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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
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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AGD Subject Code 563.

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

Dental Board of California course #02-3841-00343.

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

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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].

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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;

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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). The processing times for coronal polishing course approval are set forth in section 1069.

    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.) The processing times for ultrasonic scaler course approval are set forth in section 1069.

(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 nine governor-appointed positions: four public members, four dental hygienists, and one practicing dentist [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;
     4. 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.

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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 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 intake, complaint analysis, inspection, investigation, and probation [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 section. The Board's Enforcement Unit may be contacted at (916) 274-6326. 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.

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

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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.

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(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.

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.

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(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 a conspicuous place in his or her office the name of each and every person employed there in the practice of 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. 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:

(a) 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.

(b) 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.

(c) With fraudulent intent, makes or attempts to make, counterfeits or alters in a material regard any such diploma, certificate or transcript.

(d) 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.

(e) In an affidavit, required of an applicant for examination, license or registration under this chapter, willfully makes a false statement in a material regard.

(f) 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.

(g) 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.

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 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/pubs/manuals. The California Uniform Controlled Substances Act (part of the California Health and Safety Code) can be found at https://leginfo.legislature.ca.gov/faces/codesTOCSelected.xhtml?tocCode=HSC. 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.

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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:
   1. 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.

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(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).

(j) If the dispensing pharmacy, clinic, or other dispenser 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.

(iv) The entity has entered into a memorandum 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.

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G. The department shall not access patient-identifiable 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, decision-making, 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.

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(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. 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, radiotheraputic, 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.

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.

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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]:

- **R**outinely screen for signs and symptoms of abuse/neglect
- **A**sk direct, non-judgmental questions with compassion
- **D**ocument your findings
- **A**ssess patient safety before the patient leaves the medical setting
- **R**eview, 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 a steady increase in reporting over the last few decades [14]. Contrary to popular belief, 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 last 50 years from state institutions to the home (particularly for younger disabled individuals) [12; 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 (roughly 500,000 cases per year in the United States) [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.

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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]. In the United States in 2011, 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) had been experienced by an estimated 22.3% of women and 14.0% of men during their lifetimes [17].

Dental professionals should be vigilant in recognizing signs of abuse among adolescent and adult patients. One-half to two-thirds 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 is everything going at home?
- Is there anything going on at work/school or at home that's difficult for you to talk about or is stressful for you?
- Are you having any problems with your parents/caretakers/partner/husband?

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

- Did someone kick, hit, hurt, or threaten to hurt you? Was it your parent/caretaker or partner/husband?
- Are you in a relationship with (or do you live with) someone who hits, kicks, or threatens to hurt you?
- Have you ever been slapped, pushed, or shoved by your parent/partner?
- Have there been times when you felt afraid at home being around another person?
- Have you been hit or scared since the last time I saw you?
- Is it safe for you to go home today?

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]:

- I don't know if this is (or has ever been) a problem for you, but many of the patients I see are dealing with abuse/abusive relationships. Some are too afraid or uncomfortable to bring it up themselves, so I have started asking everyone about it.
- From past experience with other patients, I'm concerned that some of your medical problems or injuries may be the result of someone hurting you. Is that happening?

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

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

COURSE TEST - #51293 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, 2025.

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AGD Subject Code: 563.

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Dental Board of California course #02-3841-00343.

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*

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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%*

Be sure to transfer your answers to the Answer Sheet located on the envelope insert.
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.

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 the use of precautions, 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 professionals, including vaccination, education, and exposure responses.

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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Sarah Campbell

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Designations of Credit
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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 #02-3841-00344.

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

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- Complete the test and evaluation.
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INTRODUCTION

In 2018, there were more than 750,000 jobs in dental occupations in the United States [1]. In California alone there are approximately 91,000 dental healthcare professionals (DHCPs), including dentists, dental hygienists, and dental assistants. 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. In California, there are three regulatory agencies involved in infection control in the dental healthcare setting: the Dental Board of California (DBC), which sets the minimum standards, the California Division of Occupational Safety and Health (Cal/OSHA), which publishes the Bloodborne Pathogens Standard, and the California Department of Public Health, which established the Waste Management Act.

To address the issue of infection control and reduce the potential for harm, the DBC established a requirement that dental healthcare licensees in California complete a course on infection control and prevention. DBC regulations also require that licensees comply with and enforce precautions and workplace practices that minimize the transmission of pathogens in dental settings. "Standard Precautions" is the DBC term for infection control measures that encompasses both "Universal Precautions"—a term the Occupational Safety and Health Administration (OSHA) uses—and the Cal/OSHA mandate for bloodborne pathogen transmission. The DBC mandates that Standard Precautions must be practiced in the care of all patients. The same infection control precautions apply to all patients, and all body fluids, except sweat, are considered potentially infectious. Universal Precautions are measures taken when exposed to blood, while Standard Precautions apply to all potentially infectious materials. While most elements of Standard Precautions evolved from Universal Precautions, developed for protection of healthcare personnel, additional elements of Standard Precautions focus on protection of patients. Contact Precautions are used to prevent transmission of an infectious agent associated with environmental contamination (e.g., treating all environmental surfaces as potentially contaminated) that is not interrupted by Standard Precautions alone.

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 [2]. The DBC Standard Precaution guidelines are reviewed annually. Current guidelines may be downloaded at https://govt.westlaw.com/calregs/Document/I3F75D9A0B95D11E0A3CAA6663E6464AA and are found at the conclusion of this course. Significant changes in the 2011 revision include application of the guidelines to all dental healthcare professionals (not just "registered" professionals) and specific steps for disinfection [2]. The goal of these guidelines is to reduce the number of healthcare-associated infections in California dental practice settings.

OSHA AND CAL/OSHA 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]. The OSHA Standard requires employers whose employees have exposure to blood or other potentially infectious material to implement safe work practices, education, and barriers to exposure. The Standard was later amended to cover the safe use of sharps.

BLOODBORNE PATHOGENS STANDARD

The OSHA Bloodborne Pathogens Standard requires that every healthcare worker who may have contact on the job with blood or other bodily fluids (referred to as other potentially infectious material or OPIM) 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 Contact Precautions.

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 healthcare employers to develop exposure control procedures and train employees to follow those procedures [4; 5]. 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.

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; 6; 7]:

- 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 Centers for Disease Control and Prevention (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.

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 Contact Precautions are designed to interrupt the mode of transmission.

The most common modes of transmission in the healthcare setting are the hands of healthcare workers and items that move from patient to patient, both of which are examples of indirect transmission (***Table 1***). Items moving between patients should be cleaned and sterilized after each use to avoid indirect transmission of pathogens. Because it addresses the weakest link in the chain of transmission, hand hygiene is still the single most important procedure for preventing the spread of infection.

AEROSOLS, DROPLETS, AND SPLATTER

Aerosols, droplets (produced by the respiratory tract), and splatter contaminated with blood and bacteria are produced during many dental procedures [8]. 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.

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COMMON MODES OF INFECTION TRANSMISSION	
Category	**Definition**
Direct	Person-to-person transmission of pathogens
Indirect	An intermediate person or item (e.g., an instrument) acts as a transport between the portal of exit in one person and the portal of entry to the next person (e.g., unwashed hands)
Fomites	Contact with soiled objects, such as used gloves, pens, used tissues, and soiled laundry

Source: Compiled by Author *Table 1*

Several studies have shown that aerosol 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. 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.

The American Dental Association recommends that in addition to using standard barriers, such as masks, gloves, and eye protection, 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 [9].

Diseases known to spread by aerosols or droplet include:

- TB
- Pneumonic *Yersinia pestis* infection (plague)
- Influenza
- Legionellosis (Legionnaires disease)
- Severe acute respiratory syndrome (SARS)

Procedures or equipment aimed at eliminating the means of transmission include [9]:

- 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
- Gloves to minimize contamination of hands, discarded after each patient
- 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 personal protective equipment (PPE) may become contaminated with potential pathogens after care of a patient colonized or infected with an infectious agent [10].

Contaminated clothing and laboratory coats can potentially transmit infectious agents to successive patients. A 2007 study in a Maryland teaching hospital revealed that 27% of the white coats worn by 109 physicians and other healthcare professionals were colonized with *Staphylococcus aureus* and 6% were colonized with methicillin-resistant *S. aureus* (MRSA). In a follow-up questionnaire, 65% of the healthcare workers reported they had last washed their white coat more than a week ago and nearly 16% had last washed their coat more than 30 days ago [11]. A study presented at the American Society of Microbiology Conference in 2012 identified clothing and household linens (e.g., cotton towels) as a significant transmission source of infectious pathogens [12]. However, evidence linking clothing to hospital infection rates is lacking, and additional research is necessary to determine the actual extent of this risk [13].

Dental equipment and dental unit waterlines are both potential sources of transmission and potential reservoirs. Routine cleaning and sterilization and adherence to the American Dental Association's recommended procedures for treating dental unit waterlines have been shown to be effective in eliminating transmission of infectious organisms via these devices. 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. In addition, a new infection control standard that took effect on January 1, 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. This requirement is 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 [14].

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 human immunodeficiency virus (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 [8; 15]. 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 [16].

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% [17]. 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 [17]. There also has been a report of hepatitis C virus transmission that may have resulted from exposure to nonintact skin, but there is no known risk from exposure to intact skin [8]. 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.

The prevalence of hepatitis C virus infection among dentists and surgeons is similar to that among the general population, approximately 1% to 2% [15]. No studies of transmission from hepatitis C virus-infected dental healthcare personnel to patients have been reported, and the risk for such transmission appears limited [6].

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 [8; 17]. 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) [8; 17].

In the United States, the risk of HIV transmission in dental settings is extremely low. According to surveillance data from 1981 to 2010, a total of 57 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 [18]. Transmission of HIV to 6 patients of a single dentist with AIDS has been reported, but the mode of transmission could not be determined [19].

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 [20]. The risk was also increased if the exposure was to blood from patients with terminal illnesses, possibly reflecting the higher titer of HIV in late-stage AIDS patients.

PREVENTION STRATEGIES

In 1986, California became the first state to pass a comprehensive bloodborne pathogen standard [9]. The California standard provided a model for federal legislation, and in 1991, OSHA published its Bloodborne Pathogens Standard. Since then, regulatory and legislative activity has focused on implementing a hierarchy of prevention and control measures to improve infection control in healthcare settings. Respiratory hygiene, safe injection practices, aseptic technique, hand hygiene, and the use of PPE are now accepted as essential components of an effective infection prevention strategy. The Cal/OSHA ATD standard passed into law in 2009 was expected to be a blueprint for federal standards addressing aerosol transmissible diseases [5; 9]. Although permanent federal standards have not come to fruition, in June 2021, OSHA issued an emergency temporary standard addressing occupational exposure to severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2), commonly referred to as COVID-19, including patient screening and management, use of Standard and Transmission-Based Precautions, PPE, and controls for aerosol-generating procedures [21].

STANDARD PRECAUTIONS

The gradual acceptance of various infection prevention standards has changed the way we work in the provision of dental care. 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
- All bodily fluids, secretions, and excretions (except sweat), regardless of whether they contain blood
- Intact or nonintact skin
- Mucous membranes

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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.

When adhering to Standard Precautions, always:

- Use good hand hygiene.
- Use gloves for contact with blood, bodily fluids, nonintact skin (including rashes), mucous membranes, used equipment, linens, and trash.
- Use a gown any time your clothing is soiled and if a patient has uncontained bodily fluids (e.g., blood, saliva).
- Use a mask and eye protection if you may be splashed or be exposed to droplets; glasses do not adequately protect you.
- 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.
- Reuse gowns, even for repeated contacts with the same patient.
- Contaminate the environment with dirty gloves.
- Wear gloves outside the treatment area unless you can say why you are wearing them.

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 professionals 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.

ASEPTIC TECHNIQUE

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 other potentially infectious material should be kept separate from medications.

SAFE INJECTION PRACTICES

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 [22]. Guidelines on the design, implementation, and evaluation of a sharps injury prevention program have been developed by the CDC.

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. 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.

Never leave a needle or other device inserted into a vial or bottle for multiple uses. This provides a direct route for microorganisms to enter the vial and contaminate the fluid. Medications should never be administered from the same syringe to more than one patient, even if the needle is changed.

Dental professionals 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.

Cases of bloodborne pathogen transmission as a result of improper injection practices have common themes [22]. 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.

HAND HYGIENE

Despite the simplicity and effectiveness of hand hygiene in preventing the spread of infectious disease, adherence to hand hygiene practice remains unacceptably low [23]. Adherence varies among professional categories of healthcare workers but is usually estimated as less than 50%, a rate that has not changed in more than a decade [23; 24; 25]. Healthcare providers might need to clean their hands as many as 100 times in a 12-hour shift, depending on the number of patients and intensity of care [25]. For dental healthcare workers, strict adherence to hand hygiene protects both the patient and the worker. Hand hygiene should be done when you first come to work, before you touch your first patient or clean equipment, and before and after every patient contact—including after touching intact skin. In addition, perform hand hygiene:

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

A number of conditions restrict dental healthcare professionals from participating in direct patient care. These include weeping dermatitis, exudative lesions, or any hand conditions that increase the risk of disease transmission.

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. Such handwashing removes the oils that harbor the organisms. 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 [23]. 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. 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.

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 [26; 27]. In addition, antiseptics may be added to alcohol-based handrubs in order to achieve persistent germicidal activity [6]. 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.

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.

PERSONAL PROTECTIVE EQUIPMENT

PPE is defined as special coverings designed to protect healthcare personnel from exposure to or contact with infectious agents [28]. Cal/OSHA regulations require use of PPE in dental care settings to protect personnel from exposure to bloodborne pathogens. 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 [29]. 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.

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In addition to the familiar gloves 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, protective eyewear, face shields, and protective clothing.

Procedures that 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 other potentially infectious material 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.

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

Dental personnel should wear gloves to prevent contamination of their hands when touching mucous membranes, blood, saliva, or other potentially infectious material. 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 professionals should always use gloves when [28; 30]:

- Anticipating direct contact with blood or bodily fluids, mucous membranes, nonintact skin, and other potentially infectious material
- Engaging in direct contact with patients who are colonized or infected with pathogens transmitted by the contact route, such as vancomycin-resistant enterococci or 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 [28; 30].

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 [6].

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 [6].

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 [28; 30].

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 [28; 30]. When processing contaminated sharp instruments, needles, and devices, heavy utility gloves should be used to prevent puncture injuries.

Cover Garb

Gowns are intended to protect the arms and exposed body areas and prevent contamination of clothing with blood, bodily fluids, and other potentially infectious material. 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. Laboratory coats or jackets worn over personal clothing for comfort or purposes of identity are not considered PPE [28; 30].

California regulations require that dental personnel wear reusable or disposable protective attire when their clothing or skin is likely to be soiled with blood or other potentially infectious material. Gowns must be changed daily or between patients if they become moist or visibly soiled. Protective attire must be removed when leaving laboratories or areas of patient care activities. Reusable gowns should be laundered in accordance with Cal/OSHA Bloodborne Pathogens Standards [2].

Masks, Protective Eyewear, and Face Shields

In California, dental professionals 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 or other potentially infectious material. After each patient and during patient treatment (if applicable), masks must be changed if moist or contaminated. After each patient, face shields and protective eyewear shall be cleaned and disinfected, if contaminated [2].

Masks should fit snuggly 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 other potentially infectious material. 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 snuggly 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, ear pieces, 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 [30].

ENVIRONMENTAL CONTROL MEASURES

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 [31].

ENVIRONMENTAL CLEANING

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 other potentially infectious material.

If items or surfaces likely to be contaminated are difficult to clean and disinfect, they must be protected with disposable impervious barriers. Clean and disinfect all clinical contact surfaces that are not protected by impervious barriers using a California Environmental Protection Agency (Cal/EPA)-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 Cal/EPA-registered, hospital-grade disinfectant. Chemical-resistant utility gloves should be worn when handling hazardous chemicals [31].

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. Regulated medical waste is defined as [6; 31]:

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

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Regulated medical waste accounts for only 9% to 15% of total waste in hospitals and 1% to 2% of total waste in dental offices [6]. 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 [6].

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 [31].

DENTAL UNIT WATERLINES, BIOFILM, AND WATER QUALITY

The following information is taken from the Centers for Disease Control and Prevention publication Guidelines for Infection Control in Dental Health-Care Settings [6].

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.

In 1993, the CDC recommended that dental waterlines be flushed at the beginning of the clinic day to reduce the microbial load. Dental unit water that remains untreated or unfiltered is unlikely to meet drinking water standards.

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. 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 [2].

Patient material, such as oral micro-organisms, blood, and saliva, can enter the dental water system during treatment. Devices connected to the dental water system that enter the patient's mouth should be flushed to discharge water and air for a minimum of 20 to 30 seconds after each patient to remove patient material that might have entered the turbine, air, or waterlines.

Manufactured dental units are now engineered to prevent retraction of oral fluids, but some older units are equipped with antiretraction valves that require periodic maintenance. Users should consult the owner's manual or contact the manufacturer to determine whether testing or maintenance of antiretraction valves or other devices is required. Even with antiretraction valves, flushing devices for a minimum of 20 to 30 seconds after each patient is recommended. The DBC standards require that, at the beginning of each work day, dental lines and devices must be purged with air or flushed with water for at least two minutes prior to attaching handpieces, scales, air/water syringe tips, or other devices [2].

ENGINEERING AND WORK PRACTICE CONTROLS

The following information is taken from the OSHA Bloodborne Pathogens Standard, 1910.1030.

Engineering controls such as sharps disposal containers, self-sheathing 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:

- 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

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 other potentially infectious material is present.

All procedures involving blood or other potentially infectious material 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 other potentially infectious material 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.

CLEANING, DISINFECTION, AND STERILIZATION

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***) [7].

Cleaning is defined as the removal of visible soil (organic and inorganic material) from objects and surfaces; normally, it is accomplished manually or mechanically using water with detergents or enzymatic products. Decontamination reduces the number of pathogenic micro-organisms on objects, usually with a 0.5% chlorine solution [7]. 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:

- High-level disinfection: Used to disinfect patient-care 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 months on dry surfaces [32]. 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 [32]. 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 [6]. 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 [6]. 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 [6]. 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 [6]. 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

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METHODS FOR STERILIZING AND DISINFECTING PATIENT-CARE ITEMS AND ENVIRONMENTAL SURFACES

Process	Result	Method	Examples	Patient Care Items	Environmental Surfaces
Sterilization	Destroys all micro-organisms, including bacterial spores.	Heat-automated, high temperature	Steam, dry heat, unsaturated chemical vapor	Heat-tolerant critical and semicritical	NA
		Heat-automated, low temperature	Ethylene oxide gas, plasma sterilization	Heat-sensitive critical and semicritical	
		Liquid immersion[a]	Glutaraldehyde, glutaraldehydes with phenols, hydrogen peroxide, hydrogen peroxide with peracetic acid, peracetic acid		
High-level disinfection	Destroys all micro-organisms, but not necessarily high numbers of bacterial spores.	Heat-automated	Washer disinfector	Heat-sensitive semicritical	NA
		Liquid immersion[a]	Glutaraldehyde, glutaraldehydes with phenols, hydrogen peroxide, hydrogen peroxide with peracetic acid, ortho-phthalaldehyde		
Intermediate-level disinfection	Destroys vegetative bacteria and most fungi and viruses. Inactivates *Mycobacterium bovis*[b]. Not necessarily capable of killing bacterial spores.	Liquid contact	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 disinfection	Destroys most vegetative bacteria and certain fungi and viruses. Does not inactivate *Mycobacterium bovis*.	Liquid contact	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

[a]Contact time is the single critical variable distinguishing the sterilization process from high-level disinfection with FDA-cleared liquid chemical sterilants. High-level disinfection uses shorter submersion times.
[b]Inactivation of the more resistant *Mycobacterium bovis* is used as a benchmark to measure germicidal potency.

Source: [6] *Table 2*

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 [6; 7]. If packaging is compromised, the instruments should be re-cleaned, sterilized again, and packaged in new wrap [7].

