry of facial features, and clear, unblemished, and youthful skin [105; 106].

The aging process may manifest differently among various ethnic/racial group; aging promotes and accentuates intrinsic differences of facial morphology and structure. This leads to variations in aged features, such as "Caucasian corners" of lips that develop into marionette lines [94; 105].

Relative to other ethnic/racial groups, the earlier onset and more extensive facial aging common in Caucasian patients reflects the interaction of morphologic features and skin quality. Bony remodeling, facial fat and soft tissue volume loss, deflation, and descent give rise to the same common signs of aging in all ethnic groups, making restoration of volume and correction of related sequelae fundamental strategies for every patient [53; 105].

#### Skin Phototype

A powerful determinant of skin aging is the amount of melanin pigment in skin, which determines skin color or phototype. The Fitzpatrick Scale is a classification system that assigns individuals to one of six distinct phototypes based on skin complexion and response to UV radiation exposure (*Table 5*) [35; 107]. Phototype is more tied to the equatorial proximity of one's ancestors than to specific ethnicity.

#### Variations in Aging Features

In phototypes IV–VI, the thicker, more compact dermis and higher melanin content delays the onset of skin aging, skin laxity, and sagging. In these individuals, aged skin presents with muscular or expressive lines instead of early fine wrinkling [10].

Craniofacial measurements of diverse racial/ethnic groups were originally compiled for reconstructive surgeons, who required normative data in treating congenital or posttraumatic facial disfigurements. These data inform cosmetic practice in diverse patients who age differently [110; 111]. Unless otherwise stated, Caucasian facial characteristics are the point of reference for ethnic/racial variations discussed in the following sections [104]. This is the literature standard and should be taken as a guide rather than a determinate of beauty or value.

#### African

Compared with White individuals, persons of African descent have skin that maintains its structural integrity and youthful appearance. This bestows lower rates of facial rhytides, brow ptosis, lip aging, lip volume loss, and perioral rhytides formation [104; 111].

Facial aging tends to show more prominently in the periorbital region and midface. Patients with African ancestry can exhibit pronounced sagging of the malar fat pads, soft-tissue laxity, and jowl formation of the midface. Unlike the laxity and descent of Caucasian skin, the thickness and weight of skin contribute to jowling in these patients [104].

Aging Black patients often have fewer issues requiring softtissue augmentation but may seek to restore the youthful fullness of their lips. Typically the upper lip alone is treated, as the lower lip usually maintains its volume [111].

FITZPATRICK SKIN PHOTOTYPES					
Phototype	Unexposed Skin Color	Sun Exposure Response <sup>a</sup>	Examples		
Ι	Pale white	Always burns, never tans	Red hair with freckles		
II	White	Burns easily, minimal tan	Fair-haired Caucasian, Northeast Asian		
III	Olive to light brown	Burns minimally, gradually tans	Mediterranean Caucasian, East Asians		
IV	Moderate brown	Burns minimally, tans well	Some Southwest Asian (Middle East) Caucasian, South Asian, Hispanic		
V	Dark brown	Rarely burns, tans profusely	Darker Hispanic, some African		
VI	Deeply pigmented dark brown to black	Never burns, tans deeply	Darker African, Indigenous Australian		
<sup>a</sup> After one hour on sun-shielded, untanned skin.					
Source: [107; 1	08; 109]		Table 5		

SEXUAL DIMORPHISM OF THE SKULL				
Area of the Face	Female	Male		
Forehead	More straight	More oblique		
Glabella	Curved and subtle	Frontonasal suture is more prominent		
Supraorbital rim	Less conspicuous	More striking		
Midface	Subtle angles	Irregular surface and little anterior projection		
Zygoma	More prominent and curvilinear	Less prominent		
Mandible	Lighter, with subtle angles	Larger, stronger, with clear-cut angles		
Chin	Smaller and rounded shape	Larger and square-shaped		
Source: [50]		Table 6		

#### Latino/Hispanic

This heterogeneous group encompasses individuals with any combination of White, Native American, and/or African-American features. For patients with predominately Native American characteristics, approaches for East Asians are recommended; when Caucasian characteristics predominate, approaches appropriate for this group are used [111].

Patients of Mexican or Central or South American origin tend to have rounder faces with heavy eyelids, a prominent malar eminence and midface area, broader nose, abbreviated nasal length, and a recessed chin. With aging, the mid-cheek area becomes thicker and heavier, with fat pad accumulation and more prominent nasolabial folds, along with eyebrow and eyelid drooping and lower lid fat accumulation [104].

#### East Asian

East Asians tend to have a wider face with wider bitemporal and bizygomatic width, shorter in vertical height, lower structural projection of the midface, and lack of brow, nasal, and chin projection. Aging is likely to present as central face retrusion; flattening of the anteromedial midface; recessed piriform fossa; and a flatter forehead. A flatter facial skeletal framework promotes greater soft-tissue descent of the midface, malar fat pad ptosis, and tear trough formation [53; 105]. These features account for the prevalence of fillers of the medial midface, nose, chin, and forehead of younger Asian patients. In older patients, these regions are a priority, along with correcting age-related disharmonies. Volumizing is limited to the medial maxilla area to enhance central projection and to avoid further widening the midface. Lip augmentation is usually not needed, especially in patients of Southeast Asian origin who present greater lip fullness and may more likely desire lip reduction to balance the lower third of the face [53; 104; 111].

#### South Asian

South-Asian populations differ from Caucasian and East Asians, with smaller width of the malar prominences, smaller mandibular width and height, a much shorter lower third of the face compared with the middle and upper thirds, and smaller facial skeletal width compared with Caucasians. The downward medial descent of soft tissue is more aggressive due to higher volumes of facial fat pad over a smaller bone framework [56].

Bony changes and loss of lateral temple and cheek fat are best approached by volumizing the anterior mid-cheek and nasolabial fat pads, avoiding the deep medial midface fat pads. Nasolabial and medial midface correction should be very conservative, with emphasis on deep fat volumizer placement in lateral zones [56].

A concern of some patients is of repeated filler treatment producing an overtreated appearance and unsatisfying outcome. To address this concern, avoid volumizing the medial midface where soft tissue descent aggregates, compensating for this pattern by focusing on lateral midface volumizing [56].

#### GENDER CONSIDERATIONS

Men represent a small but growing proportion of cosmetic patients and distinctly differ from women in facial anatomy, physiology, and aging. Knowledge of sexual dimorphism (phenotypic differences between sexes) of the entire facial form, including the skeletal structure, musculature, vasculature, soft tissue, and skin is vital for aesthetic outcomes. Female facial characteristics remain the frame of reference for male variations [50; 112; 113; 114; 115].

Sexual dimorphism of skull characteristics is foundational to gender differences in facial features (*Table 6*). The facial vasculature of men is greater in density. Men have increased facial muscle mass, including the mimetic muscles, greater facial muscle movement, and greater upward vertical movement capacity in facial expressions (e.g., smiling, puckering of lips). Unlike the more curvilinear cheekbone in women, the male midface is more angled due to strong muscle insertions. Facial movement contributes to rhytid formation. Men have greater severity and distribution of facial rhytides; the perioral area is the only exception.

Facial subcutaneous fat exhibits sexual dimorphism. The subcutaneous fat is 1.5 times thicker in the medial malar fat compartment of women, but the distribution is uniform in men. Men have less soft tissue in the cheek area overall, and the subcutaneous fat layer is thinner in men regardless of age.

The loss of subcutaneous fat, thicker skin, and more prominent facial musculature results in deeper expression lines and contributes to the greater severity of male rhytides. The prominent volume loss makes men appear older than their age, relative to women. Aging also causes a more significant downward shift of the lower eyelid in men.

#### **Treatment Considerations**

Understanding sexual dimorphism is crucial to prevent unwanted feminization of male features, a primary concern of male patients seeking aesthetic treatment [53; 114; 116; 117]. In addition, cosmetic intervention that produces an exaggeration, rather than restoration, of typical male features can result in an aggressive or threatening appearance [115]. Of course, some men do wish to attain a more feminine or masculine appearance, but this is beyond the scope of this course, which focuses on cosmetic procedures to address unwanted facial changes associated with aging.

General approaches to minimally invasive correction of cosmetic concerns in older men vary by the area of the face [53; 113; 114; 116; 117].

#### Upper Face

Overfilling the temple should be avoided, because temporal hollowing is aesthetically appealing in many men. With botulinum toxin for rhytides, the lateral frontalis muscle is injected to prevent lateral brow arching and to maintain the flat male brow position. The frontalis may require more injections due to the larger forehead area. In a brow already lower with age, inferior frontalis injection requires caution to avoid ptosis (when brow position falls below the orbital rim) [53; 113; 114; 116; 117].

#### Midface

In the subcutaneous medial cheek fat compartment, uniform injection of filler replaces volume loss while maintaining a flatter and more angular cheek contour. The structural support may also improve the tear trough and palpebral malar groove. Fillers should be injected laterally along the zygomatic arch, avoiding a feminizing convexity from overvolumizing the anterior and medial cheeks [53; 113; 114; 116; 117].

#### Lower Face

Filler injections can restore or enhance the projection of the chin; increasing its forward projection helps tighten the jawline area, and increasing its lateral borders helps to square a recessed chin and add definition to the jawline. To restore volume or enhance shape, the supraperiosteal temporal-buccal fat pad is injected, which will project the jaw laterally and strengthen the jawline if a more square jaw is desired [53; 113; 114; 116; 117].

#### AGE CONSIDERATIONS

Aesthetic medicine professionals are confronted by increasing demand for cosmetic treatments by young patients. Treating this age group can be difficult to justify, but standard physiologic aging and individual concerns can guide age-appropriate cosmetic counseling, prevention, and intervention [118].

In patients younger than 20 years of age, minimally invasive cosmetic procedures are generally inappropriate. Emphasis is placed on prevention counseling (e.g., protection against sun damage) and addressing age-independent congenital characteristics or acquired disharmonies (e.g., acne scars) [53; 118]. Cumulative exposures to UV radiation, smoking, and pollution can initiate early collagen decline, leading to noticeable fine lines and wrinkles in some patients in their 20s. Appropriate treatment includes noninvasive modalities or botulinum toxin, which is FDA-approved for rhytides in patients 18 years of age and older [118; 119].

The typical age of patients who seek cosmetic procedures is between 30 and 50 years. When clinically indicated, fillers and toxin can demonstrably benefit older and younger patients. Patients between 30 and 50 years of age often achieve the most benefit from botulinum toxin treatment; a greater proportion of rhytides in older patients may be due to loss of skin elasticity, which is not alleviated by botulinum toxin [33]. There is no upper limit for age beyond which benefits cease, assuming that dose and injection sites are tailored to muscle mass and function [53].

## THE MINIMALLY INVASIVE TREATMENT APPROACH

In the recommended practice of minimally invasive therapy for aging features, discussion begins with an overview of evidence that informs practice and the sequence of treatment delivery. Next, for each horizontal zone, the clinical features of aging are briefly reviewed and corresponding interventions are described.

The practice standard for facial aging is volume replacement, tissue tightening, and skin rejuvenation (resurfacing). Therapies for skin resurfacing include lasers/light (e.g., intense pulsed light, fractional laser), energy (e.g., microfocused ultrasound with visualization, radiofrequency) and topical (e.g., microdermabrasion, chemical peels) modalities. These mostly noninvasive therapies are mentioned by necessity as recommended components of multimodal treatment, but specifics of their use are beyond the scope of this course.

#### RECOMMENDED THERAPY COMBINATIONS

Improved understanding of facial aging and mechanisms of therapies inform their combination and sequence of use. With superior outcomes repeatedly demonstrated with combination therapy over monotherapy, this approach is now recommended for most patients [6; 10; 33; 34; 53; 120].

#### Botulinum Toxin Plus Hyaluronic Acid Fillers

Botulinum toxin and hyaluronic acid fillers act synergistically for superior improvements and duration [34; 53; 79; 87; 120]. Recognition that hyperdynamic muscle activity leads to both soft tissue volume loss and rhytides has prompted botulinum toxin injection one to two weeks before fillers. Botulinum toxin increases filler efficacy by diminishing the dynamic muscle component of the target, and improves longevity by preventing filler breakdown from repetitive muscle activity. Fillers can extend botulinum toxin efficacy to six months.

Botulinum toxin is less effective in deep lines and creases (e.g., glabellar or forehead rhytides), and repetitive muscle contraction degrades filler efficacy to soften the appearance. Botulinum toxin/fillers overcome the respective monotherapy limitations to produce superior extent and duration of improvement, without increased bothersome or significant side effects. Outcomes are optimized by treating aesthetic units.

#### Botulinum Toxin/Hyaluronic Acid Fillers Plus Lasers/Light Therapies

Combined with energy-based therapies, the efficacy of botulinum toxin/fillers is superior to monotherapy, without increased spread of botulinum toxin, filler migration, or other untoward effects [10; 94]. Botulinum toxin before laser resurfacing improves post-laser healing, collagen remodeling, and aesthetic results, while post-laser botulinum toxin reduces wrinkle recurrence, prolonging resurfacing efficacy.

Botulinum toxin added to intense pulsed-light treatment of photoaging increases overall aesthetic benefits. Microfocused ultrasound and radiofrequency stimulate fibroblast proliferation and new collagen for efficacy in cutaneous sagging, wrinkling, and marionette lines. Outcomes are usually more satisfactory combined with hyaluronic acid fillers.

#### RECOMMENDED THERAPY SEQUENCE

Ideally, all treatments should be spaced apart at least two weeks, with botulinum toxin given two weeks before filler injections in areas of static lines, dynamic rhytides, or deep folds. However, patients may prefer same-day botulinum toxin and filler injection for convenience. This is thought to be safe, with botulinum toxin injection before fillers to avoid toxin spread beyond the treated area [8, 10, 11, 29, 30, 53; 71]. In the four weeks before and after filler injection, lasers, intense pulsed light, chemical peels, microdermabrasion, and over-the-counter or prescription wrinkle treatments should be avoided. It is also important to avoid concurrent botulinum toxin with laser resurfacing or microfocused ultrasound; increased blood flow and edema may promote toxin diffusion and side effect risks.

The midface is treated first. Patients with nasolabial fold complaints may require education that correcting midface volume naturally and effectively treats overall aging features. The filler injection sequence is lateral, then middle, then medial fat compartments; in some cases, a sequence from deep to superficial tissue planes is suitable. New filler injection over previous fillers ("layering") is discouraged due to greater risk of potentially serious complications [8; 10; 11; 29; 30; 53; 71].

#### PATIENT TAILORED TREATMENT

While minimally invasive procedures can improve facial texture and volumize, reduce, contour, lift, or reinforce soft tissue, optimal safety and aesthetic outcomes require individualized treatment planning based on assessment of skin changes, tissue quality, extent and pattern of muscle contraction, and soft/hard tissue volume loss [2; 53]. These principles become obscured when rigid adherence to algorithms or cutaneous landmarks (which shift with age) supersedes a patient-tailored approach [53].

Declining tissue quality and skin laxity are indications for combining fillers with lasers or energy-based devices. In older patients, fewer injection sites and smaller toxin doses at each site may be indicated if muscle mass or function is reduced [53].

#### THE TRI-VECTOR TECHNIQUE

Patients present with varying levels of lipoatrophy regardless of age, and the tri-vector technique adapts practice standards into an easily patient-tailored framework [121]. In each horizontal zone, this approach initiates filler injections in lateral compartments, working from lateral to medial.

In this approach, step one is supra-periosteal filler injections. In the upper face, injections are made in the temporal fossa to address forehead atrophy, brow ptosis, and temporal volume loss. Filler in the midface addresses volume loss of preauricular (in front of ear) lateral cheek and mid-cheek fat, tear trough, and infra-nasal lines/folds; in the jawline, injections can address mandibular angle changes and maxilla and mandibular fat volume loss (also marionette lines).

The second step consists of deep dermis filler injections at three ligament support sites to provide fibrous fixation points and restrain facial skin against gravitational changes. These sites are:

- McGregor patch (posterior to zygomaticus minor muscle)
- Pyriform aperture (superior part of nasolabial fold)
- Modiolus (lateral to inferior part of nasolabial fold)

The final step in this approach is patient-specific. It may include filler injection in dermal or superficial fat layers to contour the face, soften any sharp angles (especially in jawline area), or address focal superficial lipoatrophy sites [121].

#### THE UPPER FACE

In each horizontal facial zone, there are compartmentalized anatomic regions that undergo changes and/or loss of volume and tissue integrity with age. Differences in underlying bony structure, weight, and soft-tissue quality influence inter-patient variations in specific aging changes [29; 49].

The youthful upper face is characterized by a subtle convexity of the temple, forehead, and lateral brow and upper eyelid fullness [29]. The aged forehead skin, with loss of bone and fat support, is pulled by repetitive activity of depressor muscles and mimetic musculature to form horizontal rhytides. With temporal and forehead volume loss, glabellar rhytides deepen and lateral canthal rhytides (crow's feet) develop at rest and at smile [10].

The eyebrows, a powerful and versatile facial feature, greatly contribute to the perception of facial attractiveness, and fundamentally inform sexual dimorphism, facial recognition, and nonverbal communication [122]. Low medial brows, even without furrowed wrinkles, signal hostility and anger [65]. Brow ptosis develops as periorbital bone remodeling and temporal deep fat loss erode the support and fullness of the upper lid, causing the brow to descend to the superior orbital rim [4; 29]. Fixed glabellar frown lines, transverse forehead furrows, temporal hollowing, skeletonized supraorbital rim, brow ptosis, and redundant upper eyelid skin combine to form an aged appearance to the upper face [4; 29].

The forehead, glabella, and temples are treated as one aesthetic unit, with botulinum toxin for muscle modulation, fillers to improve temporal hollowing and contours of the forehead, and microfocused ultrasound to lift the ptotic brow and tighten the skin [10; 11]. This "aesthetic unit" principle is underscored by inter-relationships of the brow elevator (frontalis) and depressor (corrugator, procerus, orbicularis oculi) muscles. With antagonistic function, botulinum toxin injection in one muscle causes unopposed strength in another [11; 79].

#### Botulinum Toxin Treatment

Lines, furrows, and creases develop over time from hyperactive, repetitive use and contraction of various muscles. Botulinum toxin injection into culpable muscles can smooth vertical glabellar rhytides (glabellar complex muscles), horizontal forehead rhytides (frontalis muscle), and periorbital lateral canthal rhytides (lateral orbicularis oculi muscle) [33].

#### Horizontal Forehead Rhytides

The frontalis, the sole elevator muscle in the upper face, contracts to raise the eyebrows and upper eyelid to express surprise or fright. Frontalis contraction eventually forms horizontal forehead rhytides [33; 67].

Horizontal forehead rhytides require simultaneous botulinum toxin injections of the frontalis and brow depressors. With frontalis muscle injection alone, unopposed activity of depressor muscles will induce a lowered, angry-looking brow ptosis. Frontalis injections are 2–3 cm above the brows; closer brow placement risks inhibition of facial expression and brow ptosis [11; 33].

#### Glabellar Rhytides

Treatment of glabellar frown lines is an integral part of harmonizing the brow shape and eyebrow position. Glabellar lines are caused by contraction of the corrugator and orbicularis oculi muscles (move the brow medially) and the procerus and depressor supercilii muscles (pull the brow inferiorly). Botulinum toxin injection of corrugator and procerus muscles weakens the brow depressors to improve glabellar rhytides. Injections are made above the supraorbital rim to avoid upper eyelid ptosis. Men typically require higher doses due to greater muscle mass in this area [33].

#### Lateral Canthal Rhytides

Contraction of the lateral orbicularis oculi muscle produces lines (crow's feet) that radiate from the lateral canthus. These lines initially appear on smiling or squinting (dynamic) but can become static (at rest) due of aging, photodamage, and skin remodeling. Crow's feet are treated with multiple botulinum toxin injections into the lateral orbicularis oculi muscle, lateral to the orbital rim with the facial musculature at rest [11; 33; 79].

#### Brow Lift

Brow ptosis, a common feature of aging, can produce facial features at rest that mimic angry or scowling expressions. Brow shape and height are controlled by the opposing action of brow elevator (frontalis) and depressor muscles [33]. Botulinum toxin is injected as in treating glabellar lines (above), the lateral orbicularis oculi, and in the lateral corrugators 1–2 cm above the orbital rim to avoid the Mephisto or Spock eyebrow (quizzical look). Injections limited to the superolateral orbicularis oculi muscle (tail of the eyebrow) can give a lateral eyebrow elevation [10; 11; 33; 79].

#### Hypertrophic Orbicularis Oculi

Botulinum toxin injection can widen the ocular aperture by weakening the orbicularis oculi muscle complex, producing a wider, rounder eye during smiling and at rest [33].

#### **Dermal Fillers**

Given the substantial variability in anatomy and aging of the upper face, reversible (hyaluronic acid) fillers may be preferred; clinicians with experience and a level of comfort may consider stimulatory (PLLA) fillers [10; 11].

Fillers for temple and upper brow volume loss require elevated elasticity and viscosity for periosteal placement, to give structural and lifting support to overlying tissues with low risk of displacement (e.g., Restylane Lyft, Radiesse, Juvéderm Voluma-XC, Juvéderm Ultra Plus XC) [29]. Fillers for volumizing the upper lid, forehead, and crow's feet should have lower elasticity and viscosity for superficial placement (e.g., Restylane-L, Restylane-Silk, Belotero Balance, Juvéderm Ultra XC) [29].

The anatomic order of contouring influences the ultimate outcome of facial volumization. Augmenting the temple alone may provide lateral brow support and should be addressed before moving more caudally [29]. The upper face is a challenging area for fillers because of risk for serious complications [11].

#### **Temple Volumization**

Fillers for temporal volume loss and hollowing intend to eliminate concavity and achieve a uniform or slightly convex contour between the temporal fusion line and the zygomatic arch. Severe volume loss may require multiple treatment sessions [8, 11].

#### Brow and Upper Lid

Volume loss occurs in bone and more superficial tissues including subcutaneous fat and the retro-orbicularis oculi fat pad. To correct this deficit, the initial filler injection is directly onto periosteum 1 cm superior to the upper lateral orbital rim or just above the superior lateral brow hairline [29].

#### Eyebrow Shaping

The position and/or shape of the eyebrow often changes with aging. Fillers can enhance eyebrow contour and volume and may improve elevation of the eyebrow tail when botulinum toxin provides insufficient eyebrow lifting [11].

#### Forehead Contouring

Dynamic forehead lines are usually treated with botulinum toxin, but fillers can treat deep horizontal lines to create a smooth contour across the forehead. The filler is injected at least 2 cm above the eyebrow, with the needle tip on bone [11]. For tightening eyelid skin, radiofrequency is preferred because of its efficacy and built-in safety features [10].

#### THE MIDFACE

In facial aesthetics, the midface is a main determinant of perceptions of facial attractiveness, influenced by synergy of the eyes, nose, lips, and cheekbones (central facial triangle). It is also the focal point for restoration of a youthful topography. As such, the midface should be treated first [4; 10; 122].

Degenerative changes occur in nearly all anatomic components of the midface. The mid-cheek manifests the most complex soft tissue changes with aging, and volume loss of the deep midfacial fat is a primary determinant of an aged appearance. Fat within each compartment changes independently over time, losing volume and shifting as the facial ligaments attenuate and the bony skeleton recedes [10; 31].

Loss of maxilla projection and skeletal support and inferior displacement of soft tissues contribute to the tear-trough deformity, malar mounds, and prominent nasolabial fold and groove. The cheeks lose projection to assume a sunken appearance. Prominent transitions between cheek fat pads and flattening of the malar prominence mark the deflated midface; the heart-shaped face of youth becomes distinctly pear shaped [10; 29; 31].

Accurate assessment of midface volume loss is the single most important factor for appropriate correction of facial volume; precise restoration may rejuvenate the upper and lower face [29]. To define these midface areas, draw one line from the lateral canthus to the lateral oral commissure and a second line from the tragus to the nasal ala. The lines intersect to form quadrants. Examine the upper-outer (zygomatico-malar region), upper-inner (anteromedial cheek), and lower-outer (submalar region) quadrants for volume loss and treat accordingly [84; 123; 124].