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. These items pose the greatest risk of transmitting infection and require sterilization.

Semicritical items touch intact mucous membranes and have a lower risk of transmission. 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 [6; 7].

Noncritical items pose the least risk of transmission of infection, contacting only intact skin, an effective barrier to most micro-organisms. In the majority of cases, cleaning and disinfection with an EPA-registered hospital disinfectant is adequate. When the item is visibly contaminated with blood or other potentially infectious material, an EPA-registered hospital disinfectant with a tuberculocidal claim (i.e., intermediate-level disinfectant) should be used [6; 7].

High-speed dental hand pieces, low-speed hand piece components used intraorally, and other dental unit attachments (e.g., reusable air or water syringe tips and ultrasonic scaler tips) must be heat-sterilized between patients. Single-use disposable instruments such as prophylaxis angles, cups, brushes, tips for high-speed evacuators, saliva ejectors, and air and water syringe tips must be used for one patient only and discarded. Proper functioning of the sterilization cycle must be verified at least weekly through the use of a biologic indicator (such as a spore test). Test results should be maintained for 12 months [2]. Studies have demonstrated variability among dental practices in meeting sterilization 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 [7].

Dental unit water lines must be anti-retractive. At the beginning of each workday, dental unit lines should be purged with air or flushed with water for at least two minutes prior to attaching handpieces, scalers, and other devices. The dental unit line must be flushed between each patient for a minimum of 20 seconds [2]. Single-use barriers may be used on those environmental surfaces that are difficult to clean and disinfect.

Laboratory Areas

According to California regulations, splash shields and equipment guards must be used on dental laboratory lathes. Fresh pumice and a disinfected, 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 [2].

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 [2].

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 [33].

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 [34].

PROTECTING DENTAL HEALTHCARE WORKERS

Protecting dental professionals is an integral part of every dental organization's general program for infection prevention and control. The objectives usually include [35; 36]:

- 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 other potentially infectious material, most commonly a needlestick injury. The risk of infection depends on several factors, including:

- Whether the exposure was from a hollow-bore needle or other sharp instrument
- Whether the exposure was to nonintact skin or mucous membranes

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- 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. Only 58 cases of confirmed occupational HIV transmission to healthcare personnel have been reported in the United States, with an additional 150 possible transmissions reported to the CDC [37]. There are no documented cases of a dental healthcare professional contracting HIV from an occupational exposure.

OSHA's final rule for occupational exposure to bloodborne pathogens requires dental employers 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 other potentially infectious material. 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 infection.

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.

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 [38]. 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 [38].

TUBERCULOSIS PREVENTION

California has one of the highest incidence rates of TB in the country, primarily because of its large immigrant and other high-risk populations (e.g., homeless persons) [39]. The TB infection rate is 14 times higher among foreign-born individuals than among those born in the United States. The rates among Asian and Black individuals born outside the United States were 50 and 51 times higher, respectively, than that of U.S.-born White persons [39]. 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 [40]. In addition, the California Department of Public Health requires that healthcare facilities in California perform initial and annual TB screening of employees [41].

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.

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 [42]. 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 [42].

VACCINATION

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 [43].

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 [44]. 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 [6].

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 [45].

TRAINING AND EDUCATION

Dental professionals 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 other potentially infectious material, 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.

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 dental professionals from the transmission cycle by protecting them from contact with micro-organisms. Contact 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 dental professionals 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/I3F75D9A0B95D11E0A3CAA6663E6464AA.

CAL/OSHA COVID-19 STANDARD

In light of the ongoing COVID-19 pandemic, Cal/OSHA has developed an Emergency Temporary Standard to help protect healthcare providers and patients. The Standard must be re-authorized (and revised, if necessary) every six months. It may be accessed online at https://www.dir.ca.gov/oshsb/documents/Dec162021-COVID-19-Prevention-Emergency-txtcourtesy-2nd-Readoption.pdf.

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

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COURSE TEST - #58583 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, 2025.

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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 #02-3841-00344.

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. **Of the following, which generally poses the greatest risk for airborne infection?**
   A) Splatter
   B) Droplets
   C) Aerosols
   D) Unwashed hands

4. **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%.

5. **Standard Precautions apply to contact with all of the following, EXCEPT:**
   A) Blood
   B) Aerosols
   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.

Test questions continue on next page ➞

7. Studies have shown that which of the following types of gloves have the highest failure rates?
- *A) Vinyl*
- *B) Latex*
- *C) Nitrile*
- *D) Surgeon's gloves*

8. 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) Paper towels used after handwashing*

9. Devices connected to the dental water system that enter the patient's mouth should be flushed for how long after each patient?
- *A) 10 to 15 seconds*
- *B) 20 to 30 seconds*
- *C) 2 minutes*
- *D) 20 minutes*

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*

Be sure to transfer your answers to the Answer Sheet located on the envelope insert.
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.

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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 peer-reviewed 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

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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.

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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 non-surgical 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., ≤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 ≥50 mg morphine equivalent dose (MED) per day. Decisions to titrate dose to ≥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 cross-tolerance 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 co-management 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].

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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
Significant pain problems with objective signs and symptoms confirmed by radiologic evaluation, physical examination, or diagnostic interventions Moderate psychological problems, well controlled by therapy Moderate coexisting medical disorders that are well controlled by medical therapy and are not affected by chronic opioid therapy (e.g., central sleep apnea) Develops mild tolerance but not hyperalgesia without physical dependence or addiction History of personal or family history of alcoholism or substance abuse Pain involving more than three regions of the body Defined pathology with moderate levels of pain acceptance and coping strategies Willing to participate in multimodal therapy, attempting to function in normal daily life
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*

EVIDENCE-BASED PRACTICE RECOMMENDATION

Despite limited evidence for reliability and accuracy, screening for opioid use is recommended by the American Society of Interventional Pain Physicians, as it will identify opioid abusers and reduce opioid abuse.

(https://painphysicianjournal.com/2012/july/2012;%2015;S67-S116.pdf. Last accessed January 24, 2024.)

Level of Evidence: Limited (Evidence is insufficient to assess effects on health outcomes because of limited number or power of studies, large and unexplained inconsistency between higher-quality trials, important flaws in trial design or conduct, gaps in the chain of evidence, or lack of information on important health outcomes.)

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 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 Eye-opener) 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].

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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 clinician-directed 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," patient-administered 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 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

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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.

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-to-date 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 buprenorphine-containing 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 medication-assistant 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.

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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.

(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 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.

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(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.

(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.

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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.

ACCREDITATIONS & APPROVALS: NetCE is an ADA CERP Recognized Provider.

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10/1/2021 to 9/30/2027
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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*

Test questions continue on next page →

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 f thrown in the trash.*
D) *All of the above*

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.
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.

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Getting to the Point: Acupuncture and Acupoint Therapies

Audience
This course is designed for dental professionals whose patients are using or are interested in using acupoint and/or acupressure therapies.

Course Objective
The purpose of this course is to provide dental professionals in all practice settings the knowledge necessary to increase their understanding of acupoint and acupressure therapies.

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

1. Describe the principles from traditional Chinese medicine (TCM) that guide the practice of acupuncture and some related acupoint therapies.
2. Outline the various techniques of and available evidence regarding acupuncture.
3. Discuss the approaches to and evidence of moxibustion.
4. Review available research and techniques of acupressure.
5. Identify uses and safety concerns of transcutaneous electrical acustimulation (TEAS).
6. Compare and contrast the various acupoint techniques in terms of clinical uses and safety.

Faculty
Chelsey McIntyre, PharmD, is a clinical editor for Natural Medicines, a clinical reference database focused on natural products and alternative therapies. She earned her Bachelor of Science degree in Genetics from the University of California, Davis. She then went on to complete her PharmD at Creighton University, followed by a clinical residency at the Children's Hospital of Philadelphia (CHOP). Dr. McIntyre held the position of Clinical Drug Information and Policy Development Pharmacist at CHOP until her move to Washington state in 2017. Since that time, she has worked with the Natural Medicines database at TRC Healthcare. Her professional interests include provider and patient education, as well as the application of evidence-based research to patient care, particularly in patients with chronic conditions.

Faculty Disclosure
Contributing faculty, Chelsey McIntyre, PharmD, 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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AGD Subject Code 149.

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

Dental Board of California course #04-3841-00371.

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EVIDENCE-BASED PRACTICE RECOMMENDATION

Sections marked with this symbol include evidence-based practice recommendations. The level of evidence and/or strength of recommendation, as provided by the evidence-based source, are also included so you may determine the validity or relevance of the information. These sections may be used in conjunction with the study questions and course material for better application to your daily practice.

HISTORY: A BRIEF GLIMPSE

Traditional Chinese medicine (TCM) began more than 2,000 years ago. At that time there was no scientific concept of disease or pharmacology in terms that can be related to our modern understanding of medicine. Therefore, the principles of TCM were formed based on Taoism, a philosophical and religious system of beliefs, attitudes, and practices that focuses on harmony and nature, rather than science [1].

TCM is widely practiced in Asian countries, including China, Taiwan, and Singapore. TCM has also experienced a surge in popularity in Western countries, where it is sometimes used for promoting wellness, preventing illness, and treating chronic conditions. This ancient system of medicine encompasses a range of practices including acupoint therapies, meditation, martial arts, herbal medicine, feng shui, and massage [1].

These modalities and treatment techniques share a theoretical framework defined by the yin and yang relationship. In China, yin and yang are two forces that control the universe. Virtually all medical problems are considered to be due to imbalances in one of these forces. Chinese therapeutics intends to correct imbalances of these forces to cure disease [1].

Yin is the feminine side of nature and includes tranquility, darkness, cold, wetness, and depth. Yang is masculine and represents light, heat, activity, dryness, and height. Yin and yang are not the same as good and bad. Instead, they are considered complementary forces [1].

In TCM, it is thought that disease is caused by an imbalanced or blocked flow of energy, or *qi*. Additionally, there are 12 meridians that form a continuous pathway throughout the body; *qi* circulates through the body on these meridians (***Figure 1***).

According to TCM, acupoints are specifically chosen sites of manipulation located along meridians thought to stimulate or balance specific organs, emotions, or sensory feelings. One example is the P6 acupoint, which is found on the inner forearm, two inches above the wrist joint between the two prominent tendons (***Figure 2***). This point is frequently used in TCM modalities for the prevention and relief of nausea and vomiting in multiple settings (e.g., chemotherapy-induced, postoperative, motion-related) [1].

There are more than 350 recognized acupoints on the human body, and each acupoint is associated with a list of conditions for which it may be used. Some practitioners may also choose to use certain acupoints for nontraditional indications [2; 3].

In this practice, people are diagnosed through evaluation of the tongue and the radial pulse, and by a series of signs and symptoms unique to TCM. Although these diagnostic methods have a long history of traditional use, the findings and diagnoses achieved from these techniques do not directly correlate to Western medicine. Their use as accurate indicators of medical conditions or disease has not been validated in clinical research [1].

Pulse diagnosis and tongue diagnosis are techniques used in many traditional systems of medicine. In pulse diagnosis, practitioners assess a person's pulse for rate, strength, length, and width. The wrist is most commonly used for pulse diagnosis, and the practitioner palpates at three different pressures (superficial, middle, and deep). With tongue diagnosis, practitioners assess the tongue for color, elasticity, veining, and various other qualities. In some cases, a digital device may be used to aid in tongue diagnosis [1].

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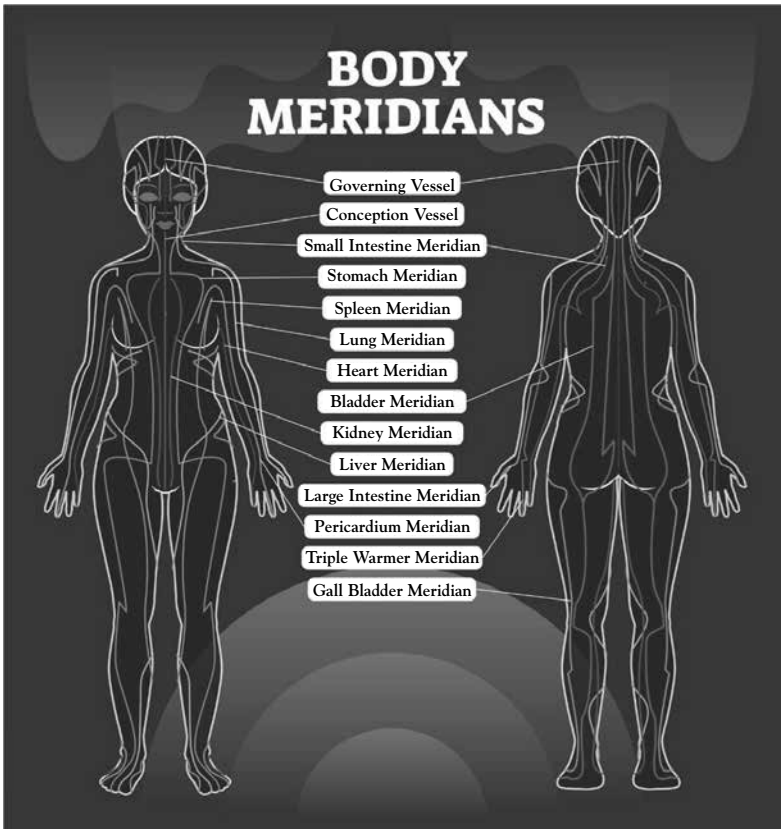
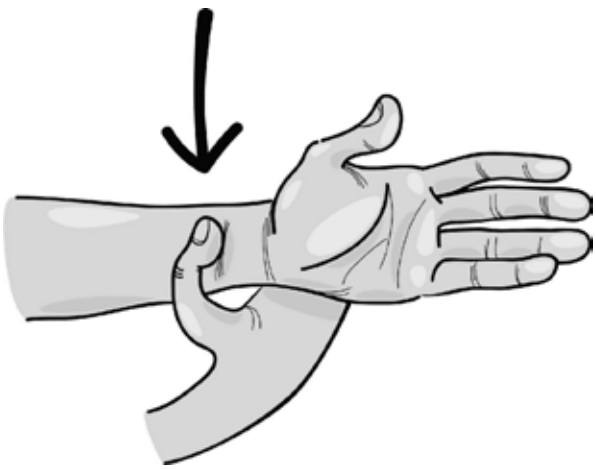
BODY MERIDIANS



Source: [1] *Figure 1*

P6 ACUPOINT



Source: [1] *Figure 2*

TCM modalities of acupuncture, moxibustion, acupressure, and transcutaneous electrical acustimulation (TEAS) are thought to stimulate energy flow, unblock energy, and rebalance energy, which results in healing.

ACUPUNCTURE

The practice of acupuncture originated in China more than 2,000 years ago as the primary treatment modality of TCM and involves the insertion of fine needles into specific points on the body along meridians. This acupoint therapy remains one of the most common components of TCM. So common, in fact, that many healthcare plans will cover this treatment. As of 2018, there were more than 35,000 actively licensed acupuncturists and more than 60 accredited acupuncture and oriental medicine schools in the United States, suggesting interest continues to grow [2].

MOXIBUSTION

Another practice of TCM, moxibustion, involves burning an herb, usually mugwort (*Artemisia vulgaris*), above the skin or on the acupoints to introduce heat into an acupoint for therapeutic effects. Moxibustion may be performed by burning a cone, stick, or loose herb a short distance away from the skin. Additionally, the burning herb may be placed on the head of an acupuncture needle to increase the temperature gradient of the needle. Theoretically, moxibustion opens the 12 meridians and removes cold, dampness, and stagnation, which improves consciousness and prevents the collapse of *qi*, particularly the yang *qi* [4].

ACUPRESSURE

Acupressure is another common treatment modality of TCM. Acupressure is similar to acupuncture; however, it involves the use of applied pressure in place of needles. Pressure is applied using hands, thumbs, fingers, or devices to specific places, or acupoints, on the body [3].

TRANSCUTANEOUS ELECTRICAL ACUSTIMULATION (TEAS)

Lastly, acustimulation, another acupoint modality, involves stimulating specific acupoints on the body along meridians. TEAS involves applying a low-intensity electrical current to specific acupoints without puncturing the skin. While this modality is based on principles of TCM, it also incorporates aspects of modern practices by utilizing recently developed medical devices [5].

Although acupuncture, acupressure, and acustimulation are similar and may be used together in a single therapy session, they are individual and specific modalities and should not be confused with one another.

Additionally, TEAS differs from another therapeutic practice, transcutaneous electrical nerve stimulation (TENS), which does not utilize acupoints. It also differs from electroacupuncture, in which an electrical current is passed through embedded acupuncture needles [5].

A NOTE ON THE EVIDENCE

Although a large number of clinical trials show some evidence for the use of acupoint therapies for certain conditions, their ability to show superiority to placebo controls has been contradictory and inconclusive, suggesting that benefits may be due, at least in part, to a placebo effect. This potential effect may also be due to the environment in which these therapies are conducted and the preconceived notions related to acupoint therapies.

The quality of available evidence is also important to note. Most research is limited by a lack of appropriate blinding or sham controls, unclear methodological quality (e.g., heterogeneity, publication bias), overall small sample sizes, and prior expectations of outcomes. Another limiting factor is geographical location. Most available research has been conducted in China; therefore, it is unclear if outcomes are generalizable to other regions or populations.

Sham acupoint procedures were developed to be used as a control intervention in clinical trials, similar to placebo pills used in pharmacological studies. Sham acupuncture treatments include inserting needles into non-acupoints, using a device that masks the presence or absence of a needle (such as the Park Sham Device), or poking acupoints with a toothpick rather than inserting a needle. Essentially, sham acupuncture is placebo acupuncture—it mimics the experience of acupuncture without implementing the methods thought to be responsible for its effects.

In order to mitigate some of the quality concerns commonly observed in acupoint research, investigators have developed a variety of sham acupoint procedures intended to be used as a control intervention in clinical trials. It is important to note that there are several different sham devices available, and the quality of sham design may vary between studies. Additionally, there are controversies surrounding the validity of this technique.

ACUPUNCTURE

Acupuncture is a modality in which needles are inserted into more than 350 key points along meridians in the body. These points are referred to as acupoints, and stimulating acupoints through a needle is thought to stimulate the body to correct energy flow and balance [2].

Prior to treatment, traditional acupuncturists conduct a comprehensive medical history and examination similar to TCM practitioners. They may examine the tongue, the face, and the quality of the pulses. Both traditional and Western acupuncturists may palpate to identify points at which pressure causes tenderness or pain. Traditional acupuncturists may also add other modalities from TCM into the acupuncture therapy session [2].

Most states in the United Stated regulate the practice of acupuncture, for which different degrees and certifications are available. The National Certification Commission for Acupuncture and Oriental Medicine (NCCAOM) works with most states to validate the competency of acupuncture practitioners prior to licensure [2].

STYLES OF ACUPUNCTURE

Traditional "Manual" Acupuncture

In this practice, needles are inserted into acupoints. An acupuncture session may involve the insertion of up to 20 very fine needles which are kept in place for different durations, usually about 10 to 30 minutes. The needles can be inserted to a depth of 5 – 40 mm and can be stimulated by winding by hand [2].

Electroacupuncture

In this practice, acupuncture needles are stimulated by a weak electrical current.

Laser Acupuncture

In this practice, lasers are used to stimulate acupoints. A typical schedule of acupuncture administration is 6 to 12 sessions over three months [2].

Thread Embedding Acupuncture

In this practice, medical threads, such as catgut or polydioxanone (PDO) sutures, are inserted into subcutaneous tissue or muscle at specific points, thus providing long-term chemical stimulation in addition to the mechanical stimulation provided by traditional acupuncture. Typically, PDO threads take approximately four weeks to reach 50% tensile strength and six months to be completely absorbed [2].

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REVIEWING THE EVIDENCE

Although there has been extensive research conducted on acupuncture, most data are inconclusive. Additionally, just as some research suggests evidence of benefit for certain indications, research for other indications suggests a lack of benefit.

Cancer-Related Conditions

Cancer-Related Fatigue

Low-quality studies suggest that acupuncture may modestly improve symptoms in patients with cancer-related fatigue. Guidelines from multiple oncology associations include acupuncture and electroacupuncture as a potential treatment option for reducing post-cancer fatigue [2].

Clinical research, mainly preliminary in design and low quality, shows that receiving acupuncture for a total of 6 to 10 sessions over two to ten weeks improves feelings of cancer-related mental and physical fatigue when compared with sham acupuncture or usual care alone [2].

The National Comprehensive Cancer Network (NCCN) guidelines for cancer-related fatigue list acupuncture as a potential nonpharmacologic treatment option for patients who have completed cancer treatment. Additionally, the American Society of Clinical Oncology (ASCO) and the Society for Integrative Oncology recommend acupuncture for patients who have finished cancer treatment and for cancer survivors [2].

Cancer-Related Pain

Low-quality studies suggest that acupuncture may modestly improve symptoms in patients with cancer-related pain. Meta-analyses and preliminary clinical research, mainly low quality, show that acupuncture has a small-to-moderate effect on malignancy-related and surgery-induced pain in patients with cancer when compared with baseline or a control group. Furthermore, when used in combination with analgesics, a meta-analysis of three studies shows that electroacupuncture decreases analgesic use by a small amount [2].

The NCCN guidelines for adult cancer pain highlight acupuncture and electroacupuncture as a potential integrative treatment for vulnerable populations, such as frail or elderly individuals who may not be able to tolerate pharmacological treatments [2].

EVIDENCE-BASED PRACTICE RECOMMENDATION

The Society for Integrative Oncology and the American Society of Clinical Oncology assert that acupuncture should be offered to patients experiencing aromatase inhibitor-related joint pain in breast cancer. (https://ascopubs.org/doi/full/10.1200/JCO.22.01357. Last accessed October 27, 2022.)

Strength of Recommendation/Level of Evidence: Intermediate/Moderate

Chemotherapy-Induced Nausea and Vomiting (CINV)

When used with antiemetics, some research shows that electroacupuncture, with or without manual acupuncture, modestly reduces nausea and vomiting associated with chemotherapy. Manual acupuncture alone also seems to be comparable to some antiemetics.

A clinical study in patients with advanced cancer shows that a combination of manual acupuncture and electroacupuncture with ondansetron during five days of chemotherapy reduces the severity of nausea and vomiting over a total period of 21 days when compared with sham acupuncture. However, it does not increase the number of patients that experience no nausea or vomiting [2].

Another clinical study shows that manual acupuncture is comparable to giving ondansetron 8 mg intravenously for preventing acute nausea and vomiting in the first 24 hours after chemotherapy with paclitaxel and carboplatin [2].

Clinical practice guidelines from the Society for Integrative Oncology (SIO) recommend that acupuncture or acupressure be considered as an adjunct to antiemetic medications for chemotherapy-induced nausea and vomiting (CINV) management [2].

Pain-Related Conditions

Some experts theorize that acupuncture may result in the release of the endogenous opioids known as enkephalins and endorphins, which naturally reduce pain. However, because some research shows acupuncture to be no more effective than sham acupuncture, it is unclear if the effectiveness is due to physiologic stimulation [2].

Back Pain

Clinical research shows that acupuncture reduces pain when compared with either sham acupuncture or no treatment in patients with either chronic or acute low back pain. For chronic low back pain, most clinical research suggests that after three months, acupuncture is no more effective than sham acupuncture, although it does seem to be beneficial when compared with no treatment. Finally, there is some evidence that the analgesic effects of acupuncture may be delayed, with greatest benefit seen months after treatment discontinuation [2].

The analgesic effect of acupuncture seems to be influenced by several factors [2]:

- Number of acupuncture sessions
- A greater number of patients achieve relief of low back pain after 10 treatments compared to only five treatments.
- Depth of needle insertion
- Deep acupuncture appears to be more effective than superficial acupuncture.
- Different acupuncture styles

Motion style acupuncture is a method combining acupuncture with Doin, a manual therapy used in Korean rehabilitation medicine. Research suggests that this treatment improves acute back pain to a greater degree than either traditional acupuncture or electroacupuncture [2].

Despite the uncertain and short-term benefits, guidelines published by the American College of Physicians recommend the use of nonpharmacologic therapy, such as acupuncture, prior to using pharmacologic therapy in patients with chronic low back pain [2].

Neurogenic Conditions

Fibromyalgia

Most preliminary clinical research and meta-analyses of clinical research show that acupuncture improves pain and stiffness and quality of life when compared with no treatment, standard therapy, or sham acupuncture, although older research shows that acupuncture is no different than sham acupuncture for reducing pain [2].

This discrepancy in results might be due to the type of sham acupuncture used and the integrity of blinding procedures. Acupuncture is more effective at relieving pain when compared with the sham acupuncture method that involves placing a needle in the acupoint with a bandage, without piercing the skin. This benefit is not observed when skin is pierced in both sham and real acupuncture groups [2].

HIV/AIDS-Related Peripheral Neuropathy

Research shows that acupuncture does not improve HIV/AIDS-related peripheral neuropathy. For instance, clinical research shows that acupuncture may not be effective for reducing peripheral neuropathy associated with HIV when compared with sham acupuncture at control sites [2].

Osteoarthritis

Meta-analyses of preliminary clinical research show that electrical, laser, and manual acupuncture modestly reduce pain and modestly improve function in patients with hip or knee osteoarthritis when compared with no treatment or sham treatment, or when used as an adjunct to standard treatment. Most individual preliminary clinical trials show sustained reductions in pain for up to 12 weeks [2].

However, available research is generally of low quality and is challenged by an array of conflicting evidence. A meta-analysis of two higher quality studies and some preliminary clinical research did not find a difference between acupuncture and sham acupuncture for improving pain in hip or knee osteoarthritis. Acupuncture is conditionally recommended by The American College of Rheumatology (ACR) for any form of osteoarthritis [2].

It is important to mention that there are a number of pain-related conditions with insufficient evidence to support the use of acupuncture. These conditions include myofascial pain syndrome, shoulder pain, sciatica, pregnancy-related pain, and others. More evidence is needed to rate acupuncture for these uses [2].

Gastrointestinal-Related Conditions

Constipation

A meta-analysis of preliminary clinical research, as well as individual clinical trials, in patients with functional constipation show that receiving manual acupuncture or electroacupuncture for 2 to 10 weeks modestly increases bowel movements and improves stool formation and symptoms when compared with sham acupuncture. However, acupuncture was no more effective than various conventional medications [2].

Dyspepsia

Meta-analyses of preliminary clinical research show that manual and electroacupuncture are more effective than sham acupuncture for improving symptoms of dyspepsia and quality of life. Some individual clinical studies have shown that acupuncture combined with Western medicine (including prokinetic agents, acid suppressants, and antidepressants) improves symptoms more than Western medicine alone [2].

There are also a variety of gastrointestinal-related conditions for which there is very limited evidence to support the use of acupuncture. These conditions include gastroparesis, ulcerative colitis, irritable bowel syndrome, and postoperative ileus [2].

Postoperative Nausea and Vomiting (PONV)

Meta-analyses suggest that acupoint stimulation with acupuncture, acupressure, and electrical stimulation can reduce PONV by up to 50% and may be as effective as conventional antiemetics. Furthermore, other analyses show that acupuncture of the P6 acupoint is effective in reducing incidence of nausea, vomiting, and need for rescue antiemetics postoperatively when compared with no treatment. The effects of acupuncture on acute and delayed vomiting and nausea appear to vary [2].

A meta-analysis of six small clinical trials suggest that acupuncture reduces postoperative vomiting in children when compared with control acupuncture surgery. Additionally, one small study shows that receiving acupuncture on the P6 acupuncture point is as effective as sham acupuncture and dexamethasone [2].

Thus far, the evidence on the use of acupuncture for PONV is promising, and patients may consider it as an adjunctive treatment option. However, there is currently very limited evidence on use for pregnancy-induced and radiation-induced nausea and vomiting.

Other Conditions

Asthma

Most research shows that acupuncture does not improve symptoms of asthma. While some preliminary clinical research suggests that acupuncture or laser acupuncture and probiotics may marginally improve asthma symptoms and pulmonary

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function, most clinical research supports that acupuncture has no effect on asthma or asthma parameters such as forced expiratory volume in one second and forced vital capacity [2].

Depression

When used with conventional antidepressants, most research shows that acupuncture modestly reduces symptoms of depression. However, it is unclear if acupuncture alone is more effective than conventional antidepressants.

Clinical evidence shows that using manual or electroacupuncture as an adjunct to antidepressants such as selective serotonin reuptake inhibitors modestly reduces depression severity when compared with antidepressants alone [2].

There is also some evidence that acupuncture may be more likely to alleviate symptoms of perimenopausal depression, post-stroke depression, or cancer-related depression when compared with antidepressants or hormone replacement therapy. However, because most of the available research has been conducted in China, it is unclear if these findings are generalizable to other geographic locations [2].

Insomnia

Clinical research shows that manual acupuncture modestly improves sleep quality and might reduce the need for medication when used as an adjunct to sleep hygiene instruction or conventional treatment, sham acupuncture, or a waitlist control group (i.e., a group that serves as an untreated comparator, but eventually goes on to receive treatment at a later date) [2].

Electroacupuncture does not seem to improve sleep efficiency, sleep onset, or insomnia severity when compared with conventional treatment or sham electroacupuncture [2].

Smoking Cessation

Clinical research shows that although acupuncture might have short-term benefits, it does not improve rates of long-term smoking cessation when compared with sham acupuncture [2].

SAFETY

Acupuncture, when used appropriately and performed with sterile needles, is generally well-tolerated and has been safely used in numerous clinical trials for up to 24 months. Some clinical research shows that acupuncture has been used in children without reports of significant adverse effects [2].

Most commonly, acupuncture is associated with dermatologic adverse effects, such as bruising, swelling, and pain. Acupuncture in the eyes can cause trauma to the eyes such as perforation and traumatic cataract. There have been case reports of epidural and subdural hematomas from improper acupuncture, resulting in paresthesia, hemiparesis, quadriparesis, and sensory deficit. There have been case reports of pneumocranium, pneumothorax, hemothorax, acute respiratory and circulatory failure, and death due to inappropriate acupuncture practices. Acupuncture needles that are not removed after treatment might embolize and cause damage to internal organs [2].

MOXIBUSTION

Moxibustion is another acupoint modality that is commonly utilized in TCM. Moxibustion involves burning moxa, a dried herbal preparation made of the aged, powdered mugwort herb, at prescribed acupoints on the body. These points are determined based on the patient's symptoms and diagnosis [4].

Moxa is considered to have a warming yang nature that is thought to prevent patients from experiencing a collapse of yang *qi* energy. There are various techniques used in moxibustion.

MOXIBUSTION TECHNIQUES

Indirect Moxibustion (Interposed Moxibustion)

The ignited moxa cone does not contact the skin directly. Instead, it is separated from the skin by ingredients such as ginseng, salt, garlic, ginger, or aconite cake. In clinical research, indirect moxibustion has improved levels of cellular mediators involved in pain [4].

Direct Moxibustion

The ignited moxa cone is used directly to warm the skin surface at the acupuncture point. Direct moxibustion can be scarring, which involves burning moxa directly on the skin, or "warming," which involves burning moxa above the skin [4].

Thunder-Fire Moxibustion

Moxa-cigars held by a moxibustion box are ignited over the treatment site. The fire head is held about an inch away from the skin and burned for about 30 minutes. To maintain the heat and reduce smoke in the air, the moxibustion treatment is covered with a thick towel [4].

Warm Needle Moxibustion/Acupuncture

This is an integration of acupuncture and moxibustion. A one-inch moxa stick is put on the handle of an acupuncture needle that has been inserted in the body, and the moxa stick is ignited. This method is purported to warm the meridians and promote the flow of *qi* and blood [4].

Electric Moxibustion

Electric moxibustion has been developed because there are safety concerns with traditional moxibustion, such as excessive heat or potentially toxic chemical components. Electric moxibustion has adjustable and constant heat stimulation that is applied either directly or indirectly to skin and has been shown to increase blood flow in healthy participants [4].

Jade Moxibustion

Involves wearing heated knee pads containing a jade stone for 20 minutes three times weekly for four weeks [4].

REVIEWING THE EVIDENCE

Pain-Related Conditions

Back Pain

Most low-quality clinical research suggests that moxibustion, when used alone or in conjunction with other treatments, may modestly reduce back pain.

A meta-analysis of small, low quality clinical studies in people with chronic low back pain shows that moxibustion reduces pain when compared with acupuncture, massage, or taking ibuprofen 300 mg daily or celecoxib 200 mg daily. Furthermore, adding moxibustion to other treatments such as massage, acupuncture, core stability training, or the medicines celecoxib or meloxicam, further reduces back pain when compared with the active treatment alone [4].

Osteoarthritis

Meta-analyses of small clinical studies in patients with knee osteoarthritis show that moxibustion modestly reduces pain and improves function when compared with sham moxibustion or usual care. A subgroup analysis suggests that moxibustion improves osteoarthritis pain when compared with taking diclofenac, but not when compared with taking celecoxib. However, this finding is limited due to the high heterogeneity of the available research, as well as a high risk for publication bias [4].

Research has also evaluated other types of moxibustion for the treatment of knee osteoarthritis. One clinical trial shows that receiving jade moxibustion improves pain to a greater degree when compared with receiving traditional moxibustion. Another clinical study shows that receiving moxibustion in 12 sessions over six weeks via a specific electrical device (Cettum) improves pain similarly to traditional indirect moxibustion and to a greater extent than usual care [4].

Gastrointestinal-Related Conditions

In human research, moxibustion has been shown to reduce levels of certain inflammatory markers. Other preliminary data suggest that moxibustion may help to protect the gastric mucosa. Due to its perceived anti-inflammatory effects, there is interest in using this therapy for gastrointestinal-related conditions.

Moxibustion has been investigated in patients with diarrhea-predominant irritable bowel syndrome (IBS-D), constipation-predominant IBS (IBS-C), and inflammatory bowel diseases. Currently, there is not enough scientific evidence to support the use of moxibustion for Crohn disease and ulcerative colitis. Additionally, there is very limited evidence on use for constipation and gastritis.

IBS-D

Moxibustion with or without acupuncture appears to be more effective than sham moxibustion, sham acupuncture, or various pharmaceutical agents for improving abdominal pain, discomfort, gas, bloating, and stool consistency. There were also overall improvements in stool form and symptom severity [4].

Clinical research in patients with IBS-D shows that moxibustion three times weekly for six weeks produces adequate relief in about 77% to 82% of patients, compared with 37% to 42% of those given sham or placebo moxibustion. These data also suggest that beneficial effects lasted for up to an additional 18 weeks after treatment completion in up to 76% of patients [4].

Thus far, the evidence on the use of moxibustion for IBS-D is promising, and patients may consider it as an adjunctive treatment option.

IBS-C

The available research in patients with IBS-C is limited to a small clinical study showing no benefit with the use of warming moxibustion six times weekly for four weeks when compared with baseline or electroacupuncture [4]. As such, available research suggests that moxibustion may not be effective in patients with IBS-C.

Crohn Disease

Moxibustion administration has only been evaluated in combination with acupuncture; its effect when used alone is unclear. Clinical research in patients with Crohn disease shows that combining herb-partitioned moxibustion with acupuncture three times weekly for 12 weeks induces remission in 74% of patients, compared with only 36% of patients given sham moxibustion and superficial acupuncture [4].

Ulcerative Colitis

A meta-analysis of low-quality clinical research shows that moxibustion with or without acupuncture improves response rate by 24% when compared to control treatment. However, these results are limited by the small number, size, and low quality of the included studies [4].

Other Conditions

Cancer

Moxibustion administration does not seem to be beneficial for cancer treatment. A meta-analysis of five clinical studies shows that moxibustion does not improve treatment response in patients with various cancer types when compared with standard care. There is limited evidence on use of moxibustion for CINV and cancer-related fatigue [4].

Dysmenorrhea

Low-to-moderate quality clinical research in patients with dysmenorrhea shows that moxibustion with or without acupuncture reduces pain, usually when compared with no treatment or usual care. Additional clinical research shows that moxibustion reduces pain intensity similarly to ibuprofen 300 mg twice daily for three days, starting the day before menstruation and repeated for three cycles. Furthermore, at three months after treatment discontinuation, pain intensity remains 13% lower in the patients that received moxibustion [4].

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Insomnia

It is unclear if moxibustion is beneficial for insomnia. Although some research has been conducted on the use moxibustion for insomnia, there is not enough reliable evidence to confirm a benefit for these indications [4].

SAFETY

Moxibustion is likely safe when administered appropriately by a qualified practitioner and has been used in clinical research without reports of serious adverse events.

Most commonly, moxibustion is associated with blisters, burns, dizziness, fainting, fatigue, gastrointestinal upset, headache, hypersomnia, itching, pain, rash, redness, and respiratory discomfort. Serious cases of adverse effects caused by moxibustion are generally related to inappropriate administration, such as not removing the moxa from the skin at the appropriate time or accidentally dropping ash onto the skin [4].

ACUPRESSURE

Acupressure involves applying pressure using hands, thumbs, fingers, or devices to acupoints. Acupressure can be self-administered or applied by a trained practitioner. Passive acupressure devices are also available that apply pressure continuously at a specific location. For example, wrist bands can apply pressure to the P6 acupoint, which is utilized for the treatment or prevention of nausea and vomiting. Most acupressure points are located near nervous tissue or structures. Duration and frequency of acupressure treatment is individualized to the patient and the condition being treated [3].

REVIEWING THE EVIDENCE

Although there is a large body of research evaluating acupressure for various purposes, most evidence is low quality and inconclusive.

Pain-Related Conditions

Most acupressure points are located near nervous tissue or structures. Researchers suggest that applying pressure at these points may block transmission of pain signals through certain neural gates [3].

Back Pain

Acupressure, administered either alone or as an adjuvant treatment, seems to reduce chronic low back pain. Clinical research in patients with lower back pain shows that acupressure, administered alone or with acupuncture, or acupressure massage with aromatic essential oil in combination with usual care, reduces pain and disability and improves walking ability when compared with physical therapy, usual care, or acupuncture alone [3].

Preliminary clinical research shows that using an acupressure backrest during sedentary work for one month reduces pain and disability by at least 30% when compared with no intervention. Other preliminary clinical research shows that using auricular acupressure for three minutes three times daily for five days each week for four weeks reduces pain by about 40% when compared with performing the same procedure on incorrect acupoints [3].

Auricular acupressure involves the taping of magnetic beads or plant seeds to the ear. In TCM, it is thought to relieve tension and improve circulation [3].

Osteoarthritis

Most research shows that manual acupressure does not improve pain or function in patients with knee osteoarthritis. Additionally, it is unclear if auricular acupressure is beneficial for osteoarthritis.

Clinical research in patients with osteoarthritis of the knee shows that self-administered acupressure alone for up to 16 weeks does not reduce knee pain intensity when compared with receiving sham acupressure, education on knee health, exercise, or no intervention [3].

A small clinical study shows that auricular acupressure four times daily for four weeks is associated with reductions in pain, stiffness, and function on days 3 and 7, but not days 14, 21, or 28, when compared with sham acupressure [3].

It is important to mention that there are a number of other pain-related conditions with insufficient evidence to support the use of acupressure. These conditions include neck and shoulder pain, postoperative pain, and neuropathic pain [3].

Cancer-Related Conditions

Cancer-Related Fatigue

Acupressure seems to improve fatigue in patients with cancer. A meta-analysis of mostly small clinical studies in patients with cancer-related fatigue shows that various forms of acupressure, either self-administered or administered by a professional, reduces fatigue by a large amount when compared with usual care, sham acupressure, or acupuncture [3].