The medial suborbicularis oculi fat migrates inferiorly with aging. The medial part of the deep medial cheek fat extends almost to the lateral incisor tooth. Volumizing both medial fat pads is crucial for correcting cheek sagging—a major contributor to deep nasolabial folds [2; 40].

Fillers are used for volumization and contouring the upper cheek and lid-cheek junction, the submalar and preauricular areas. Botulinum toxin plays a limited role [125]. Recommendations for the midface advise treating the malar area first; volumizing the malar and restoring its contours gives a lifting effect that may reduce or negate the need for filling other midface areas [30; 55]. Careful attention should be paid to restorative effects on the lower lid, nasolabial fold, nasal base, and upper lip during malar augmentation [29].

#### Malar Area

Fillers are injected to create vertical pillars over the bone to support and lift the malar area. The following injection sequence is lateral to medial, to achieve a tenting effect with less filler needed for medial injection [8; 30; 94]:

• In the lateral midface, the zygomatic (cheekbone) arch and prominence (crucial for optimal cheek restoration)

- Lateral compartment of the superficial cheek fat pad and the preauricular superficial fat compartment
- Middle compartment of the superficial cheek fat (medial sub-orbicularis oculi fat)

A variety of fillers can volumize the malar/lateral cheek region with good results (e.g., hyaluronic acid, CaHA, PLLA, PMMA) [84].

#### Lower Lid

Volume restoration of tear trough deformity with filler injection is a difficult technique in a danger zone for vascular complications and should only be performed by experts [84].

#### Deep Medial Cheek

Volumizing the deep medial cheek fat increases anterior projection, reduces the nasolabial fold, and recreates a youthful cheek within its natural boundaries [25; 40]. Juvéderm Voluma XC, Juvéderm Ultra Plus XC, Restylane Lyft, Radiesse, PLLA, and PMMA are all suited for deep midface volumizing [29; 84]. Patients with significant orbital fat herniation may benefit more from surgery; fillers alone may be inadequate to reduce the transition between protuberant fat pad and concave tear trough [84].

#### Nasal Tip and Upper Nasolabial Fold

Deep volumizing of the nasal sill can provide support to the aging nasal tip, a natural correction of the upper nasolabial fold, and a minor lift to the upper lip. Treatment requires periosteal placement of high-elasticity, large-particle fillers [29].

Botulinum toxin can correct "bunny lines"—horizontal rhytides that traverse the nasal bridge and the downward slope of the nose when the patient is smiling—and elevation of the nasal tip [10; 125]. In the midface, nasolabial folds are treated last [10].

#### Nasolabial Folds

Most fillers are indicated for treating nasolabial folds by the FDA, but unlike other midface areas, nasolabial folds hypertrophy with age. Thus, fillers are suggested to soften a prominent fold, not to volumize. First correct deficient malar volume, then soften residual nasolabial folds conservatively using moderateelasticity and -viscosity filler (e.g., Restylane-L, Juvéderm Ultra XC) injections in the superficial fat just to the dermis [29].

Low-dose botulinum toxin into each lip elevator complex above the nasofacial groove can collapse the upper nasolabial fold but may vertically lengthen the upper lip, an aging-related feature. Botulinum toxin should not be directly injected into nasolabial folds, as this may result in an asymmetrical smile or lip ptosis [33].

After addressing volume loss, microfocused ultrasound treatment of the overlying superficial musculo-aponeurotic system and skin envelope addresses laxity and bridges the aesthetic unit compartments to create a smooth cheek contour [10; 126].

#### THE LOWER FACE AND NECK

During the aging process, bony and soft-tissue structures in the lower face undergo significant alterations [4; 10; 29; 58]. Malar and perioral fat volume loss, bone resorption, and ligament laxity cause increasingly lax skin to droop downward over a changing lower face structure. The general widening and loss of integrity of the lower face can appear as a relative increase in jowl volume with decreased jawline strength and perioral/lip volume.

Jowling is one of the most unwanted effects of aging and a primary concern of aging patients. The jowls become prominent with deflation of superficial fat exposing deeper fat pads, descent of deep fat pads, and increased septal laxity. Loss of volume in the prejowl sulcus, posterior jawline, and inferior preauricular region exacerbates the appearance of jowls.

Superficial and deep atrophy of the perioral area manifests as a lengthening and flattening of the upper lip complex, loss of vermillion and vermillion border volume, and formation of vertical perioral rhytides. The oral commissures turn down, and the mentalis region flattens or becomes ptotic. Protrusion of the central chin results from loss of lateral and inferior volume. These changes are superimposed on and intensified by mandibular bony changes that result in decreased vertical ramus height, a widening mandibular angle, and loss of anterior mandibular (mental) projection. Platysma muscle contraction from support of deeper neck and floor of mouth structures promotes vertical fibrous bands on the neck; laxity in overlying skin creates horizontal rhytides.

Botulinum toxin and filler combinations are especially effective in the lower face to address dynamic musculature, loss of volume and support, and skin laxity [10]. Some believe that fillers are more important than botulinum toxin and should be used first to provide structure and support before considering botulinum toxin for dynamic lines [127].

#### Jawline

Structural volumizing of the lower face should begin with correction of the jawline, using fillers with high elasticity (Restylane Lyft, Radiesse, Juvéderm Voluma XC, or Juvéderm Ultra Plus XC) [29]. Injector preference/experience will also determine filler choice [10].

Mandibular shrinkage and redistribution of fat leads to the emergence of jowls and loss of jawline definition. To smooth the jawline and camouflage the prejowl, the inferior mandibular border is injected in the supraperiosteal plane. Injection under the mandibular rim improves the prejowl concavity. The jowl is not directly injected, to avoid blood vessels [8, 58].

A technique referred to as the "Nefertiti lift" involves small amounts of botulinum toxin injected along the jaw and into the lateral, upper platysmal band to improve the appearance of pouches. With skin laxity, the addition of microfocused ultrasound helps lift the jowls for a tighter appearance [10]. In women, an overly squared jaw can be undesired. If sagging is not an issue, botulinum toxin injection of the masseter results in a softening of the determined, clenched appearance and a more feminine face [65].

#### Chin

Botulinum toxin injections just anterior to the bony mentum on each side of the midline weaken the mentalis muscle contraction responsible for mental crease, and injections into the mentalis muscle at the prominence of the chin can help reduce a *peau d'orange* chin [33; 65]. Fillers create definition and fill residual depressions. Injection is placed on the periosteum and deep subcutaneous tissue to create vertical pillars. Fillers with greater lift are preferred [8; 58].

The perioral region is considered one aesthetic unit, comprising the lips, oral commissures, and melomental folds (marionette lines). Botulinum toxin is commonly used for perioral rhytides but requires caution, as improper injection may result in a flaccid cheek, an incompetent mouth, an asymmetrical smile, or speech pathology [10; 79]. Perioral volumization may independently restore and support the lips by enhancing lip volume and should be precede direct mucosal lip volumizing in an aging face [29].

Moderate-elasticity fillers (e.g., Restylane-L, Restylane-L Silk, Juvéderm Ultra XC, Belotero Balance) are injected in the subcutaneous plane, first in the oral commissure until a subtle upturning is achieved, then in the upper and lower lip columns for volumizing support. This will improve the appearance of vertical lip rhytides and philtral columns [29].

Vertical perioral rhytides are common cosmetic concerns, induced or exacerbated by repetitive orbicularis oris muscle contraction. With fillers, a short-lived improvement and fairly rapid recurrence is likely caused by normal perioral animation. Low-dose botulinum toxin is injected adjacent to the vermillion border in the areas of rhytides, and lateral to the Cupid's bow area of the lip. Avoid injecting the oral commissures (corners of the lip) and the midline area to reduce the risk of a drooping lateral lip [33].

Mouth frown results when the depressor anguli oris muscle pulls the corners of the mouth downward, in opposition to the action of zygomaticus major/minor muscles, producing a frowning expression. Botulinum toxin injection weakens the depressor anguli oris, allowing the zygomaticus to elevate the corners of the mouth, which return to a horizontal position. Botulinum toxin is injected into the insertion point of the mentalis muscle, because upward pull of the mentalis contributes to mouth frown [33].

Melomental folds (marionette lines) are exacerbated by contraction of the depressor anguli oris muscle. This is treated by botulinum toxin injection into the posterior margin of each depressor anguli oris immediately above the mandible [33].

#### THE NECK

Platysmal bands, often the first sign of aging of the neck, appear as two vertical, bulky cords from the lower border of the mandible to the suprasternal region. Formerly thought to result from skin laxity and loss of platysma muscle tone, these vertical muscular bands are now attributed to platysma muscle activity, treated by denervating the platysma muscle with botulinum toxin instead of tightening the skin [128]. Very-low-dose botulinum toxin is injected superficially into only specific platysmal bands, to avoid dysphagia [79]. Improvement of the overall appearance of the neck requires fillers for structural support of the chin and jawline and botulinum toxin for the masseter, platysmal bands, or horizontal neck lines [33; 127].

#### PATIENT SELECTION AND EVALUATION

As discussed, the careful assessment of patients forms the basis of individualized treatment planning. Because aesthetic procedures are elective, the benefits must clearly outweigh the risks. Healthcare providers have a responsibility to refuse requests in which the risk-benefit ratio is not in the patient's best interest, and to refer patients elsewhere for consideration of treatments the clinician cannot or prefers not to perform. Patients rely on the healthcare provider to act as a "learned intermediary" and to exercise fiduciary responsibility in advising the patient on the best course of action [95].

Patients should be carefully selected by thorough assessment of medical history, motivation, and expectations to identify contraindications. The increasing incidence of serious dermal filler complications has expanded the cutaneous and systemic contraindications to filler treatment, relevant to botulinum toxin because combined therapy is common.

Following screening, careful discussion addresses the specific cosmetic concerns and possible benefits and risks across a range of available options. A treatment plan is arrived at through shared decision-making; informed consent and documentation are made.

For those who are not proficient in English, it is important that the patient history and information regarding the risks associated with the use of botulinum toxin/dermal fillers be obtained in the patient's native language, if possible. When there is an obvious disconnect in the communication process between the practitioner and patient due to the patient's lack of proficiency in the English language, an interpreter is required.

#### SCREENING AND SELECTION

#### Screening and Assessment of Medical Contraindications

The patient may request a cosmetic therapy, but the aesthetic provider should ultimately "select" the patient. Most complications stem from inappropriate patient selection, inadequate antiseptic preparation, or improper treatment technique. Selecting appropriate patients, or perhaps more importantly, not treating inappropriate patients, is the first crucial step in avoiding complications [71]. A thorough history of skin conditions, allergies, systemic disease, current medication use, and previous cosmetic procedures is mandatory. Patients may not see important aspects of their history as relevant. To help ensure disclosure, assess skin-related and systemic conditions by linking to potential adverse effects [19; 71].

Some skin disorders and local or remote infections can promote injection seeding of infective agents that populate the filler site, or hematogenous spread to implanted fillers and later biofilm formation or transition from infection to hypersensitivity [19; 129; 130]. These conditions require careful screening. Fillers have risks of injection-site keloid formation or hyperpigmentation; patients with these conditions should avoid fillers [75].

Screening may identify conditions whereby filler therapy is contraindicated, deferred until resolution, or considered cautiously. Significant comorbidity, polypharmacy, or use of immunomodulatory drugs can greatly complicate adverse effect management if it becomes necessary [22].

## Screening and Assessment of Psychological Contraindications

Understanding the motivations for cosmetic treatment is vital to minimizing inappropriate patient selection. Unrealistic expectations, which are contraindications to cosmetic treatment, are prevalent in some psychological conditions [19; 75]. Low self-esteem can lead to unrealistic goals and expectations. High neuroticism and/or anxiety may influence expectations, and outcomes tend to be poorer [131]. The most important mental disorder consideration is body dysmorphic disorder.