Thus far, the evidence on the use of acupressure for cancer-related fatigue is promising, and patients may consider acupressure as an adjunctive treatment option. However, there is very limited evidence on use for breast cancer, cancer-related pain, and chemotherapy-related fatigue [3].

EVIDENCE-BASED PRACTICE RECOMMENDATION

According to the Society for Integrative Oncology and the American Society of Clinical Oncology, reflexology or acupressure may be offered to patients experiencing pain during systemic therapy for cancer treatment.

(https://ascopubs.org/doi/full/10.1200/JCO.22.01357. Last accessed October 27, 2022.)

Strength of Recommendation/Level of Evidence: Intermediate/Moderate

Chemotherapy-Induced Nausea and Vomiting (CINV)

It is unclear if acupressure is beneficial in patients with CINV. Data are conflicting.

Some research, but not all, suggests that acupressure modestly reduces chemotherapy-induced acute and delayed nausea, but not acute or delayed vomiting. Research using acupressure wristbands for CINV is also mixed; some research shows that using a specific passive acupressure wristband product (Sea-Band) reduces nausea and vomiting when compared with usual care alone, but it does not appear to be more effective than sham acupressure [3].

The reasons for these mixed findings may be related to the type of cancer, the chemotherapy regimen used, or the severity of CINV. Larger, higher quality studies are needed to determine which patients, if any, may benefit the most from treatment.

Other Conditions

Dysmenorrhea

Acupressure seems to reduce pain in adults and adolescents with primary dysmenorrhea. Preliminary clinical research in adolescents with primary dysmenorrhea shows that beginning acupressure shortly after menstruation onset reduces the severity of dysmenorrhea for up to two hours after treatment and improves pain and anxiety. Self-administration of acupressure also seems to help reduce pain in dysmenorrhea [3].

Insomnia

Some small clinical studies suggest that manual and auricular acupressure improves sleep in patients with insomnia or sleep disturbances due to various underlying conditions.

Improvement in sleep was reported in small clinical studies, particularly in patients with hypertension or cancer, individuals who receive routine hemodialysis, and patients who are hospitalized or residing in long term care. Larger, higher quality studies are needed to determine which patients are more likely to benefit from treatment [3].

Motion Sickness

It is unclear if acupressure is beneficial in patients with motion sickness. Some clinical research shows that acupressure does not reduce motion sickness in elderly patients, females, or male college students. However, other research in experimentally induced motion sickness shows that acupressure at the P6 point reduces nausea when compared with baseline but has mixed findings when compared with sham acupressure [3].

There are a number of other conditions with insufficient evidence to support the use of acupressure. Some examples include, but are not limited to, PONV, smoking cessation, and irritable bowel syndrome (IBS) [3].

SAFETY

Acupressure in adults and children appears well tolerated when applied appropriately and has been safely used in numerous clinical trials. Most commonly, acupressure is associated with bruising, dizziness, headache, inflammation, and skin irritation [3].

TRANSCUTANEOUS ELECTRICAL ACUSTIMULATION (TEAS)

TEAS involves applying low-intensity electrical current to specific acupoints without puncturing the skin. TEAS can be given using electric units with a transcutaneous electrical nerve stimulation (TENS) unit or a Han's acupoint nerve stimulator (HANS) dual-channel unit. The electrodes are attached to specific acupoints on the body to which a small electric current is administered. Common currents include 2–100 Hz in constant or pulsed mode [5].

A specific acustimulation device (ReliefBand) has been used with apparent safety in clinical research with no reports of adverse effects. This device is commercially available and cleared by the U.S. Food and Drug Administration (FDA) for certain types of nausea, retching, and vomiting [5]. Note that FDA clearance and FDA approval are not interchangeable terms. "FDA cleared" typically refers to medical devices, which differs from the rigorous testing required for "FDA approval," which is generally applied to pharmaceutical drugs.

Common acupoints used for acustimulation are the P6 Neiguan point on the wrist, which is used for nausea and vomiting, and the ST36 Zusanli point below the knee, which is used for gastrointestinal discomfort, stress, and fatigue. These and other acupoints have been stimulated alone or in combination in clinical research [5].

Sessions normally last for 30 to 60 minutes and are conducted two to seven days per week for 2 to 12 weeks, or as multiple sessions daily. Occasionally, acustimulation is used in surgical patients, and may be administered prior to, during, and/or daily for up to three days after surgery [5].

REVIEWING THE EVIDENCE

Chemotherapy-Induced Nausea and Vomiting (CINV)

Acustimulation does not seem to be beneficial for CINV. Several clinical trials including patients with breast and liver cancer receiving highly emetogenic chemotherapy such as cisplatin or doxorubicin shows that acustimulation, administered by wearing a specific acustimulation device (ReliefBand) or given via electrodes does not improve CINV when compared with not wearing the device, wearing the device incorrectly, wearing acupressure bands, or sham acustimulation [5].

Additionally, there is insufficient evidence to support the use of TEAS in patients with fatigue or constipation related to chemotherapy [5].

Postoperative Complications

Postoperative Cognitive Dysfunction

Acustimulation seems to be beneficial for preventing postoperative cognitive dysfunction. A meta-analysis of generally good

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quality clinical research shows that acustimulation, alone or in combination with other therapies, reduces the incidence of postoperative cognitive dysfunction in the first week after surgery by approximately 60% when compared with control groups given sham intervention, no intervention, or other treatments. Although there were also improvements seven days after surgery, these benefits were not observed on day five [5].

Additional preliminary clinical research in elderly patients undergoing laparoscopic cancer surgery shows that acustimulation from 30 minutes before anesthesia induction to the end of surgery modestly reduces the cumulative duration of cognitive decline on postoperative days two and three when compared with no acustimulation. However, there was no effect on the incidence of cognitive decline [5].

Postoperative Ileus

Acustimulation seems to be beneficial for preventing postoperative ileus. A meta-analysis and individual clinical research show that acustimulation modestly improves the time to first flatus or first defecation, the number of spontaneous bowel movements, symptoms such as appetite, belching, and abdominal distension, and the overall incidence of postoperative ileus or gastrointestinal dysfunction when compared with sham acustimulation or routine treatment alone [5].

Acustimulation has been given during or after the operation until postoperative day three for cesarean section, gastric surgery, and colorectal surgery [5].

Postoperative Nausea and Vomiting (PONV)

Acustimulation seems to be effective for preventing PONV; however, it is unclear whether acustimulation is effective for treating PONV or whether it is more effective than antiemetics alone for preventing PONV.

Most clinical research from meta-analyses and individual trials shows that acustimulation reduces the risk of PONV by up to 46% for at least 2 hours, and in some cases for up to 48 hours, after surgery. In addition, a meta-analysis of four studies shows that acustimulation at the P6 acupoint reduces the need for antiemetic rescue [5].

Many studies used acustimulation of the P6 point starting before anesthesia and continuing for up to 72 hours after surgery using a specific acustimulation band (ReliefBand) or HANS electrodes. This device has shown benefit for PONV after gynecological laparoscopy, laparoscopic cholecystectomy, and plastic surgery and appears to be most effective for preventing PONV when used perioperatively and postoperatively as opposed to only preoperative use [5].

Other clinical research in children 4 to 12 years of age undergoing tonsillectomy shows that acustimulation of 20 Hz for five minutes before the induction of anesthesia and five minutes after surgery is as effective as ondansetron 0.15 mg/kg and more effective than no treatment for reducing the incidence of postoperative retching and vomiting on the day of surgery and the day after discharge, but not immediately after surgery or on postoperative day one [5].

Postoperative Pain

Acustimulation seems to be effective for reducing postoperative pain for certain surgeries. Clinical research shows that acustimulation modestly reduces postoperative pain and/or the need for postoperative analgesics when compared with sham acustimulation or routine treatment alone. Types of surgery have included caesarian section, inguinal hernia repair, thoracoscopic surgery, spinal cord surgery, total hip arthroplasty, radical mastectomy, ureteroscopic lithotripsy, gastrectomy, and others. In some cases, acustimulation is initiated prior to, and possibly during, surgery, as well as intermittently after surgery. In others it has only been used postoperatively for up to three days [5].

However, not all research agrees. When used in combination with the antiemetics dexamethasone and tropisetron in female patients undergoing laparoscopic sleeve gastrectomy, acustimulation does not reduce postoperative pain over 48 hours or the need for opioid medication [5].

There is very limited evidence on use for acustimulation in patients with acute or chronic pain. Additionally, it is unclear if acustimulation is beneficial in patients with neck pain or if it improves pain during labor [5].

SAFETY

TEAS is generally well tolerated when used appropriately, short-term. Acustimulation via other methods has also been used with apparent safety in clinical research for up to 12 weeks [5].

CONSIDERATIONS AND COMPARISONS

REPRODUCTIVE EFFECTS

Fertility

Until more is known about the safety of acupuncture, moxibustion, acupressure, or TEAS during in vitro fertilization (IVF), recommend against the use of these modalities [2; 3; 4; 5].

Pregnancy and Lactation

Acupuncture

Some clinical research shows that acupuncture has been used during pregnancy and labor without reports of significant adverse effects when used appropriately at most acupoints and performed with sterile needles. There is insufficient reliable information available about the use of electroacupuncture or laser acupuncture during pregnancy; avoid using. There is some concern that acupuncture at the SP6 acupoint on the inner ankle can increase the risk of early contractions and miscarriage [2].

Acupressure

This therapy has been safely used during pregnancy in clinical trials without significant adverse effects [3].

Transcutaneous Electrical Acustimulation (TEAS)

There is currently insufficient reliable information available; however, there is no reason to expect safety concerns when used appropriately [5].

Moxibustion

While this therapy has been used with apparent safety during pregnancy in most clinical studies, some clinical evidence suggests that moxibustion may be associated with premature birth, premature membrane rupture, increased rate of contractions, abdominal pain due to contractions, placental bleeding, reduced or increased fetal movement, and reduced fetal heart rate [4].

There is insufficient reliable information available about the use of moxibustion during lactation; however, it is unlikely that maternal use of moxibustion would pose a significant safety risk to breastfeeding infants [4].

INTERACTIONS WITH CONDITIONS

Asthma

Theoretically, moxibustion may exacerbate asthma symptoms. Clinical reports of respiratory discomfort and asthma exacerbation due to the smoke associated with moxibustion suggest that moxibustion may not be safe for use in patients with asthma. However, some research has suggested a possible beneficial effect of moxibustion in patients with asthma. Until more is known, use with caution [4].

Other Considerations

Although there are no absolute contraindications, it is imperative that acupoint practitioners are fully informed on a patient's health history to ensure safety during treatment. Examples of conditions to watch out for include altered mental status, hemophilia, and needle phobia. Patients should inform their acupoint practitioners regarding any implanted devices, such as pacemakers. Additionally, dermatologic conditions such as cellulitis, burns, or ulcerations should be evaluated prior to treatment [2; 3; 4; 5].

COMPARING THE EVIDENCE

Because these acupoint modalities share similar characteristics and may be used together in a therapy session, patients may have questions regarding specific therapies and their efficacy for specific indications.

Back Pain

Although multiple acupoint therapies have been evaluated for back pain, the study structures and comparators used in this research has varied widely.

Acupuncture

Most research shows that acupuncture seems to reduce back pain more than no treatment. However, it is unclear if acupuncture is more effective than sham acupuncture. Receiving more than five treatments with deep acupuncture seems to offer the most long-term benefit [2].

Moxibustion

Low-quality clinical research shows that moxibustion reduces back pain when compared with acupuncture, massage, or taking ibuprofen or celecoxib. Furthermore, adding moxibustion to other treatments such as massage, acupuncture, core stability training, or the medicines celecoxib or meloxicam, further reduces back pain when compared with the active treatment alone [4].

Acupressure

Clinical research in patients with lower back pain shows that acupressure, used alone or with acupuncture, or acupressure massage with aromatic essential oil in combination with usual care reduces pain and disability and improves walking ability when compared with physical therapy, usual care, or acupuncture alone [3].

Acupuncture, acupressure, and moxibustion have a growing body of evidence suggesting at least modest benefit for back pain. TEAS has not yet been adequately evaluated for this purpose [2; 3; 4; 5].

Insomnia

Although multiple acupoint therapies have been evaluated for insomnia, research has varied widely. Take note of the differences in study structures and patient populations.

Acupuncture and acupressure have a growing body of evidence suggesting at least modest benefit for insomnia. There is currently insufficient evidence to rate the effectiveness of moxibustion for this condition; larger, higher quality studies are needed. TEAS has not yet been adequately evaluated for this purpose.

Acupuncture

Clinical research shows that manual acupuncture modestly improves sleep quality and might reduce the need for medication when used as an adjunct to sleep hygiene instruction or conventional treatment, sham acupuncture, or waitlist control [2].

Acupressure

Most small clinical studies suggest that manual and auricular acupressure modestly improves sleep in patients with insomnia or sleep disturbances due to various underlying conditions including patients with hypertension or cancer, those who are hospitalized or residing in long term care, or those receiving hemodialysis [3].

Moxibustion

Although some research has been conducted on the use of moxibustion for insomnia, there is not enough reliable evidence to confirm a benefit for these indications [4].

Osteoarthritis

Although multiple acupoint therapies have been evaluated for osteoarthritis, the affected joints, as well as the comparators used in clinical studies, have varied widely.

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Acupuncture has a growing body of evidence suggesting at least modest benefit for patients with knee or hip osteoarthritis. Some research suggests moxibustion is beneficial for knee osteoarthritis, but it is unclear how it compares to the use of other therapies.

Most research shows that manual acupressure does not improve pain or function in patients with knee osteoarthritis. TEAS has not yet been adequately evaluated for this purpose.

Acupuncture

Meta-analyses of preliminary clinical research show that electrical, laser, and manual acupuncture modestly reduce pain and modestly improves function in patients with hip or knee osteoarthritis when compared with no treatment and sham treatment and when used as an adjunct to standard treatment. Furthermore, most individual preliminary clinical trials show that acupuncture is more effective than control treatments, such as advice or sham acupuncture, for reducing pain in knee and hip osteoarthritis for up to 12 weeks. Acupuncture is conditionally recommended by the ACR for any form of osteoarthritis [2].

Moxibustion

Meta-analyses of small clinical studies in patients with knee osteoarthritis show that moxibustion modestly reduces pain and improves function when compared with sham moxibustion or usual care. A subgroup analysis suggests that moxibustion improves osteoarthritis pain when compared with taking diclofenac, but not when compared with taking celecoxib; however, these findings are uncertain [4].

Acupressure

Most research in patients with osteoarthritis of the knee shows that self-administered acupressure alone for up to 16 weeks does not reduce knee pain intensity when compared with receiving sham acupressure, education on knee health, exercise, or no intervention [3].

Postoperative Nausea and Vomiting (PONV)

Although multiple acupoint therapies have been evaluated for PONV, the study structures and comparators used in this research has varied widely. Acupuncture and TEAS have a growing body of evidence suggesting at least modest benefit at preventing PONV. Currently, there is insufficient evidence to support the use of acupressure in this setting. Moxibustion has not yet been adequately evaluated for this purpose.

Acupuncture

Meta-analyses suggest that acupoint stimulation with acupuncture, acupressure, and electrical stimulation can reduce postoperative nausea and vomiting by up to 50% and may be as effective as conventional antiemetics. Furthermore, other analyses show that acupuncture of the P6 acupoint is effective in reducing incidence of nausea, vomiting, and need for rescue antiemetics postoperatively when compared with no treatment [2].

TEAS

Acustimulation seems to be effective for preventing PONV; however, it is unclear whether acustimulation is effective for treating PONV or whether it is more effective than antiemetics alone for preventing PONV [5].

CONSIDERATIONS FOR NON-ENGLISH-PROFICIENT PATIENTS

For patients who are not proficient in English, it is important that information regarding the benefits and risks associated with acupoint therapies be provided in their 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. Interpreters can be a valuable resource to help bridge the communication and cultural gap between patients and practitioners. Interpreters are more than passive agents who translate and transmit information back and forth from party to party. When they are enlisted and treated as part of the interdisciplinary clinical team, they serve as cultural brokers who ultimately enhance the clinical encounter.

CONCLUSION

The popular practice of acupuncture has existed for centuries, with records dating back thousands of years. Acupuncture and related acupoint modalities are widely used on a global scale and continue to grow in popularity as patients seek alternative treatments for various acute and chronic medical conditions. Similarities between these modalities may make it difficult to decipher the effectiveness of individual treatments for certain conditions.

Additionally, quality of evidence remains a concern. The evidence supporting the use of acupoint therapies remains limited to low-quality research. Larger, higher quality studies are needed to determine which patients, if any, are most likely to benefit, and how these treatments compare to the use of other therapies.

Further, no treatment is without safety concerns, including adverse effects, condition interactions, and special considerations. It is imperative that clinicians provide accurate information regarding various acupoint therapies and evidence-based recommendations to help patients make informed decisions about their health.

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

COURSE TEST - #58030 GETTING TO THE POINT: ACUPUNCTURE AND ACUPOINT THERAPIES

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.

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1. Which of the following statements regarding the concepts of yin and yang is most accurate?
- *A) Yin and yang are not the same as good and bad.*
- *B) Yin and yang are considered complementary forces.*
- *C) Yang is masculine and represents tranquility, darkness, cold, wetness, and depth.*
- *D) Yin is the feminine side of nature and represents light, heat, activity, dryness, and height.*

2. In traditional Chinese medicine (TCM) practices, what is the term used to describe energy, which if imbalanced or blocked is thought to cause disease?
- *A) Meridian*
- *B) Qi*
- *C) Yin*
- *D) Yang*

3. Theoretically, moxibustion
- *A) opens 2 meridians.*
- *B) improves consciousness.*
- *C) removes heat, dryness, and activity.*
- *D) prevents the accumulation of qi, particularly the yen qi.*

4. What organization works with most states to validate the competency of acupuncture practitioners prior to licensure?
- *A) Association for Traditional Chinese Practitioners (ATCP)*
- *B) National Center for Complementary and Integrative Health (NCCIH)*
- *C) American Association of Chinese Medicine and Acupuncture (AACMA)*
- *D) National Certification Commission for Acupuncture and Oriental Medicine (NCCAOM)*

5. In traditional "manual" acupuncture, the needles are inserted to a depth of
- *A) 5–40 mm.*
- *B) 0.5–2 mm.*
- *C) 2.5–5 mm.*
- *D) 40–50 mm.*

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6. Which acupoint therapy may include a technique that employs the use of polydioxanone sutures for long-term mechanical stimulation?
- A) *Acupuncture*
- B) *Acupressure*
- C) *Moxibustion*
- D) *Transcutaneous Electrical Acustimulation (TEAS)*

7. Which of the following oncology associations include acupuncture and electroacupuncture as a potential treatment option for reducing post-cancer fatigue in their recommendations?
- A) *National Comprehensive Cancer Network (NCCN)*
- B) *American Society of Clinical Oncology (ASCO)*
- C) *Society for Integrative Oncology*
- D) *All of the above*

8. When compared with no treatment, standard therapy, or sham acupuncture, most preliminary clinical research and meta-analyses of clinical research show that for patients with fibromyalgia, acupuncture
- A) *improves pain and stiffness and quality of life.*
- B) *shows no effect.*
- C) *may result in additional adverse effects, including joint stiffness.*
- D) *Improves fatigue but not pain or stiffness.*

9. What are the most common adverse effects of acupuncture?
- A) *Dermatologic adverse effects*
- B) *Cardiovascular adverse effects*
- C) *Pulmonary adverse effects*
- D) *Ocular adverse effects*

10. Which moxibustion technique may be scarring?
- A) *Direct*
- B) *Electric*
- C) *Jade*
- D) *Thunder-fire*

11. Which of the following best characterizes the technique of thunder-fire moxibustion?
- A) *Moxa-cigars held by a moxibustion box are ignited over the treatment site.*
- B) *An ignited moxa cone is separated from the skin by ingredients such as ginseng, salt, garlic, ginger, or aconite cake.*
- C) *A one-inch moxa stick is put on the handle of an acupuncture needle that has been inserted in the body.*
- D) *A jade stone is applied via heated knee pads.*

12. For which GI condition does moxibustion have the most evidence of benefit?
- A) *IBS-C*
- B) *IBS-D*
- C) *Crohn disease*
- D) *Ulcerative colitis*

13. Preliminary clinical research in adolescents with primary dysmenorrhea shows that beginning acupressure shortly after menstruation onset reduces the severity of dysmenorrhea for up to
- A) *30 minutes.*
- B) *two hours.*
- C) *12 hours.*
- D) *three days.*

14. In patients receiving routine hemodialysis, auricular acupressure has been associated with a beneficial effect on which comorbidity?
- A) *Lower back pain*
- B) *Insomnia*
- C) *Fatigue*
- D) *Anxiety*

15. Which acupoint treatment modality utilizes an FDA-cleared medical device for the treatment of nausea, retching, and vomiting?
- A) *Acupressure*
- B) *Acupuncture*
- C) *Moxibustion*
- D) *Transcutaneous electrical acustimulation (TEAS)*

16. In transcutaneous electrical acustimulation (TEAS), which common acupoint is used for gastrointestinal discomfort, stress, and fatigue?
- A) *GV20 Bai Hui point on top of head*
- B) *P6 Neiguan point on wrist*
- C) *ST36 Zusanli point below the knee*
- D) *LI11 QuChi point on outside of elbow crease*

17. Which of the following statements regarding the use of acupuncture during pregnancy and labor is TRUE?
- A) *Only upper extremity acupoints can be used safely.*
- B) *There have been reports of significant adverse effects.*
- C) *It is safe when used appropriately and performed with sterile needles.*
- D) *All of the above*

Test questions continue on next page ➜

18. Which acupoint therapy has consistently been used safely during pregnancy in clinical research without significant adverse effects?

A) *Acupressure*
B) *Acupuncture*
C) *Moxibustion*
D) *Transcutaneous Electrical Acustimulation (TEAS).*

19. Which patient should be warned about worsening symptoms with the use of moxibustion?

A) *25-year-old with chronic back pain due to a motorvehicle accident*
B) *47-year-old with uncontrolled asthma*
C) *62-year-old with diarrhea-predominant irritable bowel syndrome (IBS-D)*
D) *70-year-old with osteoporosis-related knee pain*

20. How would you explain the efficacy of acupuncture to a patient seeking alternative treatments for chronic back pain?

A) *It has been proven that acupuncture is more effective than standard treatments for reducing back pain.*
B) *Most evidence suggests that acupuncture does not provide clinically relevant benefits in patients with back pain.*
C) *Only electroacupuncture has demonstrated consistent benefit for reducing back pain.*
D) *Research suggests that receiving more than five treatments with deep acupuncture may provide the most long-term benefit.*

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OSHA and Healthcare Facilities

Audience
This course is designed for dental professionals in all specialties.

Course Objective
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.

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

1. Explain the history of the Occupational Safety and Health Administration (OSHA).
2. Describe the purpose of the Bloodborne Pathogens Standard as it applies to the healthcare setting.
3. Review the role of OSHA standards in preventing tuberculosis (TB) transmission.
4. Explain the impact of OSHA regulations on employee health, including risk management and safety issues in a healthcare setting.
5. Discuss hazardous materials and waste management in a healthcare facility.
6. Explain the necessity for radiation safety in healthcare facilities.
7. Describe the process of handling blood and chemical spills.
8. Outline the impact of fire safety on patients and employees in the healthcare facility.
9. Discuss indoor air quality, ergonomics, and latex allergy concerns in healthcare facilities.
10. Discuss legal issues and employee safety as applied to the healthcare facility.
11. Describe what might occur during an OSHA consultation and inspection.

Faculty
Carol Shenold, RN, ICP, graduated from St. Paul's Nursing School, Dallas, Texas, achieving her diploma in nursing. Over the past thirty years she has worked in hospital nursing in various states in the areas of obstetrics, orthopedics, intensive care, surgery and general medicine.

Mrs. Shenold served as the Continuum of Care Manager for Vencor Oklahoma City, coordinating quality review, utilization review, Case Management, Infection Control, and Quality Management. During that time, the hospital achieved Accreditation with Commendation with the Joint Commission, with a score of 100.

Mrs. Shenold was previously the Infection Control Nurse for Deaconess Hospital, a 300-bed acute care facility in Oklahoma City. She is an active member of the Association for Professionals in Infection Control and Epidemiology (APIC). She worked for the Oklahoma Foundation for Medical Quality for six years.

Faculty Disclosure
Contributing faculty, Carol Shenold, RN, ICP, 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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INTRODUCTION

Death and disability due to unsafe or unhealthy workplaces remain ongoing issues in the United States. In 2021, there were 2.6 million job-related nonfatal injuries and illnesses in the private sector alone [1]. The U.S. Bureau of Labor Statistics reported a total of 4,764 employee deaths in 2021, slightly down from the number of fatal injuries reported in 2017. This figure may not include the deaths of workers due to occupationally acquired diseases [2]. The continuous efforts of the Occupational Safety and Health Administration (OSHA) to promote employee safety are part of what makes it such an important regulatory entity.

At one time OSHA compliance was considered an issue important and applicable to industry only. Healthcare facilities did not normally use heavy equipment or have issues regarding noise levels and high-level chemical spills and, therefore, felt safe. Smaller facilities may have felt protected from inspection because of the number of surveys required.

However, bloodborne pathogen compliance, waste management, tuberculosis control, and ergonomics regulations have increased awareness among healthcare facilities about the impact of OSHA. Entities such as OSHA, Medicare, and the Joint Commission now cooperate and review OSHA regulatory issues when conducting surveys.

HISTORY OF OSHA

In 1970, Congress established OSHA as part of the Occupational Safety and Health Act (i.e., the OSH Act). The Act was signed by President Nixon on December 29, 1970, and became effective on April 28, 1971. OSHA has defined its mission as assuring that working men and women are provided with safe, healthful working conditions. The agency fulfills its mission by applying and enforcing standards developed under the Act. It also provides information, education, training, and assistance to employers so they can maintain safe and healthful workplaces [3].

The OSH Act established three permanent federal agencies: OSHA, within the Department of Labor; the Occupational Safety and Health Review Commission (OSHRC); and the National Institute for Occupational Safety and Health (NIOSH), within the Department of Health and Human Services. The OSH Act covers most private sector employers and their workers, in addition to some public sector employers and workers. Its reach includes all 50 states and certain territories and jurisdictions under federal authority [3].

The duties of OSHA include writing standards, inspecting workplaces for compliance with standards, and prosecuting violations. The OSHRC is responsible for resolving disputes between OSHA and violators of the OSH Act (usually employ-

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ers). NIOSH conducts research on occupational hazards and makes recommendations for standards (e.g., N95 respirators to be used when caring for tuberculosis patients) [4; 5].

Workplace inspection is the responsibility of the Secretary of Labor and may result either from an employee complaint or from a problem identified during a previous inspection. An OSHA inspector may either order compliance with a regulation or issue a penalty, such as a fine. There is only one criminal penalty available under the Act, and this is applied if a worker dies from an employer's willful violation [6].

As mentioned, the healthcare industry had not previously considered OSHA regulations as affecting it. After all, hospitals did not use large machinery, assembly lines, or equipment that would put employees at risk for major injuries. However, research has identified a wide range of biologic, physical, psychosocial, and chemical hazards in the healthcare work environment [7; 8].

With the introduction of the human immunodeficiency virus (HIV) and a new focus on bloodborne pathogens, hospitals and other healthcare facilities were faced with the implementation of OSHA standards that would potentially cost both time and money. Many healthcare industries and organizations did not believe that the federal government should be quite so prescriptive and felt that some of the regulatory requirements for general industry might not be appropriate in a healthcare setting. To ensure that regulatory requirements are appropriate for healthcare settings, organizations such as the Association for Practitioners in Infection Control and Epidemiology (APIC) and the Centers for Disease Control and Prevention (CDC) work together with OSHA to develop standards.

In 1989, OSHA published a proposed rule regarding occupational exposure to bloodborne pathogens in hospitals and other healthcare settings. The proposed rule, based on the concept of Universal Precautions, raised concerns in the infection control community. The imbalance toward precautions that protected personnel and away from precautions that protected patients, the lack of proven efficacy of Universal Precautions, and the costs for implementing the proposed regulations were all concerns. After a series of public hearings by OSHA and a review of written comments, the proposed rule was modified and finalized in 1991. Although the final rule was expected to improve occupational safety during the care of patients infected with bloodborne pathogens, the impact on the cost of patient care and on nosocomial infection control remained undefined [9; 10].

The OSHA Bloodborne Pathogens Standard brought OSHA visibility to healthcare settings and required education about the implementation of and compliance with OSHA regulations. OSHA has become one of the most important organizations in the fight against bloodborne pathogens as a result of its ability to set standards for the use of barrier precautions and enforce the use of such precautions for employee and patient safety.

OSHA continues to urge improved safety in all categories of the workplace. In October 2010, the Assistant Secretary of Labor for OSHA reported that the agency's priorities for the coming fiscal year were to return to basics, update workplace safety and health regulations, and impose fair and strong enforcement [11].

BLOODBORNE PATHOGENS

The purpose of the Bloodborne Pathogens Standard, which was published by OSHA in final form in 1991, is to limit occupational exposure to blood, bodily fluids, and other potentially infectious materials, because any exposure could result in bloodborne pathogen transmission. This standard applies to all reasonably anticipated occupational exposures to blood or other potentially infectious materials that may result from the performance of an employee's duties [12]. "Good Samaritan" acts, such as resuscitating a co-worker, might not be considered occupational exposure [13; 14; 15].

The standard requires employers to implement an exposure control plan that mandates Universal Precautions (i.e., treating all body fluids as if they are potentially infectious). The standard also stresses hand hygiene, recommends the use of Personal Protective Equipment (PPE), sets forth processes to minimize needle sticks and blood splashing, ensures appropriate packaging of specimens, and regulates waste by employing biohazardous labeling before shipping [10; 12].

The Association of periOperative Nurses asserts that all healthcare personnel must follow the Occupational Safety and Health Administration (OSHA) bloodborne pathogens standard when there is a risk of exposure to blood or other potentially infectious materials.

(https://www.guidelinecentral.com/guideline/308628. Last accessed January 25, 2023.)

Level of Evidence: Expert Opinion/Consensus Statement

Employers must require the use of, and provide at no cost, barrier items or PPE for employee protection. This includes gowns, masks, mouthpieces, goggles, resuscitation bags, and the proper gloves for the job being performed. Also included in the standard are methods for disposing of contaminated sharps and other regulated waste in OSHA-compliant containers [10].

Another aspect of the Bloodborne Pathogens Standard is the requirement that Hepatitis B vaccination be made available at no cost and within 10 working days of assignment to all employees who have occupational exposure to blood. Postexposure evaluation and follow-up must be made available to all

employees who have had an exposure incident. Included in the evaluation and follow-up are laboratory testing, counseling, evaluation, and prophylaxis, if deemed necessary and if the employee consents [9; 12].

Some of the most common bloodborne pathogens include hepatitis C, HIV, and hepatitis B [10].

HEPATITIS C VIRUS

Hepatitis C virus (HCV) may be transmitted from patients to healthcare workers through accidental needle sticks or cuts, or through blood splashed onto the conjunctiva. Following percutaneous injury, the risk of infection is approximately 1.8% [16; 17; 18]. In 2019, 43,136 new cases of HCV were reported to CDC. This number does not include the adjustment made for under-reporting and under-ascertainment, making the estimated number of new HCV cases 57,500 in 2019. HCV is the leading cause of liver transplantation in the United States [19].

The long-term lethal potential of HCV is projected to be higher than that resulting from infection with Hepatitis B. This is due to the high rate of chronic infection and the lack of an effective vaccine. Often, patients with HIV also have HCV, and both pathogens can be transmitted in one exposure. Until 2010, HCV was usually treated with pegylated interferon/ribavirin (pegIFN/RBV); however, the treatment is expensive and has many adverse effects, and response rates were only 40% to 50% [20; 21; 22]. In 2011, the U.S. Food and Drug Administration (FDA) approved telaprevir and boceprevir for treatment of select patients with HCV infection (i.e., based on genotype) [22]. These two serine protease inhibitors are the first generation of direct-acting antiviral drugs approved for use in clinical practice. They are used in combination with pegIFN/RBV and have demonstrated response rates of 68% to 75% in naïve patients and up to 41% to 52% in previous nonresponders [23; 24; 25; 26]. The CDC has concluded that the evidence is insufficient to recommend postexposure prophylaxis for workers potentially exposed to HCV [16].

HUMAN IMMUNODEFICIENCY VIRUS (HIV)

The risk of infection with HIV following percutaneous injury is approximately 0.3%; however, risk is significantly increased if the patient has advanced acquired immunodeficiency syndrome (AIDS), the needle is visibly contaminated with blood, or if the needle has been used in an artery or vein before the exposure occurs [18; 27].

Between 1% and 2% of hospital and surgical patients have HIV. Postexposure prophylaxis with combination drug regimens has been shown to decrease seroconversion risk, but this may be compromised by the presence of increased risk factors [20; 27].

In 2013, the CDC published updated HIV management guidelines, which further refine the treatment of potential exposures to HIV in the workplace [27].

HEPATITIS B VIRUS

Hepatitis B virus (HBV) is highly infectious and transmissible by needlestick in 6% to 30% of exposures, depending on the antigen status of the source [16]. Approximately 90% of infants and 25% to 50% of children 1 to 5 years of age remain chronically infected with HBV [28]. Vaccination has dramatically reduced the threat to healthcare workers from this disease; however, not all healthcare workers who are at risk of exposure to blood have been vaccinated [20; 28]. According to the CDC, postvaccination testing to ensure an adequate antibody response is indicated for those individuals who: are immunocompromised; received the vaccination in the buttock; are infants born to HBV-positive mothers; are healthcare workers who either have had contact with blood or are at risk for continued exposure to blood or body fluids; or are sex partners of persons with chronic HBV [28].

Many exposures can be prevented, using the following guidelines [20; 29]:

- Choose effective PPE (i.e., the right equipment for the job).
- Find alternatives for sharps, such as staples for skin closure, rounded tip scissors, nonpenetrating towel clips, needleless intravenous (IV) systems.
- Use safer sharps.
- Pass and handle sharps safely.
- Adopt safe habits (e.g., make certain that knife blades are removed from knife handles before instruments are sent to be cleaned).
- Dispose of sharps safely.
- Avoid recapping needles.
- Evaluate new safety devices carefully.

The CDC has estimated that 385,000 hospital-based healthcare workers suffer sharps injuries each year [30]. The wounds can range from pinpricks to deep cuts. Statistics such as this spurred OSHA, in 1999, to require facilities to put an exposure control plan into place and update it at least annually. OSHA expects healthcare employers to explore and incorporate new methods to protect staff and patients from bloodborne pathogens [12; 31].

OSHA regulations require that an employer provide a copy of the Bloodborne Pathogens Standard to the healthcare professional evaluating an employee after an exposure to blood or other potentially infectious material. An employer should also have a copy of this regulation accessible to employees who are receiving bloodborne pathogen training. In addition to providing a copy of the standard to employees, training regarding the standard should take place as each employee is hired and on an annual basis. All training should be documented and its effectiveness evaluated. Integral to the Bloodborne Pathogens Standard is a requirement that each job in a facility is evaluated for its risk of exposing the employee to body fluids [9].

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As administrators and researchers explore new methods to protect patients, healthcare providers, and the environment from bloodborne pathogens, changes should be balanced with the impact on patient care and user satisfaction. OSHA has cited employers who have failed to implement available safer technology and safe work practices for handling sharps as part of their overall exposure control plan [20].

TUBERCULOSIS CONTROL

The United States has been waging a war against tuberculosis (TB) for more than 150 years. After it was found that a multidrug regimen could effectively kill the *Mycobacterium tuberculosis* organism, the number of those infected decreased dramatically, and many sanitariums were closed. By 1980, prevention programs were ended, and pharmaceutical companies had stopped manufacturing streptomycin. By 1985, the number of new cases of TB had increased, and by the early 1990s, the development of multidrug-resistant TB caused the epidemic to begin anew [32]. Due to recent attention and increased vigilance, incidence rates for TB infection in the United States have begun to decline. In 2021, a total of 7,882 cases of TB were reported in the United States, a 12.4% decrease from 2019. It should be noted that a decrease in 2020 (incidence rate: 7,171 cases) followed by a slight increase in 2021 was observed, but the increase is most likely due to under-reporting, delayed healthcare access, and/or missed diagnosis in 2020 as a result of the COVID-19 pandemic. Overall, the incidence rate has remained relatively stable, at approximately 2.5 cases per 100,000 persons [33]. However, it has been estimated that up to 13 million persons in the United States have latent TB infection, with 5% to 10% at risk for future disease [34; 35]. Furthermore, the increasing incidence of multidrug-resistant strains of the disease remains a problem.

Some of the increase in TB cases in the 1980s and 1990s could be partially attributed to immigration from developing countries, where routine immunization and treatment of communicable diseases was enforced less vigorously than in the United States. It could also be attributed partially to the susceptibility of immunocompromised patients, such as those with HIV. Substance abuse, homelessness, poverty, and a deterioration in public health infrastructures were other factors in the resurgence of TB [36].

This increase in TB prompted the CDC, in 1989, to issue a strategic action plan with the goal of decreasing the case rate of TB to less than 1 per million population by the year 2010. However, the plan was not fully implemented, and the number of TB cases increased. In 1993, the CDC outlined basic guidelines for TB control, including the recommendation that all facilities have a formalized plan for the control of TB [36; 37; 38].

Bacille Calmette-Guérin (BCG) is the vaccine for TB disease, although it is not commonly used in the United States. It is most often given to infants and children in countries where TB is common, and it should be considered for only select people in the United States. Healthcare workers may be considered as candidates for the BCG vaccine if they work in a setting in which a high percentage of patients are infected with TB strains that are resistant to both isoniazid and rifampin; there is ongoing transmission of drug-resistant TB strains to healthcare workers and infection is likely; or comprehensive TB infection-control precautions have been implemented but have not been successful [84].

In 2019, the CDC updated their guideline for the prevention of TB transmission in healthcare settings [64; 72]. The updated guideline recommends baseline (preplacement) TB testing and screening for all U.S. healthcare personnel. Although routine follow-up screening is not recommended, healthcare facilities should aim to identify latent tuberculosis infection among personnel and to encourage treatment. Postexposure screening and testing should be conducted for any healthcare personnel with known exposure to a person with potentially infectious TB disease. Healthcare personnel with a newly positive test result should undergo a symptom evaluation and chest radiograph to assess for TB disease. Personnel with latent TB infection and no prior treatment should be offered, and strongly encouraged to complete, treatment with a recommenced regimen, unless a contraindication exits. Finally, the CDC also recommends that healthcare facilities should provide annual education on TB, including risk factors, signs, and symptoms [64; 72].

OCCUPATIONAL EXPOSURE

In 1997, OSHA proposed a rule to establish a standard for occupational exposure to TB. In 1998 and 1999, the agency held public hearings and gathered comments regarding the proposed rule. Following a lull in activity, OSHA reopened the comment period in 2002 [39].

APIC worked to ensure that OSHA had all of the most recent TB studies, contending that those studies that depicted current TB epidemiology should be admitted and considered carefully before OSHA issued a final rule. Other groups, including the American Hospital Association, the American Lung Association, and the American Healthcare Association, all agreed on the need for OSHA to consider current clinical information before finalizing rules that would affect all healthcare facilities.

Despite these recommendations, OSHA concluded that a new rule was not needed due to the decline in the number of TB cases. The agency further concluded that a new rule would create confusion for healthcare facilities that were already voluntarily following TB guidelines published by the CDC. In 2003, OSHA withdrew the standard that applied only to respiratory protection against TB. In response, the American Nurses Association, as well as several labor groups, expressed dismay, believing that TB still posed a serious risk to healthcare workers [39].