Body dysmorphic disorder is a psychiatric disorder characterized by preoccupation with an imagined defect in appearance or distorted perception of one's body image. These patients may be unduly invested in the cosmetic procedure as the solution to other life problems. Unrealistic expectations are followed by dissatisfaction with results that do not correlate with objective outcomes [132; 133]. Dissatisfied patients with body dysmorphic disorder have been reported to retaliate against their cosmetic providers with lawsuits, threats of violence, physical assault, and in rare cases, homicide [134; 135].

Compulsive behaviors have been described in patients who, driven by the quest for physical perfection, demand and obtain multiple sequential cosmetic injections despite the increasing risk. Compulsive demand for cosmetic procedures falls on a spectrum of dysmorphophobic behaviors [136; 137]. Body dysmorphic disorder is also associated with "doctor-shopping" [131].

Whether the diagnostic threshold for body dysmorphic disorder is a contraindication to nonsurgical cosmetic procedures is unresolved, but many consider signs of body dysmorphic disorder a firm contraindication to cosmetic treatment [19; 131; 132; 138]. Appropriate onward referral may be required when psychopathology is apparent [131; 139].

#### PATIENT EVALUATION AND CONSENT

After the patient has been screened for medical and psychological contraindications to cosmetic treatment, the next step is to determine if treatment expectations can be met or managed with education and counseling. Following this, treatment options are explored and a plan is developed and documented.

#### Patient Motivation and Treatment Expectations

American healthcare consumers are both aging and youthoriented [94]. A majority of the population is dissatisfied with their appearance, rates of cosmetic interventions continue to increase, and the expectations of many patients have risen proportionately [131].

Patient motivation for cosmetic therapy, benefits anticipated, and satisfaction with the outcome are closely inter-related. The expectations and motives for seeking treatment are complex and diverse. Patient dissatisfaction usually derives from failing to manage or meet expectations, underscoring the importance of identifying expectations at the first consultation and documenting this discussion [131]. The clinician should establish underlying motivations, differentiate patient wants from needs, and temper expectations within realistic goals [19].

Patient motivation is considered external when expecting physical changes to influence some aspect of their life (e.g., partner will love them more, career success). Unrealistic expectations with external motivation require discussion, as these patients are more likely to be dissatisfied with outcomes. In contrast, internally motivated patients (driven by a desire to look better for themselves) are good candidates [131; 138].

Other factors can influence expectations [94; 131]. Younger patients can be especially sensitive to peer group acceptance and social media images, but correction of an objectively undesired feature can also be therapeutic. Traditional and digital media promote unrealistic expectations of an idealized appearance, and along with marketing, this has led some patients to believe a youthful appearance can be maintained indefinitely, has a quick fix, or is guaranteed with a "miracle treatment." Partners, families, and friends can exert strong influences that can be helpful to separate from the patient's own expectations. Expectations tend to be higher among more educated patients.

#### **Expectation Management**

Patient expectations should be managed so they do not envisage an unrealistic outcome. The treatment of inadequately informed patients is fraught with potential problems and risks of dissatisfaction [71].

Patient education on the risks, potential benefits, and limitations of cosmetic procedures may modify expectations. Good information is associated with better outcomes, and hearing these details may lead the patient to prefer a different course of treatment than first proposed [131].

A 2016 guideline stresses the importance of giving prospective cosmetic patients time to reflect on what they learned during the initial consultation—a "cooling-off period" [140]. However, a 2015 consensus statement suggested initiating at least part of the treatment plan the same day to build patient confidence in aesthetic procedures and in the clinician [94]. It may be best to assess on a patient-by-patient basis which approach is appropriate.

The FACE-Q is a validated screening instrument that measures patient expectations of cosmetic treatment, such as appearance-related psychosocial distress and how they expect their appearance and quality of life to change after cosmetic treatment [141]. Use of the FACE-Q can help augment, but not replace, patient-clinician discussions of factors that influence expectations of cosmetic treatments [131].

An effective approach to expectation management is the mnemonic STEP [94]:

- Stress what can and cannot be done with minimally invasive aesthetic treatments.
- Target specific areas of patient concern.
- Envision what the effect of the aesthetic outcome would be like to the patient.
- Preframe the patient to the expected outcome.

#### Developing a Treatment Plan

The clinician should be both probing and empathetic. Patients may be ashamed they look older than their peers but too embarrassed to directly discuss it. Others may see their concerns as vain and frivolous. Many patients are unaware of the range and versatility of cosmetic procedures or believe their concerns are beyond remediation [94]. Keep the focus on cosmetic concerns rather than any preconceived treatment approach.

Educate the patient to focus on the underlying cause, not the superficial manifestation, of her/his cosmetic complaint. For example, sagging skin is often caused by volume loss, making volume augmentation the appropriate treatment [94].

Discuss realistic expectations for the results of specific treatments. For example, if a patient requests a specific treatment for prominent nasolabial folds with the goal of looking younger, explain that nasolabial folds can be treated directly, but would not produce a more youthful appearance—correcting the underlying volume loss could restore a youthful appearance, even with some residual folds [94].

Many patients have concerns about several facial areas. Asking: "If you could fix only one thing today, what would it be?" can help clarify their relative priorities to base a reasonable sequence of procedures [94].

Clarify expectations of time frame to determine what is realistic and feasible when patients require the desired effects before an important event, such as a wedding. Other patients may want progressive, rather than immediate, aesthetic improvement. Also understand the degree of patient risk tolerance in treatment selection [94]. Discuss the implications of botulinum toxin treatment of the orbicularis oris muscle. The reduction of fine motor control around the mouth may be detrimental to professional speakers, vocalists, or musicians [94].

#### Informed Consent and Documentation

The risk of malpractice claims is highest in cosmetic medicine. Most result from inadequate informed consent instead of procedural failures [16]. To fully inform decision-making and consent to treatment of patients, carefully discuss the possible benefits, disadvantages, and limitations over a broad range of options [7; 95].

Beyond an unnatural look, the three main patient concerns are pain, complications, and costs. It is essential to discuss treatment costs, obtain financial consent, and plan over the long term to obviate financial stress. Addressing these issues upfront is instrumental in establishing the trust that underpins true patient satisfaction [19].

Shared decision-making, an essential element of evidencebased medicine, explores available treatment options, possible benefits and harms of each option, and best match to the patient's characteristics and preferences [142]. Obtaining signed informed consent is crucial in creating awareness and acceptance of potential complications. An informed consent document confirms patient understanding of the potential adverse effects and expected treatment outcome. The document should outline common and uncommon but serious adverse events. Supplying written pre- and post-instructions during the initial consultation can help to establish realistic expectations and minimize dissatisfaction [19; 34].

Photographic documentation is essential for medico-legal purposes and appraisal of results. To ensure good quality preand post-treatment photographs, the patient should remove all makeup and jewelry and pull hair back or up using a hairband; a black/dark background is preferred. Multiple images at rest and during animation are recommended, including anterior, oblique, and lateral views with the head in a neutral, neckextended, and neck-flexed position. Proper lighting, consistent angles, and a fixed camera distance are mandatory. A singlelens reflex camera and tripod are recommended instead of smartphones [19].

#### ADVERSE EFFECTS

As mentioned, there is increasing concern of serious adverse events involving dermal filler injections. Some experts noted that by 2010, the increasingly sophisticated training in nonsurgical cosmetic treatment was already neglecting adverse events and their management [22]. With the rapid growth in consumer demand for injection cosmetic therapies, the quality of training, skill, and credentialing of injectors and facilities are increasingly unclear. Along with inadequate regulation, the net effect is described as compromising not only patient safety but the reputation of the field [19; 20; 23]. With serious adverse events a focus of concern, there is an expansion of recommended measures to prevent, reduce, and manage adverse events before they become disastrous complications.

#### PREVENTION AND RISK REDUCTION

Several approaches are recommended before injection therapy to prevent or reduce complications by mitigating patient, clinician, or procedure risk factors.

#### Pretreatment Patient Management

Some complications may be prevented by careful pre-treatment patient management. Filler injection can reactivate latent herpes simplex virus (HSV) infection. Prophylactic antivirals (e.g., acyclovir, valaciclovir, famciclovir) are recommended with patient history of HSV in the intended injection area. Patients with a current outbreak of HSV should receive antivirals, with fillers deferred until resolution of herpes lesions [143, 144]. For two to four weeks before and after filler treatment, patients should be counseled to avoid [92; 143; 144]:

- Dental procedures, oral hygienist visits, tooth bleaching/whitening
- Immunizations/vaccinations
- Other medical procedures
- Any facial procedure inducing inflammation or skin barrier disruption

In addition, products with blood-thinning effects should be avoided the week before filler treatment. This includes food/ beverages (e.g., red wine, dark chocolate, grapefruit) and certain supplements/over-the-counter medications (e.g., vitamin E, gingko biloba, fish oils, St. John's wort, nonsteroidal antiinflammatory drugs [NSAIDs]). Prescribed anticoagulants (e.g., aspirin, warfarin, clopidogrel, apixaban, rivaroxaban, dabigatran) should also be withheld, but only when cleared by the prescribing physician [92; 143; 144].

A pretreatment checklist should be provided to the patient that includes these points and explains the importance of having any infective or inflammatory conditions treated before the procedure; the treatment should be rescheduled if the pretreatment checklist is incomplete. The patient should receive the checklist with sufficient time to plan relevant medical visits around the treatment date. Contact patients one week pretreatment to ensure they possess and understand the checklist and have no precluding factors [19].

#### Procedure- and Clinician-Related Factors

Knowing previous surgical (e.g., rhinoplasty) or nonsurgical cosmetic procedures and locations is vital to prevent complications. Fixation, scarring, or alteration of underlying vasculature and anatomy at procedure sites can facilitate intravascular filler injection. "Layering" new fillers over a previously injected semi/ fully intact filler can provoke dormant biofilm or inflammatory response [19; 71; 145].

#### Vascular Complications

Vascular occlusion from injected filler material may lead to potentially catastrophic complications of tissue necrosis, blindness, or stroke. Even with advanced knowledge of facial anatomy, vascular injury cannot be avoided with 100% certainty. However, measures can be taken to help reduce risks and mitigate intravascular adverse events if they develop. A key step is understanding the danger zones for vascular occlusion, areas where arteries have little or no collateral circulation, extensive anastomoses with the internal carotid artery, or are prone to external compression. Risk factors for vascular occlusion are summarized in **Table 7** [19; 146; 147]. **Table 8** outlines strategies to mitigate these potential complications.

#### Infection Risk

To minimize infection, stringent aseptic technique is mandatory [19; 151]. Prior to any intervention, it is vital to clean, degrease, and disinfect the patient's skin. Remove makeup and cleanse carefully with 2% chlorhexidine in 70% alcohol, avoiding ocular exposure. When treating the perioral area, consider antiseptic mouthwash containing chlorhexidine or povidone-iodine for sterilizing the oral cavity.

The clinician should remove all jewelry, wash hands with antiseptic cleanser, and use gloves for all injections. Once the syringe is held, sterility is lost and aseptic technique is crucial. Not touching any needle or cannula component that penetrates the skin may further reduce infective complications. Cleansing a broad area avoids infective risk from inadvertently resting a cannula on adjacent uncleaned skin. Frequently change needles/cannula when using multiple entry points.

Biopsy can play a crucial role in diagnosing and treating fillerrelated adverse events, but cosmetic patients strongly resist facial biopsy unless absolutely necessary. A medicolegal process is always justified [152].

After treatment is administered, it is important to assess the patient's response. Clinicians should routinely check perfusion in treated and watershed (e.g., glabella, nasal tip, upper lip) areas [19]. Consider that makeup can obscure skin tone and signs of vascular compromise. Patients should be furnished with written post-treatment instructions and contact numbers. A follow-up call to the patient should be made within 24 hours, and the clinician/clinic should be available by phone for 48 hours postprocedure [19].

All facilities should have easily accessible protocols for early and delayed-onset reactions [19]. Resuscitation measures (e.g., epinephrine, IV access, fluids) and an adequate supply of hyaluronidase should be kept on hand, with regular checks of expiration dates on emergency drugs. In addition, contact information for an ophthalmologist or oculoplastic surgeon experienced in treating retinal artery occlusion should be maintained.

RISK FACTORS FOR VASCULAR COMPLICATIONS DURING FILLER INJECTION				
Factor	Description			
Injection site danger zones	Injections to the nose, nasolabial fold, forehead, and glabella are at increased risk for blindness. Injections to the glabellar region, nasal tip/alar triangle, and lips increase the risk for necrosis.			
Injected volume	Bolus injections near danger zones increase risk of necrosis.			
Filler type	Non-hyaluronic acid fillers cannot be dissolved. Necrosis is more common with denser or more permanent fillers.			
Needle gauge	Sharp needles puncture arteries more easily. Aspiration before injecting is suggested, but unreliable. Blunt cannulas are less likely to puncture vessels.			
Scarring	Scarring from prior cosmetic procedures or trauma can alter the local vascular pattern.			
Source: [70; 145; 146; 147; 148; 149; 150] Table				

RISK MITIGATION STRATEGIES FOR FILLER-RELATED VASCULAR COMPLICATIONS				
Step	Recommended Strategy			
Knowledge	Know injection-site vascular anatomy, and be aware of inter-patient variations.			
"Go easy"	Inject slowly, and apply the least amount of pressure necessary. Keep the needle moving. Restrict bolus injections to periosteal plane.			
Monitor closely	Watch for blanching or any changes in skin color.			
Be aware	In a vascular occlusion, epinephrine can mask skin blanching, and local anesthetic or lidocaine can mask pain.			
Listen to your patient	Immediately stop injecting if resistance is encountered, or if patient reports pain, discomfort, or changes in vision.			
Have a plan	Onsite protocols for immediate, early, and late adverse events should be easily accessible.			
Discharge instructions	Describe in writing the signs/symptoms of vessel occlusion and where and why to seek medical attention.			
Staff education	Educate clinic staff on accurate assessment and appropriate referral of patients who report filler adverse events.			
Report the incident	Report vascular compromise adverse events to the FDA and filler manufacturer.			
Source: [70; 145; 146; 147; 148;	Source: [70; 145; 146; 147; 148; 149; 150] Table 8			

#### Anesthesia/Analgesia

Pain control is crucial to ensuring a positive experience for patients [76]. Topical anesthetics or local nerve blocks are commonly used to reduce pain, although many fillers are also formulated with lidocaine. To reduce pain, use the smallest suitable needle, slow infiltration, and the least needle punctures necessary. Other measures to help reduce pain include ice application, skin vibration, patient distraction, and a relaxed, soothing treatment environment [34].

#### COMMON ACUTE SIDE EFFECTS

Pain, bruising, redness, itching, and swelling are common, self-limiting side effects following dermal filler injections. Persistence beyond seven days should be closely assessed [144].

#### Pain

Pain is relatively common and is more likely with multiple needle punctures. However, pain may also be a sign of impend-

ing vascular compromise, discussed in detail later in this course. Pain can be minimized by using slow needle introduction, ice anesthesia, and filler warmed to body temperature [70].

#### Erythema

Erythema (redness) usually resolves without treatment. Longerlasting or persistent erythema suggests hypersensitivity reaction or infection and requires careful evaluation. Oral tetracycline, isotretinoin, topical tacrolimus, or medium-strength topical steroids are suggested for persistent erythema; long-term, highpotency topical steroids should be avoided. In severe cases, oral propranolol (20 mg) can make erythema less evident [70; 143].

#### Edema

Edema (swelling) in the first few days is normal with all fillers and can be managed by gentle pressure and ice packs [83]. Episodic swelling and edema following filler injection can occur after sun exposure, exercise, or saunas. It is important not to confuse normal edema with allergic reaction; manage with ice packs, topical steroids, and avoidance of vasodilating stimuli [70].

Ice is recommended and commonly applied on the injection site to prevent and manage pain and edema, but it has also been associated with infection. An Oregon plastic surgery clinic described an outbreak of facial *Mycobacterium chelonae* infection (presenting as swollen skin nodules with drainage or discoloration three to six weeks after inoculation) following filler injections. The infections required three to four months of multiple oral or IV antimicrobial agents to resolve. The source was traced to clinic tap water, used for ice applied immediately pre- or post-injection [153]. As such, cold packs rather than ice may be safer options.

#### Bruising

Bruising, hematoma, and ecchymosis can result from needle pricks and bleeding. This can be minimized by firm pressure on the needle insertion site and prevented by cessation of alcohol and supplements with anticoagulant effects one week before treatment. Intense pulsed light and vascular lasers have been used to treat persistent symptoms [70].

#### Lesions

Papulopustular lesions occur when filler injected too superficially in the papillary dermis occludes, or extrudes through, sebaceous or sweat gland openings and mimics bacterial infection or acneiform eruption. Post-injection massage can help in prevention, and topical astringents can help in their resolution [70].

Overcorrection can appear as bumps, nodules, or irregularities when too much material is injected. In these cases, hyaluronic acid products should be resolved using hyaluronidase. With non-hyaluronic acid fillers, puncture and drainage of excess product may suffice [70].

#### INFREQUENT ACUTE ADVERSE EVENTS

#### Dysesthesias and Paresthesia

Dysesthesias and paresthesia are symptoms of nerve injury following direct trauma, injection of filler into a nerve, or tissue compression by the product. Nerve damage is usually transient and reversible, infrequently permanent, with the infraorbital nerve the most common site [143].

#### Intracranial Penetration

For deep periosteal or supraperiosteal injections, the needle is advanced to the level of the bone and retracted slightly. Accidental intracranial penetration is a demonstrated risk, but the prevalence is unknown [70].

#### VASCULAR COMPROMISE

Vascular compromise is the result of vascular occlusion following inadvertent intravascular filler injection or vascular compression by adjacent filler material. Embolism occurs when filler material enters the vasculature, impeding blood flow. Vascular compromise can involve arterial or venous occlusion [70; 143; 150].

Areas at highest risk of embolism have minimal collateral circulation (the nose), terminal blood supply (the glabella), large vessels (the nasal artery), or large areas (forehead) supplied by a vessel with minimal collateral circulation (terminal supratrochlear artery) [154]. Embolization of filler material is a potentially catastrophic complication with possible sequelae of tissue necrosis, blindness, or cerebrovascular accident. The literature is replete with examples of permanent blindness following hyaluronic acid, PLLA, or CaHA filler injections [122; 155]. Intravascular injection occurs more frequently than assumed. In a study of expert aesthetic physicians, 62% reported inducing one or more such events [156].

#### **Tissue Necrosis**

With embolism induced by intra-arterial injection, damage to endothelial cells leads to ischemic changes in the skin, tissue degradation, and necrosis [71]. Cells undergoing necrosis swell and then burst, releasing their contents to trigger a local inflammatory reaction, with swelling, pain, heat, and redness. Intra-arterial injection can lead to embolism, platelet aggregation, subsequent occlusion in a terminal branch, and delayed-onset necrosis [145].

Necrosis can follow vascular occlusion due to vessel compression by filler material or filler-induced tissue swelling, and onset can be delayed. Tissue necrosis can occur with all dermal filler types but is more likely with particulate fillers [83; 145]. With blood supply reliant on a single arterial branch, the glabella, nasal ala, and nasolabial folds are most vulnerable to necrosis [70; 83].

The cardinal features of vascular occlusion and necrosis are changes in skin color and pain [70; 71; 145; 150]. Skin blanching and severe pain are immediate with arterial occlusion. However, as noted, epinephrine use may mask blanching, and pain may not fully appear until local anesthetic or nerve block wears off. If not swiftly resolved, the affected skin will develop reticulated erythema, purpura, ulceration, and scarring.

With venous occlusion, red/bluish skin color changes appear immediately to hours later, with or without pain, progressing to blisters, pustules, and tissue necrosis within a few days.

#### Blindness

The most feared complication of filler injections is blindness following occlusion of the central retinal artery, the final branch of the ophthalmic artery. Comparing average diameters, injected hyaluronic acid filler particles (400 mcm) easily move through the ophthalmic artery (2 mm) to block the central retinal artery (160 mcm) [122; 154; 157].

The routes to occlusion and blindness vary by proximal branch of the ophthalmic artery inadvertently injected. When the force of injection exceeds intra-arterial pressure, the injectate can move proximally in the angular artery and then proximal of the origin of the central retinal artery. With pressure on the

syringe released, the material moves distally into the retinal artery. Central retinal artery occlusion follows injection into the glabellar region (through the supratrochlear artery into the supraorbital artery) or the nasolabial fold (in any anastomosis of the dorsal nasal artery from the ophthalmic artery) [154]. Blindness, visual field deficit, or blurring is instant, often with excruciating ocular pain [70; 83; 143].

#### Stroke

With greater pressure on the plunger or for a longer time, the filler may travel into the internal carotid artery and then enter cerebral circulation, producing a stroke [122; 150]. Unilateral blindness and left-sided hemiplegia immediately following glabellar area injections are reported. However, these effects are rare with dermal fillers and more likely with autologous fat injections [70]. Pulmonary embolism and panophthalmoplegia have also been reported with filler injections [19].

#### Management of Vascular Compromise

Intense pain is considered an initial sign of intravascular filler injection, but as noted, it may be obscured by lidocaine in fillers or by local anesthetic. Vigilance for skin color change is mandatory [19]. With any suspicion of vascular occlusion from inappropriate pain, skin blanching, or mottled discoloration, immediately stop injecting and aspirate any product when withdrawing the needle (if possible). It is vital to facilitate an immediate, aggressive response to remove the product and promote blood flow [19; 71].

#### Hyaluronidase Reversal

With hyaluronic acid fillers, hyaluronidase injection is the foundation of emergent therapy for most adverse events, a powerful advantage of these products, as no other dermal filler material has a reversing agent [19]. Hyaluronidase injection enzymatically dissolves the hyaluronic acid filler material [68].

Hyaluronidase is indispensable in resolving acute hyaluronic acid filler adverse events. All clinicians who provide hyaluronic acid filler injection should always have an adequate supply of hyaluronidase in the office for emergencies and regularly check the product expiration date [122].

Hyaluronidase is recommended in vascular compromise from all filler types to reduce edema and potentially decrease vesseloccluding pressure. When injected immediately, hyaluronidase degrades hyaluronan, a potent proinflammatory mediator associated with tissue necrosis [58; 71].

High-dose hyaluronidase (500–1,000 IU) mixed with lidocaine is injected in the affected vessel, the surrounding path of the vessel, and its terminal branch; a large-bore cannula avoids bruising that obscures signs of improving skin color. Doses up to 1,500 U may be used if needed; the consequences of inadequate dosing are dire. Repeat hourly for three to four hours and daily for at least four days or as long as signs of ischemia persist [71; 146; 158; 159].

Injecting high-dose hyaluronidase diluted with lidocaine induces vasodilation and hyaluronic acid dispersion and, with

saline, allows coverage of a larger area [71]. Vigorously massage the treated area during and after all hyaluronidase injections to optimize the results and aid mechanical breakdown [158].

Because anaphylaxis is a potential side effect of hyaluronidase and skin testing for hypersensitivity reaction is not an option in emergencies, risk mitigation requires full resuscitation equipment on site and training in its use [34; 95; 158].

#### Promote Blood Flow to the Affected Area

Apply warm compresses, and vigorously massage or tap the area. To limit platelet aggregation, clot formation, and further compromise, the patient should be administered two tablets (650 mg) of aspirin to chew and swallow, followed by 75 mg per day until necrosis resolves [19; 71; 145].

Some experts recommend nitroglycerin paste 2% to promote vasodilation [70; 145; 160; 161]. However, others caution against its use before the hyaluronic acid has dissolved with two or three days of treatment, as dilation of adjacent unobstructed vascular pathways may propagate the embolus toward the orbital area [19]. Low-molecular-weight heparin has also been used in the management of patients with filler-induced vascular occlusion [34].

#### Additional Recommendations

Necrotic cells and tissue invite opportunistic infection. The measures needed to promote healing and prevent further complications depend on the extent of necrosis and range from appropriate dressing and wound care with topical and/or oral antibiotics to surgical debridement for removal of dead tissue. Susceptible patients may require antiherpetic medication with perioral-area necrosis [145].

Necrosis can be very painful, and pain management should be considered. While over-the-counter analgesics may be adequate in some cases, more severe pain can require opioids [145]. Because necrosis can cause significant scarring and distress to patients, practitioners should prepare for a possible malpractice claim filed by the patient [145].