In 2010, OSHA published a request for information to determine whether existing standards and organizational voluntary guidelines are effectively protecting healthcare workers from occupational exposure to infectious agents such as TB [42].

RESPIRATORY PROTECTION PROGRAM

The General Industry Standard mandates that all healthcare facilities in which healthcare workers use respiratory protection establish and implement a written respiratory protection program that includes procedures specific to the worksite. Employers must provide respirators, training, and medical evaluation at no cost to employees [43].

Training

The CDC has recommended that healthcare workers receive annual training on the nature, extent, and hazards of TB in the healthcare setting. Recommended training topics include risk assessment, use of environmental controls, how to select and use a respirator, and OSHA regulations regarding respirators. Trainees should be given opportunities to practice handling and wearing a respirator to achieve proficiency. They also should be provided with copies of training materials for future reference [44].

Respirator Selection

The CDC has recommended that protective devices used in healthcare settings be certified by CDC/NIOSH as either a nonpowered particulate filter respirator (i.e., N-, R-, or P-95, 99, or 100) or a powered air-purifying respirator and properly fitted to the wearer. The minimum respiratory protection is a filtering facepiece respirator (e.g., N95 disposable) [44].

Fit Testing

Fit testing ensures that the user understands what constitutes a proper fit in order to select a device that provides adequate protection. Periodic fit testing should be included in the initial respiratory protection program training and conducted periodically thereafter as a supplement to employee training and retraining [44].

OSHA AND EMPLOYEE HEALTH

The Employee Health Department of the healthcare facility has a critical role in the interpretation and implementation of OSHA guidelines. The employee health professional is the point person for many issues discussed in the first sections of this course. Depending on the facility's policies and structure, its Employee Health Department may be responsible for the oversight (in conjunction with the Infection Control Department) of many OSHA-related issues, from employee injuries and bloodborne pathogen exposures to high-efficiency particulate air (HEPA)-type mask fit-testing records.

Because the Employee Health Department is usually the keeper of records related to employee injuries, it becomes responsible for tracking bloodborne pathogen exposures and ensuring that employees are treated appropriately, that laboratory testing follows the appropriate guidelines, and that prophylaxis, if needed, is available. These records should be retained and recorded on the *OSHA 300 Log*.

In 2002, OSHA revised the rule addressing the recording and reporting of occupational injuries and illnesses. The goal of this revision was to simplify the overall recordkeeping for employers, generate more accurate information about occupational injuries, and better protect employee privacy. In 2015, OSHA again updated the recordkeeping rule to include two changes. The first change updated the list of industries that are exempt from routinely keeping OSHA injury and illness records. The second change expanded the list of severe work-related injuries and illnesses that all covered employers are required to report to OSHA. In 2016, OSHA published the new "injury and illness reporting rule." It does not change core recordkeeping requirements, but it does require that select recordkeeping forms be submitted to OSHA annually [45]. In 2019, OSHA published a rule to eliminate the requirement for establishments with 250 or more employees to submit certain forms electronically that may be used to protect personally identifiable information and data, although electronic submission of other forms is still required [45]. *Code of Federal Regulations*, title 29, sec. 1904, addresses recordkeeping [9].

One of the most confusing parts of recordkeeping is determining whether an injury or illness is recordable based on first aid or medical treatment. The revised standard sets new definitions of medical treatment and first aid to simplify recording decisions. An injury or illness is considered work-related if an event or exposure in the work environment either caused or contributed to the condition or significantly aggravated a pre-existing condition [9].

Work-related injuries and illnesses should be recorded if they result in [9; 45]:

- Death
- Hearing loss
- Loss of consciousness
- Days away from work
- Restricted work activity or job transfer
- Medical treatment beyond first aid

Work-related fatalities should be reported within eight hours. Work-related injuries and illnesses that are significant or meet any of the additional criteria listed below should also be recorded. Any significant work-related injury or illness that is diagnosed by a physician or other licensed healthcare professional or that involves cancer, chronic irreversible disease, a fractured or cracked bone, or a punctured eardrum should be recorded as well [9].

The following conditions should be recorded when they are work-related [9; 46]:

- Any needlestick injury or cut from a sharp object that is contaminated with another person's blood or other potentially infectious material
- Any case requiring an employee to be medically removed under the requirements of an OSHA health standard

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- Tuberculosis infection as evidenced by a positive skin test or diagnosis by a physician or other licensed healthcare professional after exposure to a known case of active tuberculosis
- Hearing loss as evidenced by a hearing test (audiogram)

Hearing loss has occurred when the audiogram reveals that the employee has experienced a standard threshold shift (STS) in hearing in one or both ears (averaged at 2,000, 3,000, and 4,000 Hz), and the employee's total hearing level is 25 decibels or more above audiometric zero (also averaged at 2,000, 3,000, and 4,000 Hz) in the same ear(s) as the STS [46].

The following interventions are considered medical treatment and are almost always recordable on the *OSHA 300 Log* [9; 45]:

- Administration of immunizations, such as Hepatitis B or rabies (does not include tetanus)
- Use of wound-closing devices, such as sutures and staples
- Use of rigid means of support to immobilize parts of the body
- Physical therapy or chiropractic treatment

Medical treatment does not include [9]:

- Visits to a physician or other licensed healthcare professional solely for observation or counseling
- The conduct of diagnostic procedures (e.g., x-rays and blood tests), including the administration of prescription medications used solely for diagnostic purposes
- Any procedure that may be labeled first aid

If the incident required only the following types of treatment, it is considered first aid and is not reportable [9; 45]:

- Use of a nonprescription medication at nonprescription strength
- Administration of tetanus immunizations
- Cleaning, flushing, or soaking of wounds on the surface of the skin
- Use of wound coverings (e.g., bandages or gauze pads)
- Application of hot or cold therapy
- Use of any nonrigid means of support (e.g., elastic bandages, wraps, and nonrigid back belts)
- Use of temporary immobilization devices while transporting an accident victim (e.g., splints, slings, neck collars, or back boards)
- Drilling of a fingernail or toenail to relieve pressure, or draining fluid from a blister
- Use of eye patches
- Removal of foreign bodies from the eye using only irrigation or a cotton swab
- Removal of splinters or foreign material from areas other than the eye by irrigation, tweezers, cotton swabs, or other simple means
- Use of finger guards
- Administration of massage
- Drinking of fluids to relieve heat stress

If an injury is considered reportable, and therefore recordable, it should be recorded on the *OSHA 300 Log*. In addition, the injury or illness should be recorded on either the *OSHA Form 301* or an equivalent. The *OSHA Form 301* provides more information about the case and the individual involved. Information such as the events leading up to the injury or illness, affected body parts, and objects or substances involved should be included [45]. Any form, such as a workers' compensation report or accident report, may be used as long as it contains the same information. *OSHA Form 300A* should be used to record work-related hearing loss [46]. Other items that should be covered following an employee injury include:

- Prompt reporting of the injury
- Thorough documentation and investigation
- Timely treatment if the injury requires medical attention
- Consistent follow-up of an accident without injury or lost time to ensure that time is not lost at a later date
- Immediate notification of any insurance carriers
- Fast repair of any involved equipment
- Prompt recovery of a physician statement
- Retention of a physician's release to return to work before the employee returns to duty
- Methods of returning employees to work as early as possible through prompt rehabilitation or temporary job description alteration
- Accurate reporting on the *OSHA 300 Log*

An annual summary of injuries and illnesses that occurred during the calendar year should be reported. The annual summary (*OSHA Form 300A*) is a total of all the columns to the right of the dotted line on the *OSHA 300 Log* [45]. A company executive should certify that the summary is correct and complete, and it should be posted for 3 months in areas where other employee notices are normally posted. The *OSHA 300 Log*, privacy case list (if one exists), annual summary, and *OSHA 301 Incident Report Form*, or other suitable form (e.g., state workers' compensation report, insurance claim report, employer's accident report form) should be retained for 5 years following the calendar year to which they relate [9; 45].

In the hospital setting, most PPE is used as a barrier to blood and body fluids, such as blood-tinged mucous, blood, and urine. *Code of Federal Regulations*, title 29, sec. 1910.132 to 1910.139, originally published in 1994, address PPE. Subsequent revisions to this standard have incorporated current guidelines, hazard assessments for employee work areas, employee training, and properly fitting PPE. Hand equipment should fit properly and provide the proper protection. The type of glove used for protection from blood or body fluids would

not be sufficient for a housekeeper handling caustic chemicals. The right glove for the job being performed is an important consideration [9].

The Employee Health Department is often considered to be the expert on PPE. OSHA addresses employee training in *Code of Federal Regulations*, title 29, sec. 1910.132(f). Employees should be trained regarding [9]:

- When to wear PPE
- What type of PPE is necessary
- How to properly don, doff, adjust, and wear PPE
- Limitations of PPE
- Care, maintenance, useful life, and disposal of PPE

To ensure that each employee is properly trained, clear and measurable objectives should be developed. Because the regulation requires that employees demonstrate an understanding of the PPE guidelines, objectives should center on these criteria.

The employer should verify that employees have been provided with all the necessary training. A written form of documentation with the name of the employee and date of training is required, as well as documentation of retraining [9].

SAFETY/RISK MANAGEMENT

Depending on the size of the healthcare facility, the risk manager (in conjunction with the Employee Health Department) may also be responsible for safety issues. All employee injuries and illnesses should be assessed with regard to safety and the possibility that it may somehow have been compromised. When evaluating an employee injury, the safety issues that might affect the outcome (e.g., lifting, glove use, ergonomics, or air quality) should be examined to ensure that no overall safety issues exist. Any safety issues discovered should be documented and reported through the facility's Safety Committee to prove that the issues have been addressed and that no hazards are being neglected. Careful documentation will help the facility avoid the perception that it is ignoring OSHA regulations.

ROLE OF MANAGEMENT

Paramount to a successful employee risk management program is the involvement of the managerial and supervisory staff of the facility. This staff is the first line of defense. It will know the employees and what needs to be done, and it will understand that its example will be emulated. Middle management staff is vital to an employee program. Eliciting cooperation from this staff (i.e., supervisors/managers) will greatly increase the program's success. The staff's concerned attitude, use of necessary protective equipment, and safe work habits will encourage employee participation [47].

The supervisor is frequently first on the scene after an incident is reported and may be responsible for conducting the initial investigation. The supervisor's commitment to safety and accident prevention is key. Strong organizational policies and procedures that are consistently followed may determine whether an incident results in an employee or patient injury [47].

In addition, the direct supervisor may also be first to spot safety hazards, such as unsafe lifting, failure to wear PPE, employees who ignore wet floor signs, or the improper disposal of sharps that could lead to a blood or body fluid exposure. Prompt correction and disciplinary action, when indicated, are effective tools in preventing a reoccurrence of the incident. Consistency, fair play, and discipline, when necessary, are fundamental aspects of employee safety [47].

Controlling Costs

Some facilities have opted to use onsite care for the injured employee in order to control the employee's care and treat the injury quickly, with as little lost work time as possible. Other facilities have opted to contract with a physician who agrees to see all employees injured at the facility. The physician's familiarity with all injuries may help to cut costs and discover fraud. Injury prevention programs and aggressive workers' compensation case management are keys to controlling costs. The primary objective is to eliminate workplace injuries and lost-time accidents [47].

An inherent problem related to employee injury may result from conflict between the employee's private physician and the facility's physician. This situation may result in the failure of the employee to receive any medical or monetary benefits for an injury. Reform legislation in Oklahoma, passed in 2005, allows employers to select the employee's physician as part of the terms of employment [48]. Since then, other states have adopted similar laws.

Incident reporting, documentation, and investigation are all aspects that will be covered later in the course, but all of these factors may have a direct effect on successful cost containment for a facility [47].

WORKERS' COMPENSATION

One of the factors that will complicate any employee injury is workers' compensation. Each state has its own set of laws; however, prompt reporting of treated injuries and an accurate OSHA accident log will help to lessen any conflicts.

Hundreds of thousands of dollars are spent every year on workers' compensation claims, including money for medical/surgical costs, rehabilitation, and legal fees. Back injuries top the list of employee injuries; in a healthcare facility, these are frequently due to a combination of improper patient lifting and failure to ask for assistance when lifting patients. Slips and falls on wet floors account for many employee injuries as well. The physical building, outside surroundings, patient population, equipment in use, and staffing plan all play a part in the assessment of employee risk.

Workers' compensation court usually requires an initial accident report and a first injury report to be filed within ten days of the injury, even if the injury leads to no lost time. The documentation of the injury should be complete and kept

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at the facility. OSHA requires employee health records to be kept confidential [9].

A record of an employee injury is also provided to any third-party payer (i.e., insurance carrier). Some facilities are self-insured. Others have one insurance company that specializes in employee injuries and a second company that handles liability claims, such as physician malpractice or patient/visitor injuries. Prompt reporting to the facility's various carriers will put the facility in the best position to keep costs down. In addition, a good relationship with the insurance carriers will often result in the receipt of educational material that may lighten the risk manager's education responsibilities.

Employees should understand that prompt reporting will lead to effective treatment and lower overall costs to the facility. Risk managers should be familiar with the workers' compensation laws in their own states. It is wise to have the handbook available for reference.

VIOLENCE IN THE WORKPLACE

Violence in the workplace is an issue that is increasingly receiving public attention. An estimated 2.6 million workers are injured each in the workplace, of which more than 37,000 injuries are intentionally caused by another person. While a majority of these injuries are nonfatal, the U.S. Bureau of Labor Statistics (BLS) reported that of the 5,190 fatalities in the workplace in 2021, 761 workers were fatally injured by assault and/or violent attack [40; 49; 51].

The BLS also has reported that in 2020, the majority (61%) of nonfatal workplace assaults occurred in service settings, most commonly affecting healthcare support, followed by healthcare practitioner and technical occupations (24%) [50]. This increased risk may be attributed to several factors, such as the prevalence of weapons (e.g., firearms) among patients, their families, or friends; the use of hospitals by the criminal justice system as places to hold disturbed and/or violent individuals; the unrestricted movement of the public in healthcare facilities; and isolated work with patients [50; 51]. Workplace assaults result in lost workdays and millions of dollars in lost wages each year [51]. For healthcare workers, these assaults comprise 10% to 11% of workplace injuries involving days away from work, compared with 3% for private sector employees [50; 51].

Ongoing and thorough employee safety education should be an inherent component of the facility's risk management and employee injury prevention programs. Education on back injuries is especially important, as such injuries are costly. In addition, safety information should always be part of a new employee's orientation to a facility and should include safe patient lifting, hazardous material handling, bloodborne pathogen precautions, sharps handling, and incident reporting. Documentation of this education is essential.

The mission of OSHA is to provide a safe workplace for all employees. A well-organized employee health risk management program can help a facility meet OSHA requirements.

SAFETY DATA SHEETS/ HAZARDOUS MATERIAL

The Hazard Communication Standard, also known as the Right-to-Know Law, was first enacted by OSHA in 1983. It was modified in 1987–1989, 1994, and 2012 and is referenced as *Code of Federal Regulations*, title 29, sec. 1910.1200 [9; 52].

The purpose of this standard is to ensure that chemical hazards in the workplace are identified and evaluated. This is the responsibility of chemical manufacturers and importers, who are required to provide hazard information to employers who purchase their products [53]. Employers are then required to inform employees about the hazards of workplace chemicals—from liquid correction fluid to formaldehyde—to ensure that employees can monitor their exposure to hazardous chemicals and protect their health. Employers who neither produce nor import chemicals are only required to ensure that hazard information is transferred to its employees by means of a comprehensive hazard communication program, which should include container labeling and other forms of warning [9]. Regardless of who performs the hazard determination, the procedures used must be described in writing and made available on request to employees and their designated representatives, as well as to OSHA and NIOSH officials [53].

The Hazard Communication Standard defines a hazardous chemical as one that presents either a physical hazard (i.e., fire, explosive, or reactive) or a health hazard (i.e., one with systemic or target organ effects) in the workplace. Certain chemicals have been specifically designated as hazardous. A list of these chemicals is provided by several agencies, including [53]:

- OSHA Toxic and Hazardous Substances (*Code of Federal Regulations*, title 29, sec. 1910.1030 App A)
- American Conference of Governmental Industrial Hygienists
- National Toxicology Program Annual Report on Carcinogens
- International Agency for Research on Cancer Monographs

If a chemical is encountered that is not found on one of these lists, it is the employer's responsibility to search other scientific literature to determine if the chemical is hazardous [53]. Every chemical used or encountered in the facility should have a Safety Data Sheet (SDS) readily available to employees, which should be updated on a regular basis. Training and documentation of the training should be provided and take place at the time of initial assignment, whenever a new, potentially dangerous chemical is introduced into the workplace.

A hazard communication program may include, but is not limited to [9]:

- Understanding OSHA requirements
- Assigning responsibility for tasks

- Preparing an inventory of chemicals
- Determining where to maintain a list of the hazardous chemicals (i.e., in each work area or in a central location)
- Ensuring that containers are labeled
- Obtaining SDS for each chemical
- Ensuring that employees are informed of the hazards associated with chemicals contained in unlabeled work areas
- Developing and maintaining a written hazard communication program for the workplace
- Preparing and distributing SDS to workers
- Training workers regarding hazards and protective measures
- Establishing procedures to evaluate the program's effectiveness

HAZARDOUS WASTE

Approximately 15% of wastes generated by healthcare facilities are considered hazardous materials that may be infectious, toxic, or radioactive. These materials include [54]:

- Infectious and anatomic waste (This represents the greatest proportion and consists of cultures/stocks of infectious agents; wastes from infected patients; wastes contaminated with blood/blood derivatives; infected laboratory animals; contaminated medical supplies or equipment; and recognizable body parts.)
- Chemicals (e.g., solvents/disinfectants) and pharmaceuticals
- Sharps (e.g., syringes, disposable scalpels, or blades)
- Genotoxic waste (i.e., highly hazardous, mutagenic, or carcinogenic), radioactive matter, and wastes with high heavy metal content (e.g., broken mercury thermometers)

Hospitals and other healthcare facilities, laboratories, research clinics, mortuaries, autopsy clinics, blood banks, and nursing homes are major sources of healthcare waste. The wealthiest nations can produce up to 5 kg of hazardous waste per person per year. Although poorer nations generate lesser amounts of waste, they typically do not distinguish between hazardous and nonhazardous waste [54]. Each facility that generates infectious waste should have a waste management plan that covers: the segregation, packaging, storage, treatment, transport, and disposal of the waste; and employee training on the proper handling of the waste. Sharps should be kept in leak-proof, rigid, puncture-resistant containers that are either red in color or visibly labeled with the word "sharps" and the biohazard symbol. Infectious waste, other than sharps, should be kept in containers that are impenetrable to moisture, strong enough to resist tearing, and stored in a secure area. The area should be air conditioned and inaccessible to animals, rodents, and vermin [10].

The waste should be autoclaved or incinerated before being disposed of in regular landfills, depending on state laws. If waste is transported away from the facility, it should be placed in containers or compartments that prevent scattering, spillage, and/or leakage of waste during transport, and it should not be transported along with noninfectious waste unless all of the waste is handled as infectious [10].

Assessment of a facility's waste management program should include [55; 56]:

- The importance of a facility-wide approach to ensure compliance
- The necessity for use of established benchmarks, such as pounds of regulated medical waste (RMW) per patient day, or pounds of RMW as a percentage of overall waste in the facility
- The careful placement of RMW containers
- The issues relating to bidding for services
- The appropriateness of waste logos
- Reusable versus disposable issues
- The treatment options for medical waste

Determining how to reduce waste is an ongoing concern. Comprehensive education that encourages replacing disposable waste items from dialysis, surgery, or autopsy (e.g., towels, sheets, lab coats, underpads) with reusable items has the potential to reduce red-bag waste to only 6% to 10% of a hospital's total waste [56; 57]. It is estimated that only 2% to 3% of hospital waste truly needs to be disposed of as red-bag waste [56].

RADIATION

Employers are responsible to evaluate and measure levels of any radiation or concentrations of radioactive material present, where applicable. Appropriate personnel monitoring equipment, such as film badges, should be available, and each radiation area should be conspicuously posted with a sign or signs bearing the radiation caution symbol [9]. (Employers should refer to state guidelines for information regarding the radiation produced by radiographic [x-ray] machines.)

The Nuclear Regulatory Commission (NRC), OSHA, and individual states all provide regulations regarding radiation safety. It is the responsibility of the healthcare organization to determine which regulations are applicable to its facility. NRC regulations apply to facilities that have radioisotopes on site, such as facilities that are engaged in nuclear medicine and using radioactive sources. OSHA regulations apply to organizations that are merely performing medical imaging,

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including magnetic resonance imaging (MRI). If the facility is a Veteran's Administration or other federal facility, it should always comply with OSHA regulations. However, if a facility is located in a state that has an agreement with OSHA to set its own occupational safety standards (which must be at least as stringent as OSHA's), then the state's requirements apply [58; 59].

OSHA has set standards for radiation exposure levels and requires a radiation monitoring program. However, the radiation monitoring program need not continue indefinitely. Employers are not required to provide monitor badges to employees just because they work in an area where radiation is used. They are only required to provide monitor badges to those employees likely to receive a dose of radiation in excess of 25% of the allowed quarterly exposure limits and to employees who work in a high-radiation area. When an organization has compiled the necessary data through radiation surveys and monitoring results, it may reduce the scope of a program that is costly and time-consuming. The acquired data should document that employee exposure levels to radiation are less than 25% of the allowed quarterly limits set by OSHA [9].

If data are available to show that employee exposures do not exceed 25% of these quarterly limits and that the employees do not work in a high-radiation area, then the employees need not be monitored or provided with monitor badges. Additional monitoring requirements may apply to employees younger than 18 years of age or those working with radioisotopes. They may also apply if new equipment and processes have been introduced [9].

The radiation monitoring requirements for the majority of small, rural healthcare organizations are minimal for two reasons. First, these smaller facilities typically use only general radiographic equipment, and second, they do not normally have nuclear medicine programs that utilize radioisotopes.

CHEMICAL AND BLOOD SPILLS

Part of the healthcare facility's responsibilities for workplace safety rests with its ability to have a plan in place for managing spills of all kinds [9]. Both blood spills and chemical spills (e.g., formaldehyde) contain the potential for employee injury.

Because of the potential for injury, these spills (and their cleanup) are regulated by OSHA [9; 10; 53]. Factors to consider if a spill occurs include:

- Location of the spill (i.e., counter, cabinet, or surgery)
- Quantity of the chemical or biologic product released
- Physical properties of the released substance
- Hazardous properties of the material released (i.e., toxicity, flammability, and corrosivity)
- Types of protective equipment needed

Clean-up supplies should include, but are not limited to:

- Neutralizing agents, such as sodium bicarbonate or sodium bisulfate
- Absorbents, such as sand or vermiculite
- Pans, small shovels, or scoopers
- Containers with lids for disposal

The healthcare facility should follow these guidelines if a spill occurs:

- Attend immediately to all personnel who may have been contaminated.
- Notify personnel in the immediate area of the spill.
- If spilled material is flammable, turn off any electrical sources.
- Contain the spill using an absorbent material, for example:
  - Pour absorbent material around the perimeter of the spill.
  - Once contained, pour additional absorbent into center of spill.
  - Use a small shovel or scooper to work absorbent located around the perimeter into the middle until all the chemical is absorbed.
- During clean up, use protective equipment, such as gloves, safety glasses, and respiratory protection.
- Leave on or establish exhaust ventilation, if safe to do so.

Spill kits for both chemical and blood spills should be placed strategically around the facility. All personnel should be trained in the use of the spill kits, and the training should be documented. Policies should be in place that cover spill cleanup, protective equipment, handling solid or liquid spills, and the storage and handling of any chemicals.

The easiest way to prevent spills is through careful storage and handling. Chemicals should be stored in properly labeled containers with special attention to hazard warnings. Flammables should be stored in special storage areas; this includes items such as paint and turpentine. Water-reactive chemicals require dry storage. Compressed gas cylinders should be secured and properly supported.

FIRE SAFETY

Workplaces that handle flammable chemicals, process hazardous waste, or house patients should be concerned with the risk of fire. Fire safety should be part of any hazard communication training program. Smoke alarms, sprinklers, and/or fire extinguishers should be present. All employees should know about the fire risks associated with chemicals, gases, or equipment used. They should also know how to respond to a fire, which

includes how to rescue patients and other employees, and how to locate and properly use fire extinguishers.

EVIDENCE-BASED PRACTICE RECOMMENDATION

According to the American Society of Anesthesiologists, all anesthesiologists should have fire safety education, specifically for operating room fires, with emphasis on the risk created by an oxidizer-enriched atmosphere.

(https://pubs.asahq.org/anesthesiology/article/118/2/271/13592/Practice-Advisory-for-the-Prevention-and. Last accessed January 25, 2023.)

Level of Evidence: Expert Opinion/Consensus Statement

Fire safety plans should include fire emergency preparation, including alarm systems, marked exits, and written emergency plans. Many hospitals use acronyms such as RACE (Rescue, Alert, Confine, Extinguish) to help employees remember the proper steps for fire emergency response.

Annual inspections by the fire marshal, quarterly fire drills, annual fire safety in-services, and monthly fire extinguisher documentation are all elements of a successful fire safety program. Staff education and documentation of the education are integral parts of the fire safety plan.

OSHA requires that employers develop and maintain on site a written fire prevention plan. The plan must be available for employee review; employers with 10 or less employees may orally communicate the plan. The plan should include a list of all major fire hazards, proper handling and storage procedures for hazardous materials, potential ignition sources and how to control them, and the type of protective equipment needed to control each type of hazard [9].

INDOOR ENVIRONMENTAL QUALITY

Over the last several decades, concerns about the quality of indoor office environments have risen dramatically in the United States. The term "sick building syndrome" (SBS) describes a range of acute health and comfort effects that workers link to time spent in a building. Workers identify the building as the cause of their symptoms because they find relief from the symptoms when they leave the building [60]. SBS may be caused by inadequate ventilation, chemical contaminants from indoor or outdoor sources, and biologic contaminants. Although some symptoms and illnesses have been associated with a building's characteristics (e.g., dampness), medical and environmental tests often are not able to identify an offending contaminant in SBS. In contrast, a building-related illness (BRI) is one in which the symptoms of a diagnosable illness can be both identified and directly attributed to a specific airborne building contaminant. Examples of such illnesses include asthma, hypersensitivity pneumonitis, inhalation fever, rhinosinusitis, and infection [60; 61; 62].

NIOSH uses the term indoor environmental quality (IEQ) to describe the problems associated with air quality in an office or other building environment. NIOSH investigates potential health hazards in the workplace by means of a Health Hazard Evaluation (HHE), conducted under the authority of the OSH Act. Results of HHEs have indicated that, in addition to concerns about a building's air quality, employees have reported concerns about comfort, noise, and lighting as well as job-related ergonomic and psychosocial stressors [61].

When NIOSH conducts an HHE, it investigates a building's pollutant sources and pathways, its heating, ventilating, and air conditioning (HVAC) system, and its occupants. The HVAC system impacts how pollutants are distributed throughout the building as well as how they are removed from the building's air supply. Common pollutants and their sources include carbon dioxide, molds, bacteria, cleaning products, copy machines, and pesticides. An improperly maintained HVAC system may also be a source of pollutants [61].

An area of IEQ concern for hospitals is the operating room, where workers may be exposed to waste anesthetic gases, including nitrous oxide and halogenated anesthetics (e.g., halothane, enflurane, and isoflurane), while administering anesthesia. Exposure may also occur in the recovery room when the patient exhales the gases.

Some studies have reported miscarriage, genetic damage, and cancer among workers in operating rooms who have experienced long-term exposure to low concentrations of these gases. Exposure to high concentrations may cause headache, irritability, fatigue, nausea, drowsiness, difficulties with judgment/coordination, and liver and kidney disease. NIOSH has recommended the following safeguards to reduce worker exposure to waste anesthetic gases [63]:

- Install a well-designed scavenging system that includes securely fitting masks, sufficient flow rates for the exhaust system, and properly vented vacuum pumps.
- Install a ventilation system that circulates and replenishes the air in operating rooms and recovery rooms.
- Monitor anesthetic equipment with leak test equipment and monitor the room air. Maintain good records of all collected air samples.
- Prevent leakage from the anesthetic delivery system by replacing loose-fitting connections, loosely assembled or deformed slip joints and threaded connections, and defective or worn seals, gaskets, breathing bags, and hoses.
- Provide employee training on hazard awareness, prevention, and exposure control.
- Obtain baseline liver/kidney data for operating-room workers and periodically monitor their organ functioning.

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ERGONOMICS

The word ergonomics is derived from the Greek words *ergon* (work) and *nomos* (principle or law). It was first coined by a Polish scientist and educator in 1857 [65]. The science of ergonomics was not widely applied until World War II, when the fast pace of war manufacturing created physical and psychologic problems among workers [65]. Ergonomics is now defined as the science of fitting workplace conditions and job demands to the capabilities of the working population. Successful fits assure high productivity, reduced worker illness and injury, and increased worker satisfaction [66].

Although the scope of ergonomics is broad, OSHA primarily uses the term to define and assess work-related factors that put individuals at risk of musculoskeletal disorders (MSDs), which account for 33% of all worker injury and illness cases annually [65]. Examples of ergonomic risk factors have been identified in jobs and tasks that require prolonged, repetitive movements; recurrent heavy lifting, pushing, or pulling; and prolonged, awkward working positions. Employee exposure to vibration and cold may also be risk factors [66].

When seeking to identify conditions that may be contributing to MSDs, OSHA has recommended that employers [66]:

- Review/analyze injury/illness records (i.e., *OSHA 300 Logs*, and workers' compensation claims) to determine whether certain jobs/tasks are associated with ergonomic-related injuries;
- Analyze the jobs/tasks before assigning them to workers and before injuries have occurred; include employee input and make corrections where necessary; and
- Be aware of industry-wide conditions that contribute to ergonomic-related injuries (e.g., back injuries among healthcare workers).

Medical management, employee training and education, and workstation design are important components of an ergonomics program. Many hospitals and physicians' offices have gone paperless, and millions of workers in the United States work with computers every day [65]. OSHA has developed guidelines for helping employers and employees create workstations that are both safe and comfortable [67]. Although no single correct posture or workstation arrangement exists, adhering to some basic design goals may help to minimize or eliminate problems. Adjustable chairs, footrests, armrests, and computer monitors may help to reduce injuries. Lighting, work processes, and worker posture are additional factors to consider when conducting an ergonomic assessment of the workplace [68]. Employees should be trained on ergonomic issues to help them identify problem areas within their jobs. Failure to recognize some of the early warning signs (e.g., numbness, blurred vision, aching or tingling, and weakness) may allow a small problem to become a serious injury [68].

In 1999, OSHA published a proposed Ergonomic Program Standard. This proposed standard applied to general-industry employers whose employees performed manufacturing or manual handling tasks and reported MSDs [69]. In 2000, the House voted to block federal rules aimed at preventing some of the 1.8 million workplace injuries that American workers were suffering annually. In 2001, President George W. Bush signed a joint resolution of Congress that disapproved OSHA's proposed Ergonomics Standard. As a result, the standard is no longer in effect, and employers and employees are not bound by its requirements [65; 70].

Although no standards exist to universally regulate ergonomics, OSHA has established a protocol for developing industry and task-specific ergonomic guidelines [63]. OSHA has developed guidelines for poultry processing, retail grocery stores, shipyards, and nursing homes [66]. Although specific ergonomic standards for healthcare professionals have yet to be established, in 2014, OSHA published a new educational web resource that contains a variety of guidance products and materials to help hospitals prevent worker injuries, assess workplace safety needs, and enhance safe patient handling programs. The products and materials are available at https://www.osha.gov/hospitals [71].

Despite the lack of a final standard, employers are still obligated to follow the General Duty Clause, Section 5(a)(1), of the OSH Act, which requires employers to maintain a workplace that is free of serious hazards, including ergonomic hazards, whether or not voluntary guidelines exist. OSHA will continue to cite for ergonomic hazards [73; 74].

LATEX ALLERGY AND GLOVE MANAGEMENT

Concern over public health issues and the need for occupational PPE has led to an increase in the use of latex gloves among healthcare workers. This increase has in turn resulted in high reports of skin reactions to latex among this population [75]. OSHA has estimated that 8% to 12% of healthcare workers may be sensitive to latex [76]. Most reactions are not serious and can be prevented. However, for some individuals, exposure to latex may be life threatening. Sensitivity to latex has been found to persist for as long as five years beyond discontinued use among some healthcare workers [77].

Individuals with a high risk of developing a latex allergy include healthcare workers, those with a history of allergies, and anyone who frequently comes in contact with latex products. Latex allergies commonly begin with a rash on the hand after wearing a latex glove. The three main types of reactions are irritant contact dermatitis, allergic contact dermatitis, and hypersensitivity immune system response [78].

Irritant contact dermatitis is a nonallergic, inflammatory response characterized by dry, itchy, flaky skin (usually on the hands) with cracks and sores. It may be caused by skin irrita-

tion from wearing gloves, exposure to other products and chemicals in the workplace, or repetitive hand washing and drying. Powders added to gloves, combined with sweat, may aggravate existing dermatitis. Wearing cotton liners, choosing a nitrate or vinyl glove, and avoiding the use of gloves when possible may provide relief for the dermatitis [78; 79].

Allergic contact dermatitis, also referred to as delayed hypersensitivity or chemical sensitivity dermatitis, is not easily distinguished from irritant contact dermatitis because the reactions resemble those caused by poison ivy. However, in spite of the similar symptoms, allergic contact dermatitis is caused by a cellular immune response in the body, activated by repeated exposure to the allergen, latex [78; 79].

Hypersensitivity immune system response is an actual latex allergy. This type of response is characterized by pruritus, inflammation, swelling, hives, and wheezing, usually immediately after exposure. Even low levels of exposure may trigger allergic reactions in some sensitized individuals. The response may progress to anaphylaxis in susceptible individuals, which is evidenced by hypotension, confusion, and extreme airway constriction. Individuals experiencing anaphylactic shock require immediate treatment. Allergy to latex should be suspected in any individual who develops specific symptoms, such as nasal irritation, hives, shortness of breath, wheezing, or unexplained shock [78; 79].

Changing to a nonlatex glove to eliminate reactions may not work because some nonlatex gloves may still contain chemical sensitizers. Gloves labeled hypoallergenic do not necessarily eliminate allergic reactions. The use of hypoallergenic gloves may minimize the likelihood of an allergic reaction but will not eliminate the possibility of a reaction. Additional protective measures recommended by NIOSH include [78]:

- Good housekeeping practices in the workplace to minimize dust that contains latex
- Employee education and training on latex allergy
- Periodic screening for high-risk employees
- Employer evaluation of prevention strategies

Employers should take all measures to find the kind of glove that may be worn safely by employees without exposing them to the external hazards of harmful material or the internal hazards of a reaction to the equipment providing protection [9].

TRAINING AND EDUCATION

Employee training and education are emphasized throughout the OSHA standards. Employers should consider the following components when developing a training program [9]:

- Designate a person responsible for conducting the training
- Design a specific format for the training program (e.g., audiovisuals on classroom instructions)
- Identify the important elements of the training program
- Develop and implement procedures to train new employees at the time of their initial assignments

When OSHA visits a facility, it expects the facility to be able to produce a written training program that addresses all aspects of safety, including fire safety, hazard communication, and disaster plans. OSHA will additionally expect employers to provide proof of employee education (e.g., lesson plans, inservice dates, sign-in sheets, and education evaluations). The Bloodborne Pathogens Standard requires employee education to occur immediately on hire and at least annually thereafter. Documentation should reflect that this has occurred [80].

LEGAL ISSUES

In today's litigious society, any facility is at risk for lawsuits. If an employee is injured on the job and able to show that a lack of safety equipment or training or unsafe conditions caused the injury, the facility is at risk for litigation. Lack of proper treatment of the injury and continuing unsafe conditions might also contribute to an employer's risk for litigation.

Attorneys who investigate incidents of employee injury will expect to be able to examine available documentation, including incident reports, medical records that include treatment of the employee, and training and education records. Safety conditions that might have caused the injury, any perceived unsafe conditions that exist, the safety committee minutes that show how the facility has addressed the condition, and further actions to correct the condition may also be reviewed.

Knowing what the standards prescribe for a particular facility and properly documenting all programs (e.g., written plans, the education program, or follow-up of existing conditions) will provide the employer with the best protection possible. Employers should carefully read the standards and provide training seminars and other relevant employee resources to ensure that their facilities are in compliance.

SURVEYS, COMPLIANCE, AND DOCUMENTATION

CONSULTATION

The General Duty Clause mandates employers to furnish employees with a workplace that is free from recognized hazards that may cause death or serious physical harm. To avoid citations, employers should comply with standards. This may be accomplished by employing an internal safety staff or by employing an outside private consultant. Free consultations are available to small businesses with no more than 250 employees at one site and no more than 500 employees total at all sites [81]. Consultation may be invaluable for small, rural facilities.

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Requests for the OSHA consultation service may be made in person, over the telephone, or in writing. The consultation will include an opening conference and an inspection to examine building structure, air and noise monitoring procedures, PPE, job training, safety and health programs, injury and illness records, and hazard communication procedures [81].

After the inspection has been completed, a closing conference will occur during which potential problems will be discussed. If the consultant has deemed a condition to be an "imminent danger," the employer should take immediate action to correct the condition. If a condition is deemed to be a "serious violation" (according to OSHA regulations), the consultant and employer will together devise a corrective action plan. The consultant may also recommend increased training and monitoring, safety promotion, and accountability procedures [81].

Employers may benefit from a one-year exemption from inspection (not including inspections prompted by employee complaints or fatalities) if all identified hazards have been corrected and the employer has instituted a comprehensive safety program. The consultant will not issue citations, impose penalties, routinely report violations to OSHA, or guarantee that a worksite will pass an OSHA inspection [81].

SURVEYS/OSHA INSPECTIONS

An OSHA inspector will visit a facility to conduct either a programmed inspection or an unprogrammed inspection. A programmed inspection is generally scheduled due to OSHA's selection criteria, such as injury/death rates, toxic substance exposure, and a high number of lost workdays for the industry type. An unprogrammed inspection occurs when an employee formally complains to OSHA about either a potentially unsafe working condition or an imminent danger at the workplace [82].

Employers should understand the limits of the OSHA inspection. For example, employers may voluntarily consent to an inspection but they are not required, according to the Fourth Amendment to the U.S. Constitution, to admit inspectors who do not present a warrant [83]. Although the additional time it takes OSHA to secure a warrant may allow the employer to resolve immediate and critical compliance issues, employers who proactively create and use area-specific self-inspection checklists may help minimize hazards and avoid compliance violations [83].

OPENING CONFERENCE

During the opening conference, the OSHA inspector will explain the purpose of the visit, provide OSHA pamphlets, request identification of trade secrets, and review the employer's records. Employers are not required to provide records that are not specified by the warrant. Records and programs that are usually specified include the written hazard communication and safety programs, the injury/illness log, and hazard exposure records. The results of the records review determine whether a comprehensive workplace inspection is needed. A short tour of the facility may also be conducted [81; 82; 83].

TOUR OF THE FACILITY

The OSHA inspector and any accompanying representatives determine the route and duration of the tour; however, the inspector should always be accompanied by a representative of the employer. If the inspector wishes to see a specific part of the facility, the employer's representative should escort the inspector directly there. During the tour the inspector may talk with employees or meet with them in private (with their permission), take notes, make instrument readings, and take photos or videos. If the inspector takes notes or measurements or uses a camera, the employer should do the same and should also record everything that has happened during the tour, noting the time and date. If the inspector has identified potential problems (even when the employer agrees and immediately corrects the problems), the inspector will likely issue citations and fines [82].