#### **Ophthalmic Events**

An ophthalmic event is a medical emergency, with 60 to 90 minutes the absolute time window for saving vision. Blindness from central retinal artery occlusion is resolvable following hyaluronic acid filler injection only with rapid intervention by retrobulbar injection of hyaluronidase. Occlusion longer than 60 to 90 minutes is irreversible [19].

An ophthalmologist or oculoplastic surgeon should be contacted immediately and the patient transported to the clinic. The general emergency department is inappropriate [122].

To save vision, a needle is advanced in the inferotemporal quadrant of the orbit, inferior and lateral to the optic nerve, with hyaluronidase 2–4 cc (150–200 U/mL) injected into the inferolateral orbit [122]. Attempt rapid ocular pulsed massage. Having the patient hyperventilate in a paper bag may promote retinal vessel dilation. If possible, annotate the time of the

vascular event and the visual acuity if lack of light perception or loss of vision occurs [19].

#### ALLERGIC/HYPERSENSITIVITY REACTIONS

Acute infections appear as acute inflammation or abscesses at the injection site. If left untreated, the initial reddening and hardening can result in fistula formation, discharge of pus and filler, and potentially permanent disfigurement [162].

Hypersensitivity/allergic reactions occur when injected filler material triggers an immune response. Etiology differs by post-injection onset: acute (minutes to hours) or delayed (within days) [19; 71; 143; 163].

#### Acute Hypersensitivity Reaction

Type I hypersensitivity reactions, mediated by immunoglobulin E (IgE), may present with angioedema or anaphylaxis. Check vital signs; anaphylactic shock is a medical emergency. Angioedema can also progress to airway obstruction. Any systemic manifestation should be considered impending anaphylaxis and treated as such. This involves immediately administering IV epinephrine; if insufficient to maintain perfusion, consider additional vasopressor agents (e.g., dopamine, norepinephrine, glucagon). H1-receptor antagonists (plus cimetidine) are recommended for histamine-induced hypotension.

Hospital admission should be considered for more severe cases, as late-phase reactions may occur more than 36 hours after onset. If possible, remove the dermal filler using hyaluronidase as needed.

#### Delayed Hypersensitivity Reaction

Type IV hypersensitivity reactions, mediated by T lymphocytes and not antibodies, usually present with induration, erythema, edema, or various types of skin lesions, including painful erythematous nodules. Management consists of cold compresses for localized angioedema and H1-receptor antagonists for histamine-induced hypotension and pruritus. H2-receptor antagonists, oral corticosteroids, and ibuprofen are additional measures.

#### DELAYED COMPLICATIONS: INFLAMMATION OR INFECTION?

Understanding of delayed dermal filler adverse events and pathogenesis has been a slowly evolving process, impeded by the inconsistent terminology describing these adverse events [148; 152]. Delayed filler adverse events have long been considered foreign body immune responses or type IV immunologic reactions to filler materials or contaminants from production, reinforced by negative bacterial culture tests of pus from nodules and the low-grade nature of most inflammations [69; 144; 150; 164]. Sporadic findings of bacterial infection in late-onset nodules were often ascribed to departures from antiseptic standards in skin prep or handling of fillers [165; 166]. However, steroid or high-dose NSAID therapy to suppress a presumed inflammatory/immune response led to worsened inflammation and abscesses in some patients, who often required IV antibiotics or surgery [22; 162]. In 2009, molecular diagnostics with fluorescence in situ hybridization and advanced imaging established bacterial colonization of tissue and filler material as the causality of chronic inflammation and nodules [165; 167; 168]. In 2010, the role of biofilm in late filler complications gained attention, helping explain adverse reactions to steroid therapy. These dense bacterial colonies on surfaces secrete extracellular polymers, forming a protective matrix against host defenses and antibiotics. Knowledge of biofilm involvement improved the characterization of filler adverse events [152; 162].

A foreign body granuloma results when immune response, unable to enzymatically degrade a foreign body, forms lymphocytic inflammation and fibrosis entrapping the body, preventing its migration. Foreign body granulomas are histologically distinct from inflammatory nodules [70; 71; 150].

Foreign body granuloma formation can involve biofilm which, protected from host immune response, remains semidormant until activated months or years later by host conditions that favor replication (e.g., new filler injection, dental/medical surgery, local or remote infection, trauma). Activated biofilm can cause an immune response, granulomatous inflammation, abscesses, or nodules, and flu-like illness can precede late-onset nodules [19; 22; 69].

Thus, late-onset nodules or granuloma may represent an immune/inflammatory response secondary to biofilmcolonized filler. Clinical differentiation is challenging. Foreign material in the dermis or sub-dermis can lead to sterile abscesses, granulomas, cellulitis, or nodules. Infection months or years after injection may have similar signs, varying from erythema, edema, inflammatory nodules, and pain/itching to systemic responses [165].

Therapy for late-onset nodules or granuloma consists of [19; 68; 69; 150]:

- Oral antibiotics with immunomodulatory and anti-inflammatory efficacy, with a macrolide (e.g., clarithromycin) or a tetracycline (e.g., minocycline or doxycycline)
- Systematic and intralesional corticosteroids
- Topical tacrolimus (0.1%) or pimecrolimus (1%)
- Intralesional 5-fluorouracil
- Laser treatment
- Surgical excision

#### **Biofilm in Dermal Filler Infections**

Biofilm as an increasing concern is reflected in surgical and infectious disease practice guidelines; uptake in cosmetic/ aesthetic medicine is more recent. The skin is understood as a microbiota ecosystem, colonized by diverse micro-organisms. In normal skin flora, most bacterial constituents are harmless. Some are beneficial, such as *Staphylococcus epidermidis*, which inhibits the growth of pathogenic *Staphylococcus aureus* [169; 170].

S. *aureus*, the most commonly isolated pathogenic bacteria in surgical-site infections, colonizes tissue and artificial surfaces and is found on 30% to 60% of healthy Americans. A disturbed balance of the skin ecosystem can favor S. *aureus* proliferation and biofilm [171; 172; 173; 174].

On unbroken skin, *S. aureus* can remain asymptomatic; on injection sites, it can seed infections. The needle breaks the skin barrier, picking up bacteria that are delivered into the dermal filler and setting up infection in the tissue. Preoperative skin preparation for open surgery fails to remove 20% of resident skin flora [21; 165; 175].

Dermal filler skin prep is less stringent than presurgical site prep. However, it is important to remember that Isopropyl alcohol, chlorhexidine, and povidone iodine are demonstrably insufficient in preventing *S. aureus* biofilm transfer to tissue during filler injection [165; 170].

S. aureus biofilm-seeded hyaluronic acid injections have been linked to bacterial infection in studies comparing subjects who developed late infection to complication-free subjects, matched on age and hyaluronic acid treatment (e.g., filler properties, injections, volume). Bacterial skin flora were cultured from nasal swabs in both groups and filler injection sites in patients with late bacterial infection repeatedly over 12 months [164]. S. epidermidis dominated the bacterial flora on facial skin in 100% of subjects without complications, but pathogenic S. aureus and Klebsiella spp. dominated the bacterial flora on the facial skin of subjects with late bacterial infection. Late bacterial infection was diagnosed a mean 5.5 months after filler injection; pus and inflammatory tissue cultures were negative for bacterial growth. No subjects consented to biopsy, but exhaustive exclusion of other etiologies suggested bacterial biofilm infection [164].

#### **Concerns of Antibiotic Resistance**

Bacteria in a biofilm matrix exchange DNA mutations to spread antibiotic-resistant genes and biodiversity. As biofilms mature, antibiotic and antimicrobial resistance strengthens [162; 172; 173; 175]. A lack of biofilm-specific biomarkers has made noninvasive detection and diagnosis very difficult [174].

Biofilms are very difficult to treat and can require antibiotic concentration over 32 times that necessary for planktonic bacteria. Even the highest tolerable antibiotic dose can be insufficient [176]. Filler explant may be needed, putting the patient at risk for tissue scarring, deformity, and nerve or structural damage. Minimally biodegradable fillers have higher rates of delayed-onset infection [165]. MRSA is a serious concern because few remaining antibiotics are effective. Vancomycin-resistant S. *aureus* has also emerged—a potentially incurable infection [174]. In the general U.S. population, 20% are persistently colonized with S. *aureus* (i.e., carriers) and 2% are MRSA carriers. MRSA carriage among surgical staff (4.5%) and healthcare workers (5%) is higher, and many studies support MRSA transmission from healthcare workers to patients [170; 177]. As such, MRSA carriage screening and decolonization of surgical staff and patients can reduce MRSA surgical infections. However, no protocols or data are available on plastic surgeon MRSA carriage, association with filler-site infections, or decolonization [178; 179].

Management of biofilm infection consists of oral antibiotics with immunomodulatory and anti-inflammatory efficacy [19; 22; 143; 150]. The first-line choice is a macrolide (e.g., clarithromycin) or a tetracycline (e.g., minocycline or doxycycline) for two weeks. Second-line therapy is dual macrolide- and tetracycline-class therapy. The addition of a quinolone (e.g., ciprofloxacin) is reserved as third-line therapy due to potential serious class-wide adverse events. Patients with systemic symptoms or more severe local infection may require hospitalization and IV antibiotics.

Additional treatment options include hyaluronidase, laser, surgical drainage of the abscess, and filler excision. Note that intralesional hyaluronidase requires extreme caution, as it can facilitate the spread of active infection into adjacent tissues.

Another strategy for treating biofilm is low-dose triamcinolone injection mixed with 5-fluorouracil at regular intervals until resolution. The efficacy of 5-fluorouracil may involve its interaction with *ariR*, a regulatory gene that inhibits biofilm formation [34].

#### CONCLUSION

The importance for primary care clinicians to understand aesthetic medicine, patient variables, and market factors is brought to light by the increasing rates of aesthetic injections performed by non-board-certified physicians, nurses, and minimally trained aestheticians at inadequately equipped clinics, office settings, and spas [20]. Primary care providers are well-placed to importantly inform their patients about many aspects related to aesthetic medicine but benefit from educational intervention to become most effective in this role.

Customer Information/Answer Sheet/Evaluation insert located between pages 68-69.

#### COURSE TEST - #50201 BOTULINUM TOXIN AND DERMAL FILLERS FOR FACIAL AGING

This is an open book test. Please record your responses on the Answer Sheet. A passing grade of at least 70% must be achieved in order to receive credit for this course.

#### This 10 CE Credit Hour activity must be completed by March 31, 2027.

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Designations of Credit: NetCE designates this activity for 10 continuing education credits. AGD Subject Code: 780.

This course meets the Dental Board of California's requirements for 10 units of continuing education. Dental Board of California course #10-3841-00415.

#### 1. There has been a paradigm shift from "wrinklechasing," with isolated clinical benefit, to

- A) a focus on surgical management of facial aging.
- B) recognition of facial aging as the result of extrinsic factors only.
- C) a three-dimensional, multilayered treatment approach.
- D) All of the above
- 2. Among patients treated by members of the American Society of Plastic Surgeons (ASPS) in 2020, what proportion was White?
  - A) 60%
  - B) 66%
  - C) 80%
  - D) 92%
- 3. In 2020, how many dermal filler procedures were performed by members of ASPS ?
  - A) 2.1 million
  - B) 3.4 million
  - C) 7.2 million
  - D) 15.7 million
- 4. The total minimally invasive procedures reported by the ASPS and ASDS in 2020
  - A) is not considered reliable.
  - B) overestimates the total performed in the United States.
  - C) underestimates the total performed in the United States.
  - D) accurately reflects the total performed in the United States.

- Age-related changes that involve specific facial tissue levels are best described by
  A) horizontal zones.
  - B) the two-dimensional model.
  - C) the three-dimensional model.
  - D) the aesthetic zones/units model.
- 6. In terms of aging and the facial skeleton,
  - A) resorption and atrophy are uniform.
  - B) greatest resorption occurs with the maxilla.
  - C) greatest resorption occurs with the frontal bone (forehead).
  - D) the facial skeleton is largely irrelevant to cosmetic concerns.
- 7. Which of the following is TRUE regarding onabotulinumtoxinA?
  - A) It was first marketed in Europe.
  - B) It is the original, most-studied formulation.
  - C) It is the only approved serotype-B formulation.
  - D) It is newer and less-studied, and FDA approval is pending.
- 8. Long-term follow-up of patients treated with botulinum toxin for glabellar lines suggests
  - A) efficacy sustained with increased dosing.
  - B) the development of antibodies with loss of efficacy.
  - C) efficacy sustained with decreasing injection intervals.
  - D) patients reported greater reductions in their perceived age with increasingly longer treatment durations.

- 9. In which of the following patient populations is botulinum toxin injection very likely to be effective?
  - A) Kinetic
  - B) Hypertonic
  - C) Hyperkinetic
  - D) Deep static lines with loss of skin elasticity

## 10. Poor botulinum toxin treatment response can result from

- A) anatomical variation.
- B) insufficient or incorrect dosing.
- C) errors in drug handling during preparation, storage, or administration.
- D) All of the above

## 11. The only permanent dermal filler approved by the FDA is

- A) hyaluronic acid.
- B) poly-L-lactic acid (PLLA).
- C) calcium hydroxylapatite (CaHA).
- D) polymethylmethacrylate (PMMA).

## 12. Dermal fillers most suitable for deep-tissue placement to re-volumize are characterized by

- A) Low elasticity and high viscosity.
- B) High elasticity and high viscosity.
- C) High elasticity and low viscosity.
- D) Low elasticity and low viscosity.

## 13. Greater risk of intra-arterial complications may be related to using

- A) Sculptra.
- B) Bellafill.
- C) Radiesse.
- D) Revanesse.

#### 14. Deoxycholic acid (Kybella) is best described as

- A) an alternative to liposuction.
- B) a volumizer for submental fat atrophy.
- C) extensive in cosmetic medicine following its approval.
- D) a reducer of fat accumulation in any subcutaneous tissue.

## 15. Which of the following is an important consideration in minimally invasive therapy of male patients?

- A) Understanding sexual dimorphism
- B) Preventing unwanted feminization of male features
- C) Preventing an exaggeration of typical male features
- D) All of the above

- 16. What is the optimal sequence of minimally invasive treatment delivery?
  - A) Concurrent fillers with laser resurfacing
  - B) Concurrent botulinum toxin with laser resurfacing
  - C) All treatments spaced apart at least two weeks, regardless of modality
  - D) Same-day treatment to fully capitalize on the synergistic interactions
- 17. What feature of facial aging may also result from improper botulinum toxin injection?
  - A) Jowls
  - B) Brow ptosis
  - C) Nasolabial folds
  - D) Lateral canthal rhytides
- 18. Which area of the face is recommended for initial treatment?
  - A) Upper
  - B) Mid
  - C) Lower
  - D) Neck
- 19. What is the recommended approach to a primary complaint of prominent nasolabial folds?
  - A) Volumizing the malar area is attempted first.
  - B) The nasolabial fold is injected directly with fillers.
  - C) Treatment is confined to the lower nasolabial fold.
  - D) The nasolabial fold is injected directly with botulinum toxin.
- 20. Better understanding of adverse events has greatly expanded the contraindications of
  - A) patient age.
  - B) autoimmune disorders.
  - C) skin conditions and disorders.
  - D) over-the-counter vitamin and supplement use.

## 21. Aggrieved dissatisfaction with cosmetic results is most likely in which patients?

- A) Younger age
- B) Lower education
- C) Body dysmorphic disorder
- D) Those seeking surgical procedures
- 22. Which of the following is a positive predictor of patient satisfaction with cosmetic outcomes?
  - A) Peer pressure
  - B) Low self-esteem
  - C) Internal motivation
  - D) External motivation

Test questions continue on next page  $\rightarrow$ 

- 23. Which of the following is an essential element of ensuring patients do not envisage an unrealistic outcome?
  - A) Confidence-building
  - B) Expectation management
  - C) Accurate marketing and promotion
  - D) Treatment planning guided by the patients' preconceived treatment approach

## 24. Most malpractice claims in cosmetic medicine result from

- A) a botched procedure.
- B) adverse complications.
- C) inadequate informed consent.
- D) technique that falls below patient expectations.

## 25. Which of the following is TRUE of vascular compromise during filler injections?

- A) It is largely prevented by improved filler rheology.
- B) Complications are now decreasing with better training.
- C) It is a potentially catastrophic complication and a risk even with expert injectors.
- D) It is a potentially catastrophic complication prevented by proper aseptic injection prep.

## 26. If visual impairment and ocular pain occurs during filler injection,

- A) central retinal artery occlusion is likely.
- B) withdraw needle and inject another site.
- C) apply warm compresses until vision returns.
- D) apply nitroglycerin paste 2% to promote vasodilatation.

- 27. Among filler types, the distinct safety advantage with hyaluronic acid fillers isA) lack of migration.
  - B) the proven absence of immune responses.
  - C) adverse events self-limiting from the brief duration in tissue.
  - D) availability of hyaluronidase to reverse many adverse events.

## 28. Which of the following statements regarding acute hypersensitivity reactions is FALSE?

- A) It can represent a medical emergency.
- B) Cold compresses are effective management.
- C) Local angioedema can progress to airway obstruction.
- D) Any systemic manifestation should be treated as impending anaphylaxis.

#### 29. Biofilm infections are thought to arise from

- A) manufacturing contamination.
- B) foreign body immune responses.
- C) type IV immunological reactions.
- D) skin surface bacteria inserted into tissue during filler injection.
- 30. Bacterial biofilm infections are concerning because
  - A) biofilms are very difficult to detect.
  - B) biofilms are typically very difficult to treat.
  - C) filler explant, and risks of scarring and deformity, may be required.
  - D) All of the above

Be sure to transfer your answers to the Answer Sheet located on the envelope insert located between pages 68–69. DO NOT send these test pages to NetCE. Retain them for your records.

#### PLEASE NOTE: Your postmark or facsimile date will be used as your test completion date.

## **Course Availability List**

These courses may be ordered by mail on the Customer Information form located between pages 68–69. We encourage you to **GO GREEN**. Access your courses **online** or download as an **eBook** to save paper. Additional titles are also available.

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#### **ORAL AND MAXILLOFACIAL TRAUMA**

#### #50003 • 5 CE Credit Hours • \$45

**Purpose**: The purpose of this course is to provide dental professionals with a deeper understanding of and appreciation for oral and maxillofacial trauma. **Faculty**: Mark J. Szarejko, DDS, FAGD

Audience: This course is designed for all dental professionals, especially those who work in emergency and trauma care.

AGD Subject Code: 070

#### **OSHA AND HEALTHCARE FACILITIES**

#### #51234 • 5 CE Credit Hours • \$45

**Purpose**: The purpose of this course is to provide information that will allow facilities to more easily comply with the broad spectrum of rules covered by the OSHA regulations.

Faculty: Carol Shenold, RN, ICP

Audience: This course is designed for dental healthcare staff in all specialties.

AGD Subject Code: 550

### CONTROVERSIAL ISSUES IN DENTISTRY

#### #51391 • 5 CE Credit Hours • \$45

**Purpose**: The purpose of this course is to provide factual information about controversial topics in dentistry, allowing professionals to objectively assess the issues and discuss them with patients and other professionals. **Faculty**: Mark J. Szarejko, DDS, FAGD

Faculty: Mark J. Szarejko, DDS, FAGD

Audience: This course is designed for dental professionals in all practice settings.

AGD Subject Code: 750

#### SMOKING AND SECONDHAND SMOKE #51784 • 10 CE Credit Hours • \$90

**Purpose**: The purpose of this course is to provide dental professionals with a formal educational opportunity that will address the impact of tobacco smoking and secondhand exposure in public health and disease as well as interventions to promote smoking cessation among their patients.

**Faculty**: Mark S. Gold, MD, DFASAM, DLFAPA **Audience**: This course is designed for dental professionals who may intervene to stop patients from smoking. **AGD Subject Code**: 158

#### DENTAL CARE FOR PATIENTS WITH DISABILITIES #51913 • 5 CE Credit Hours • \$45

**Purpose**: The purpose of this course is to focus awareness upon the difficult oral health issues that patients with disabilities face on a daily basis and to provide dental professionals with the necessary information to improve patients' oral and systemic health.

Faculty: Mark J. Szarejko, DDS, FAGD

**Audience**: This course is designed for dental professionals involved in assessing and promoting optimum oral care for special needs patients. **AGD Subject Code**: 750

#### DENTAL TREATMENT OF PEDIATRIC AND ADOLESCENT PATIENTS

#### #52163 • 6 CE Credit Hours • \$54

**Purpose**: Dental professionals are frequently involved in the care of pediatric and/or adolescent patients. The purpose of this course is to outline the oral health needs and problems unique to the pediatric and adolescent populations.

Faculty: Mark J. Szarejko, DDS, FAGD

**Audience**: This course is designed for dental hygienists and assistants whose patient populations include children and/or adolescents. It may also be of interest to dentists with pediatric patients. **AGD Subject Code**: 430

ORAL HEALTH ISSUES DURING PREGNANCY #53074 • 2 CE Credit Hours • \$18

# **Purpose**: The purpose of this course is to provide dental professionals with the information necessary to appropriately intervene to promote good oral health in pregnant patients, with lasting positive effects to the patient and fetus.

Faculty: Mark J. Szarejko, DDS, FAGD

Audience: This course is designed for all dental professionals involved in the care of pregnant patients.

AGD Subject Code: 750

#### ANTIBIOTICS REVIEW

#### #55074 • 5 CE Credit Hours • \$45

**Purpose**: The purpose of this course is to provide a review of the major classes of antibiotics and their characteristics as well as an overview of selected individual agents within each class that are most useful for today's clinical practitioner.

Faculty: Donna Coffman, MD

Audience: This course is designed for dental providers who prescribe and administer antibiotics to patients.

AGD Subject Code: 148

#### MEDICAL MARIJUANA AND OTHER CANNABINOIDS #55173 • 5 CE Credit Hours • \$45

**Purpose**: The purpose of this course is to provide dental professionals with unbiased and evidence-based information regarding the use of marijuana and other cannabinoids for the treatment of medical conditions.

Faculty: Mark Rose, BS, MA, LP

**Audience**: This course is designed for dental professionals involved in the care of patients who use or who are candidates for the therapeutic use of marijuana and other cannabinoids.

AGD Subject Code: 149

Prices are subject to change. Visit www.NetCE.com for a list of current prices.

## Course Availability List (Cont'd)

#### LOCAL ANESTHETICS IN DENTISTRY

#### #55182 • 5 CE CREDIT HOURS • \$45

**Purpose**: The purpose of this course is to provide dental professionals with a comparative perspective on the use of local anesthetics.

Faculty: Mark J. Szarejko, DDS, FAGD

Audience: This course is designed for all dental professionals whose patients may be administered local anesthetics.

AGD Subject Code: 340

#### COCAINE USE DISORDER

#### #56944 • 5 CE CREDIT HOURS • \$45

**Purpose**: The purpose of this course is to provide a current, evidence-based overview of cocaine abuse and dependence and its treatment, in order to allow dental professionals to more effectively identify, treat or refer cocaine-abusing patients.

Faculty: Mark Rose, BS, MA, LP

Audience: This course is designed for dental professionals who are involved in the evaluation or treatment of persons who use cocaine. AGD Subject Code: 157

#### **METHAMPHETAMINE USE DISORDER**

#### #56954 • 5 CE CREDIT HOURS • \$45

**Purpose:** Methamphetamine use has risen alarmingly, reaching epidemic proportions in some regions. The purpose of this course is to provide a current, evidence-based overview of methamphetamine abuse and dependence and its treatment in order to allow dental professionals to more effectively identify, treat, or refer methamphetamine-abusing patients. **Faculty:** Mark Rose, BS, MA, LP

Audience: This course is designed for dental professionals who are involved in the evaluation or treatment of persons who use methamphetamine. AGD Subject Code: 157

#### SEXUAL HARASSMENT PREVENTION: THE CALIFORNIA LAW

#### #57481 • 2 CE CREDIT HOURS • \$18

**Purpose**: The purpose of this course is to provide information on what constitutes sexual harassment, how to prevent it in the workplace, and to define the roles and responsibilities of creating a safe work environment as it applies to both supervisors and employees.

Faculty: Lauren E. Evans, MSW

Audience: This course is designed for dental professionals who may act to prevent sexual harassment.

AGD Subject Code: 550

### TOP-SELLING HERBAL SUPPLEMENTS

#### #58080 • 3 CE Credit Hours • \$27

**Purpose**: The purpose of this course is to provide dental professionals in all practice settings the knowledge necessary to increase their understanding of the most popular herbal supplements and to better counsel patients regarding their use.

Faculty: Chelsey McIntyre, PharmD

**Audience**: This course is designed for dental professionals whose patients are taking or are interested in taking herbal supplements. **AGD Subject Code**: 149

#### ORAL PATHOLOGY REVIEW #58664 • 5 CE Credit Hours • \$45

**Purpose**: The purpose of this course is to provide dental professionals with the information necessary to identify, assess, and treat or refer patients with a wide range of conditions of the hard and soft tissues of the oral and maxillofacial complex resulting from pathologic entities of microbial, autoimmune, and behavioral origin.

Faculty: Mark J. Szarejko, DDS, FAGD

**Audience**: This course is designed for all dental professionals who care for patients who may have oral pathology.

AGD Subject Code: 730

#### SLEEP DISORDERS

#### #58884 • 10 CE Credit Hours • \$90

Purpose: Many of the complications associated with sleep disorders are preventable, making early diagnosis



and appropriate treatment vital. The purpose of this course is to provide dental professionals with the information necessary to identify and contribute to the treatment of sleep disorders, thereby improving patients' quality of life and preventing possible complications.

Faculty: Teisha Phillips, RN, BSN

Audience: This course is designed for all dental professionals who are involved in the care of patients experiencing a sleep-related disorder. AGD Subject Code: 730

Prices are subject to change. Visit www.NetCE.com for a list of current prices.



Price BEFORE

March 31, 2026

Marc \$

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Complete all six courses for a maximum payment of \$105 (or pay the individual course price).

105	✓	Course #	Course Title / CE Credit Hours	Price
		51294	The California Dental Practice Act / 2 CE Credit Hours	\$18
		58584	Infection Control for Dental Professionals: The California Requirement / 2 CE Credit Hours	\$18
Price AFTER Jarch 31, 2026		55290	Responsibilities & Requirements of Prescribing Schedule II Opioid Drugs / 2 CE Credit Hours	\$18
\$140		57510	Intercultural Competence and Patient-Centered Care / 4 Credit Hours	\$36
°143		53384	Women's Health for Dental Professionals / 5 CE Credit Hours	\$45
		50201	Botulinum Toxin and Dermal Fillers for Facial Aging / 10 CE Credit Hours	\$90

#### Additional Courses Available by Mail (ACCESS ONLINE FOR A DISCOUNT!) Payment must accompany this form. To order by phone, please have your credit card ready.

~	Course #	Course Title / CE Credit Hours	Price	✓	Course #	Course Title / CE Credit Hours	Price
	50003	Oral and Maxillofacial Trauma / 5	\$45		55173	Medical Marijuana and Other Cannabinoids / 5	\$45
	51234	OSHA and Healthcare Facilities / 5	\$45		55182	Local Anesthetics in Dentistry / 5	\$45
	51391	Controversial Issues in Dentistry / 5	\$45		56944	Cocaine Use Disorder / 5	\$45
	51784	Smoking and Secondhand Smoke / 10	\$90		56954	Methamphetamine User Disorder / 5	\$45
	51913	Dental Care for Patients with Disabilities / 5	\$45		57481	Sexual Harassment Prevention: The California Law / 2	\$18
	52163	Dental Treatment of Pediatric & Adolescent Patients / 6	\$54		58080	Top-Selling Herbal Supplements / 3	\$27
	53074	Oral Health Issues During Pregnancy / 2	\$18		58664	Oral Pathology Review / 5	\$45
	55074	Antibiotics Review / 5	\$45		58884	Sleep Disorders / 10	\$90

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VISA / MasterCard / AmEx / Discover	

Please print name (as shown on credit card)						
Credit card #						
Expiration date	Security code	Security signature four num on front o	code is l e area or bers ab of AmEx	last th n back ove th c card:	nree nur k of crea ne acco s.	nbers in the dit card or unt number
Signature						

3	Special Offer (BEFOR	<u>*105</u>	
<sup>\$</sup> 143 ( <b>AFTER March 31, 2026</b> )			
	l would mailed f		
		Additional Courses	
	Expedited mail delivery within 2 to 3 days is available in most areas at an additional charge of \$35.	Subtotal	. <u></u>
		Expedited Delivery	
	Call for information on international delivery.	Grand Total	

Stor.

Prices are subject to change. Visit www.NetCE.com for a list of current prices.

## **Answer Sheet**

(Completion of this form is mandatory)

#### Please note the following:

- A passing grade of at least 70% must be achieved on each course test in order to receive credit.
- · Darken only one circle per question.
- Use pen or pencil; please refrain from using markers.
- Information on the Customer Information form must be completed.

#### #51294 THE CALIFORNIA DENTAL PRACTICE ACT-**2 CE CREDIT HOURS**

#### Please refer to page 27.

Expiration Date: 01/31/28					BE TA	AKEN I	NDIVIL	DUALLY	FOR \$18
Α	В	С	D		Α	В	С	D	
1. O	0	0	0	6.	0	0	0	0	
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5. O	0	0	0	10.	0	0	0	0	

#### **#55290 REQUIREMENTS OF PRESCRIBING** SCHEDULE II OPIOID DRUGS-2 CE CREDIT HOURS Please refer to pages 59-60.

EXPIRATION [	DATE: (	)1/31/	27	MAY BE	TAKEN	INDIVI	DUALLY	′ FOR \$18
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#### **#58584 INFECTION CONTROL FOR DENTAL** PROFESSIONALS: THE CA REQ.-2 CE CREDIT HOURS Please refer to pages 45.

		-							
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#### **#57510 INTERCULTURAL COMPETENCE AND PATIENT-CENTERED CARE-4 CE CREDIT HOURS**

Please refer to pages 79-80.

Expiration Date: 09/30/26					Мау в	E TA	KEN I	NDIVIE	UALLY	r for \$36
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9.	0	0	0	0						
10.	0	0	0	0						

#### **#53384 WOMEN'S HEALTH FOR DENTAL PROFESSIONALS-5 CE CREDIT HOURS**

Please refer to pages 100-101.

Expiration Date: 01/31/26					ΜΑΥ	BE T	AKEN I	NDIVIL	DUALLY	Y FOR \$45
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4. (	С	0	0	0	14.	0	0	0	0	
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8. (	С	0	0	0	18.	0	0	0	0	
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10. 🤇	С	0	0	0	20.	0	0	0	0	

#### **#50201 BOTULINUM TOXIN AND DERMAL FILLERS** FOR FACIAL AGING-10 CE CREDIT HOURS

Please refer to pages 132-134. EXPIRATION DATE: 03/31/27 MAY BE TAKEN INDIVIDUALLY FOR \$90 В С Α В С D Α D 1. 0 0 0 0 16. O 0 0 0 2. 0 0 0 0 17. O 0 0 0 3. O 0 0 0 18. O 0 0 0 0 0 0 0 19. O 0 0 0 4. 5. 0 0 0 0 0 20. O 0 0 0 0 0 21. O 0 0 0 6. O 7. O 0 0 0 22. O 0 0 0 8. O 0 0 0 23. O 0 0 0 9. O 0 0 0 24. O  $\mathbf{O}$ 0 0 10. O  $\mathbf{O}$  $\mathbf{O}$  $\mathbf{O}$ 25. O  $\mathbf{O}$  $\mathbf{O}$ 0 26. O 0 11. O 0 0 0 0 0 12. O 0 0 0 27. O 0 0 0 0 0 0 13. O 0 28. O 0 0 0 0 14. O 0 0 29. O 0 0 0 15. O 0 0 30. O 0 0 0



## **Evaluation**

CADN25

(Completion of this form is mandatory)

Last	Name First Nam	e MI
State	e License #	Expiration Date
	To receive continuing education credit, complet	ion of this Evaluation is mandatory.
Plea 1. 2. 3. 4.	ase read the following questions and choose the most appropriate answ Was the course content new or review? How much time did you spend on this activity, including the test questi Would you recommend this course to your peers? Did the course content support the stated course objective? Did the course content demonstrate the outbor's knowledge of the sub-	ver for each course completed. ons?
5. 6. 7.	Was the course content demonstrate the author's knowledge of the sub Before completing this course, did you identify the necessity for educa	tion on the topic to improve your professional practice?
8. 9. 10.	Have you achieved all of the stated learning objectives of this course? Has what you think or feel about this topic changed? Did evidence-based practice recommendations assist in determining th	e validity or relevance of the information?

- 11. Are you more confident in your ability to provide patient care after completing this course?
- 12. Do you plan to make changes in your practice as a result of this course content?

<b>#51294</b>	<b>#58584</b>	<b>#55290</b>	<b>#57510</b>	<b>#53384</b>	<b>#50201</b>
2 CE Credit Hrs	2 CE Credit Hrs	2 CE Credit Hrs	4 CE Credit Hrs	5 CE Credit Hrs	
1. New	1. New	1. New	1. New	1. New	1. New
Review  2 Hours	2 Hours	2 Hours	2 Hours	2 Hours	2 Hours
3. ∐Yes ∐No	3. ∐ Yes ∐ No	3. ∐Yes ∐No	3. ∐Yes ∐No	3. ∐Yes ∐No	3. ∐Yes ∐No
4. ∐Yes ∐No	4. ∐ Yes ∐ No	4. ∐Yes ∐No	4. ∐Yes ∐No	4. ∐Yes ∐No	4. ∐Yes ∐No
5. ∐Yes ∐No	5. ∐ Yes ∐ No	5. Yes No	5. ∐Yes ∐No	5YesNo	5. ∐Yes ∐No
6. <u></u> Yes <u></u> No	6. ∐ Yes ∐ No	6. Yes No	6. ∐Yes ∐No	6YesNo	6. ∐Yes ∐No
7. ∐Yes ∐No	7. ∐Yes ∐No	7.  Yes  No	7. ∐Yes ∐No	7.  Yes  No	7. ∐Yes ∐No
8. <u></u> Yes <u></u> No	8. ∐Yes ∐No	8. Yes  No	8. ∐Yes ∐No	8. Yes  No	8. <u></u> Yes <u></u> No
9. □Yes □No	9. □Yes □No	9. □Yes □No	9. □Yes □No	9. □Yes □No	9. □Yes □No
10. ⊠N/A	10. ⊠N/A	10. ⊠N/A	10. ⊠N/A	10. ⊠N/A	10. ⊠N/A
11. ∐Yes ☐No	11. ∐Yes ☐No	11. ∐Yes ☐No	11. ∐ Yes ☐ No	11. ∐Yes ☐No	11.
12. ☐Yes ☐No	12. ☐Yes ☐No	12. ☐Yes ☐No	12. ☐ Yes ☐ No	12. ☐Yes ☐No	

#51294 The California Dental Practice Act – If you answered YES to question #12, how specifically will this activity enhance your role as a member of the interdisciplinary team?

#58584 Infection Control for Dental Professionals: The California Requirement – If you answered YES to question #12, how specifically will this activity enhance your role as a member of the interdisciplinary team?

#55290 Responsibilities and Requirements of Prescribing Schedule II Opioid Drugs – If you answered YES to question #12, how specifically will this activity enhance your role as a member of the interdisciplinary team?

#57510 Intercultural Competence and Patient-Centered Care – If you answered YES to question #12, how specifically will this activity enhance your role as a member of the interdisciplinary team?

#53384 Women's Health for Dental Professionals – If you answered YES to question #12, how specifically will this activity enhance your role as a member of the interdisciplinary team?

#50201 Botulinum Toxin and Dermal Fillers for Facial Aging – If you answered YES to question #12, how specifically will this activity enhance your role as a member of the interdisciplinary team?

Signature

Signature required to receive continuing education credit.

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