CLOSING CONFERENCE

The purpose of the closing conference is to [82]:

- Advise the employer about conditions observed in the facility
- Obtain further information
- Relate possible citations, appeal rights, and associated time limits
- Answer the employer's questions

If violations are voluntarily and immediately corrected, the employer should make certain that the inspector acknowledges this before leaving the facility. This should be confirmed in the presence of a witness, with the date and time noted.

The U.S. Department of Labor will notify the employer, in writing, about any citations or penalties. The employer then has 15 working days to either pay the penalties or to contest the citations, penalties, or both. If the employer fails to contest the citations, the penalties are final [82; 83].

In 2015, Congress enacted legislation requiring federal agencies to adjust their civil penalties to account for inflation, resulting in a 78% increase in penalties. The adjusted penalties took effect August 1, 2016. Since then, the maximum penalty has been adjusted for inflation each year [82].

As of January 2023, the violations, and their associated penalties, that have been structured for the workplace include [41; 82]:

- **Willful violation**: Given when the employer intentionally and knowingly commits a violation. The penalty may be up to $156,259 per violation. The minimum willful penalty is $5,000. A willful violation that causes an employee's death may result in a fine of up to $250,000 (or $500,000 if the employer is a corporation), or imprisonment up to six months, or both. A second conviction doubles the possible term of imprisonment.

- **Serious violation**: Given when the employer is aware of a hazard that may result in death or serious physical harm (e.g., not locking out or tagging out equipment). The fine may be up to $15,625for each violation.
- **Other than serious citation**: Given when violations are not likely to cause death or serious harm (e.g., lack of labeling a biohazard). The fine may be up to $15,625.
- **Failure to abate**: Given when the employer has not corrected a previously issued OSHA citation and the abatement date has passed or when the employer has not timely complied with interim measures involved in a long-term abatement. The fine may be up to $15,625 per day.
- **Repeat violation**: Given when a violation has not been corrected. The fine may be as much as $156,259 for each such violation within the previous three years.

To plan for an OSHA inspection, employers should understand the law (consult *Code of Federal Regulations*, title 29, sec. 1910), know what the inspector is likely to do, develop and implement a self-inspection program, and ensure that safety and health training programs are in place.

GLOSSARY OF ACRONYMS

AIDS: Acquired immune deficiency syndrome

APIC: Association for Practitioners in Infection Control and Epidemiology

BRI: Building-related illness

CDC: Centers for Disease Control and Prevention

CFR: Code of Federal Regulations

HBV: Hepatitis B virus

HCV: Hepatitis C virus

HEPA: High-efficiency particulate air

HHE: Health Hazard Evaluation

HIV: Human immunodeficiency virus

HVAC: Heating, ventilating, and air conditioning

IEQ: Indoor environmental quality

IV: Intravenous

MRI: Magnetic resonance imaging

NIOSH: National Institute for Occupational Safety and Health

NRC: Nuclear Regulatory Commission

OSHA: Occupational Safety and Health Administration

OSH Act: Occupational Safety and Health Act

OSHRC: Occupational Safety and Health Review Commission

PPE: Personal protective equipment

RACE: Rescue, alert, confine, extinguish

RMW: Regulated medical waste

SBS: Sick building syndrome

SDS: Safety Data Sheet

STS: Standard threshold shift

TB: Tuberculosis

UP: Universal Precautions

VDT: Video display terminals

RESOURCES

The most important resource is the *Code of Federal Regulations*, title 29, sec. 1910. Additional resources include:

Association for Professionals in Infection Control and Epidemiology
1400 Crystal Drive, Suite 900
Arlington, VA 22202
(202) 789-1890
https://apic.org

National Institute for Occupational Safety and Health (NIOSH)
Patriots Plaza 1
395 E Street, SW, Suite 9200
Washington, DC 20201
(800) 232-4636
https://www.cdc.gov/niosh

National Institute of Environmental Health Sciences (NIEHS)
P.O. Box 12233, MD K3-16
Research Triangle Park, NC 27709-2233
(919) 541-3345
https://tools.niehs.nih.gov/wetp

U.S. Department of Labor, Bureau of Labor Statistics
Postal Square Building
2 Massachusetts Avenue, NE
Washington, DC 20212-0001
(202) 691-5200
https://www.bls.gov

U.S. Department of Labor, Occupational Safety and Health Administration
200 Constitution Avenue NW
Washington, DC 20210
(800) 321-6742
https://www.osha.gov

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

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COURSE TEST - #51234 OSHA AND HEALTHCARE FACILITIES

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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1. **The Occupational Safety and Health Act established all of the following federal agencies, EXCEPT:**
   - A) *Centers for Disease Control and Prevention (CDC)*
   - B) *Occupational Safety and Health Administration (OSHA)*
   - C) *National Institute for Occupational Safety and Health*
   - D) *Occupational Safety and Health Review Commission*

2. **The Bloodborne Pathogens Standard requires facilities to implement a(n)**
   - A) *control plan.*
   - B) *TB control plan.*
   - C) *exposure control plan.*
   - D) *None of the above*

3. **How many new tuberculosis (TB) cases reported occurred in the United States in 2021?**
   - A) *7,882*
   - B) *136,520*
   - C) *1.3 million*
   - D) *13 million*

4. **The CDC has recommended that protective devices used in healthcare settings be**
   - A) *certified by CDC/NIOSH.*
   - B) *properly fitted to the wearer.*
   - C) *a nonpowered particulate filter respirator or a powered air-purifying respirator.*
   - D) *All of the above*

5. **Which of the following is considered to be medical treatment, recordable on the *OSHA 300 Log*?**
   - A) *Application of sutures*
   - B) *Administration of immunizations*
   - C) *Physical therapy or chiropractic treatment*
   - D) *All of the above*

6. **How many workers were fatally injured by assault and/or violent attack in the workplace in 2021?**
   - A) *761*
   - B) *1,250*
   - C) *6,430*
   - D) *9,500*

Test questions continue on next page ➔

7. **One way to determine if a chemical is hazardous is by consulting a list provided by the**
   A) *OSHA Toxic and Hazardous Substances.*
   B) *American Conference of Governmental Industrial Hygienists.*
   C) *National Toxicology Program Annual Report on Carcinogens.*
   D) *All of the above*

8. **The greatest proportion of hazardous waste generated by healthcare facilities is in the form of**
   A) *sharps.*
   B) *genotoxic waste.*
   C) *infectious and anatomic waste.*
   D) *chemicals and pharmaceuticals.*

9. **Radiation badges are required to monitor employees likely to receive a dose in excess of what percentage of the allowed quarterly exposure limits?**
   A) *10%*
   B) *25%*
   C) *40%*
   D) *75%*

10. **If a chemical or blood spill occurs, a factor to be considered is**
    A) *spill location.*
    B) *physical and hazardous properties of the material.*
    C) *quantity of the chemical or biologic substance released.*
    D) *All of the above*

11. **To ensure a successful fire safety program, the fire marshal should inspect the facility**
    A) *weekly.*
    B) *monthly.*
    C) *quarterly.*
    D) *annually.*

12. **A familiar term for an indoor air quality problem is**
    A) *sick air syndrome.*
    B) *sick building syndrome.*
    C) *indoor contamination syndrome.*
    D) *contaminated building syndrome.*

13. **An area of concern for operating room air quality is the presence of**
    A) *oxygen.*
    B) *iron oxide.*
    C) *nitrous oxide.*
    D) *All of the above*

14. **An example of an ergonomic risk factor is**
    A) *prolonged, awkward working positions.*
    B) *recurrent heavy lifting, pushing, or pulling.*
    C) *tasks that require prolonged, repetitive movements.*
    D) *All of the above*

15. **Which of the following reactions to latex is the most serious in terms of medical sequelae?**
    A) *Anaphylaxis*
    B) *Allergic contact dermatitis*
    C) *Irritant contact dermatitis*
    D) *Hypersensitivity immune system response*

16. **An area a lawyer might investigate in connection with an employee incident could be**
    A) *safety conditions.*
    B) *employee medical records.*
    C) *training and education records.*
    D) *All of the above*

17. **To qualify for a free OSHA consultation, a facility must have no more than**
    A) *100 employees at one site.*
    B) *250 employees at one site.*
    C) *500 employees at one site.*
    D) *750 employees at one site.*

18. **A condition requiring immediate action that is found during a consultation is called a(n)**
    A) *"safety violation."*
    B) *"unsafe condition."*
    C) *"imminent danger."*
    D) *"identified hazard."*

19. **If an inspector arrives at your facility without a warrant and you refuse to allow him in, you are availing yourself of your**
    A) *right to privacy.*
    B) *employee rights.*
    C) *Fourth Amendment right.*
    D) *Fifth Amendment right.*

20. **A violation that the employer intentionally and knowingly commits is referred to as**
    A) *repeat.*
    B) *willful.*
    C) *serious.*
    D) *other than serious.*

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Diagnosing and Managing Headaches

Audience
This course is designed for dental professionals who may encounter patients who complain of headaches.

Course Objective
Given the common and difficult diagnoses associated with headaches, the purpose of this course is to educate the dental professional about the epidemiology and treatment of the various types of headaches so they may make early and accurate diagnoses, begin effective treatment, and/or refer patients to a specialist when necessary.

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

1. Illustrate the epidemiology and economic impact of headaches.
2. Demonstrate the pathophysiology of headaches.
3. Recognize the signs and symptoms of headaches, focusing on history and physical exam, and discuss the role of an interpreter in assessing non-English-proficient patients.
4. Identify the appropriate imaging modalities for headaches and their specific indications.
5. Describe the epidemiology, diagnosis, and treatment of migraine headaches.
6. Differentiate the signs and treatments for cluster and tension headaches.
7. Identify the secondary causes of headaches.
8. Compare and contrast the differences between acute and chronic headaches.
9. Recognize indications for specialist referral.
10. Analyze medico-legal issues surrounding headache diagnosis and management.

Faculty
John J. Whyte, MD, MPH, is currently the Chief Medical Officer at WebMD. In this role, he leads efforts to develop and expand strategic partnerships that create meaningful change around important and timely public health issues. Previously, Dr. Whyte was the Director of Professional Affairs and Stakeholder Engagement at the FDA's Center for Drug Evaluation and Research and the Chief Medical Expert and Vice President, Health and Medical Education at Discovery Channel, part of the media conglomerate Discovery Communications. (A complete biography can be found online at NetCE.com.)

Faculty Disclosure
Contributing faculty, John J. Whyte, MD, MPH, has disclosed no relevant financial relationship with any product manufacturer or service provider mentioned.

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INTRODUCTION

Headaches are considered one of the most common types of pain and one of the most frequent causes of presentation to physician offices and clinics. Nearly 50 million adults seek treatment from physicians each year related to headache pain [1; 2]. As a result, headaches represent a significant cause of morbidity. It has been estimated that headaches result in billions of dollars in expenses, job absenteeism, and decreased annual productivity. They also result in decreased quality of life. Coping with a chronic headache disorder may predispose the individual to other illnesses. For example, depression is three times more common in people with migraine or severe headache than in healthy individuals [3]. A clear understanding of the types and causes of headache pain is essential for physicians and other healthcare providers to adequately address and manage the patient with headaches.

Headaches may be categorized as either primary or secondary. Most headaches are primary in origin—this includes migraine, cluster, and tension headaches. Secondary headaches, which are secondary to another cause (e.g., trauma, infections) are fewer in number; however, because most of the secondary causes have been well studied, secondary headaches generally can be effectively treated. Before assuming a diagnosis of primary headache, it is important to screen for headaches secondary to an underlying cause. Although anecdotal reports abound of individuals who have been diagnosed with a brain tumor following onset of headaches, one should bear in mind that intracranial malignancy is uncommon and a highly unlikely diagnosis when the patient's headaches are intermittent and nonprogressive in severity. Many imaging technologies have become available to help in the diagnosis of headaches. These include computed tomography (CT), magnetic resonance imaging (MRI), magnetic resonance angiography (MRA), and nuclear medicine studies. It is important that physicians understand the indications and limitations of each test so that patients are not put through unnecessary and/or costly procedures.

Several therapies are available for managing headaches. These include pharmacologic medications and nonpharmacologic interventions (e.g., alternative medicines and therapies). There are also new approaches to preventing headaches for those patients who are experiencing chronic headaches. Physicians and other clinicians should familiarize themselves with the latest evidence regarding diagnosis and management of headaches. The third edition of the International Headache Society (IHS) Classification of Headache Disorders provides clinical criteria for the diagnosis of specific headache types [43]. The IHS guidelines have been used throughout this course; however, it should be noted that changes to these specific criteria may be made in the future.

The following case study will be referenced throughout the text to illustrate the challenges of treating a patient who presents with a headache.

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Mrs. T is an African American woman, 68 years of age, with a past medical history significant for type 2 diabetes, hypertension, hyperlipidemia, osteoarthritis, and coronary artery disease. She presents to the clinic with a chief complaint of "headache." Mrs. T describes the headache as a dull pain that has been intermittent over the past several weeks. It is not localized to any particular area, but rather seems to be more diffuse. It does not radiate to the neck, back, or any other parts of the body. It first started about a month ago.

She has taken ibuprofen and aspirin sporadically with some relief. As the headache has been persistent over the past few weeks, she thought it was important to come in and be evaluated. She states that she has been looking up information on headaches on various health websites and she now thinks she needs a "brain scan." She has no prior history or family history of migraines; she does report a history of what she considers to be some tension-type headaches in the past few years. She believes these are due to stress at work, as they usually resolve within a day with relaxation, rest, and ibuprofen. She has never been evaluated for these episodes. The patient also remarks that over the past several days she has occasionally felt a little dizzy and light-headed, but those symptoms have largely resolved. She denies any confusion or loss of consciousness, but her daughter, who accompanies her to the clinic, states that Mrs. T had an episode about a week ago where she seemed disoriented in the morning for approximately an hour. According to the daughter, "Lately, Mom sometimes seems in a fog."

EPIDEMIOLOGY

Almost everyone experiences a headache at some point in their life. In fact, approximately three-fourths of all adults in the United States experience some type of headache each year. The prevalence of headache varies by gender, with women having a greater incidence of headaches than men. It has been estimated that nearly nine out of ten women, and seven out of ten men, have a headache at least once during her/his lifetime [4]. In developed countries, tension-type headache is more common in women, usually by a factor of about two to one [3].

In most cases, headaches are transient and benign. People simply treat the headache with either rest and/or relaxation, or they utilize various over-the-counter analgesics. In fact, the public spends more than $2 billion annually on over-the-counter medications to treat headaches [5]. Less than 5% of adults with headaches seek medical attention. Even with this small percentage, however, headaches are one of the most common complaints addressed by primary care physicians and clinicians and represent the reason for nearly 3% of all visits to the emergency department [1].

People typically seek medical care when they have increased headache frequency, an unusually intense headache, or persistent symptoms. Headaches can be one of the most difficult and challenging disorders to accurately diagnose and treat, so it is important for physicians and other clinicians to become familiar with the latest evidence on headache diagnosis and management.

ECONOMICS

Headaches are a costly condition. It has been estimated that headaches are responsible for nearly 30 million days of lost productivity, both in terms of lost days at work, as well as decreased effectiveness while at work. Headaches cost an estimated $18 billion in both direct and indirect expenditures yearly. Most costs are indirect as many headache sufferers do not seek medical attention [2; 7; 8; 9].

Although migraine is more disabling than tension-type headache, tension-type headache is more common. Each year, more than 70% of the global population has episodic tension-type headache and 1% to 3% has chronic tension-type headache (i.e., headache occurring at least 15 days per month). The World Health Organization (WHO) has confirmed that the problem of lost productivity in the workplace is worldwide, with headache disorders being the third most common cause of years lost to disability and migraine alone being the sixth most common cause [2; 3; 6; 10].

Headaches also represent a significant socioeconomic burden. Along with lost and reduced work, headaches also affect other activities, such as one's ability to perform effectively in school or enjoy time with family and friends. In essence, headaches reduce the quality of life.

BASIC PATHOPHYSIOLOGY

The pathophysiology of headaches is multifactorial and complex. When lesions of the brain cause headache (e.g., mass, fluid, hemorrhage), they do so by involving pain-sensitive structures inside the skull, such as arteries at the base of the brain, the dura area blood vessels, and certain cranial nerves (e.g., CN V, VII, IX, X) that carry pain fibers. In addition, the external structures of the head are all pain-sensitive and give rise to a variety of headaches.

TYPES OF HEADACHES

As noted, headaches may be categorized as either primary or secondary in nature. Primary headaches are pure headache syndromes, meaning they are self-originating and not triggered or produced by other disorders. Primary headaches include migraine, cluster, and tension-type headaches [11]. Nearly 90% of all headaches are primary in nature [12]. Although migraine headaches receive a great deal of press in medical and lay literature, of the primary headaches, tension-type is the most common, followed by migraines, and then cluster [13]. It is important to note that primary headaches are diagnosed only when other underlying disease processes have been eliminated.

Secondary headaches, as the name indicates, occur secondary to another cause (i.e., they are a symptom of other diseases). These may include vascular, traumatic, neoplastic, infectious, pressure, and metabolic disorders [11]. Secondary headaches account for only 10% of headaches. Although some causes of secondary headache are common, others are important

to recognize because they are dangerous and may require specific treatment [12]. For example, patients with chronic tension headaches may present with an epidural hematoma, and patients with migraine may have a brain tumor. Primary and secondary headaches should not be considered mutually exclusive when evaluating a patient with headache. It is helpful to consider secondary headaches in terms of etiologic categories. Some of the more common causes of secondary headaches are as follows [13]:

Traumatic

- Epidural hematoma
- Subdural hematoma

Vascular

- Subarachnoid hemorrhage
- Giant cell arteritis
- Arterial dissection
- Stroke

Neoplastic

- Primary brain tumor
- Metastatic brain tumor

Infectious

- Meningitis
- Encephalitis
- Sinusitis
- Abscess

Pressure

- Hypertension
- Idiopathic intracranial hypertension

Metabolic

- Toxic ingestions (e.g., carbon monoxide, lead poisoning)

Other

- Syringomyelia
- Dental and myofascial
- Cervicogenic
- Medication overuse
- Herbal medications

WORK-UP OF HEADACHES

The work-up of headaches includes the patient's history and a thorough physical examination and may also include laboratory studies, imaging procedures, and a lumbar puncture.

ASSESSING HEADACHES IN PATIENTS WITH THE ASSISTANCE OF AN INTERPRETER

As a result of the evolving demographics in the United States, interaction with patients for whom English is not a native language is inevitable. Because patient history is such a vital aspect of the assessment of headaches, it is each practitioner's responsibility to ensure that information and instructions are explained in such a way that allows for patient understanding. 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. Many view interpreters merely as neutral individuals who communicate information back and forth. However, another perspective is that the interpreter is an active agent, negotiating between two cultures, and assisting in promoting culturally competent communication and practice [15]. Interpreters who are professionally trained have covered aspects of ethics, impartiality, accuracy, and completeness [16]. They are also well-versed in interpreting both the overt and the latent content of information without changing any meanings and without interjecting their own biases and opinions [16]. Furthermore, knowledge about cross-cultural communication and all the subtle nuances of the dynamics of communicating in a mental health or general health setting is vital [17].

In this multicultural landscape, interpreters are a valuable resource to help bridge the communication and cultural gap between clients/patients and practitioners. Interpreters are more than passive agents who translate and transmit information back and forth from party to party. When they are enlisted and treated as part of the interdisciplinary clinical team, they serve as cultural brokers, who ultimately enhance the clinical encounter. In any case in which information regarding diagnostic procedures, treatment options, and medication/treatment measures is being provided, the use of an interpreter should be considered.

HISTORY

As with any disease, history-taking is critical in determining the correct diagnosis. The goals of history taking are to classify the headache type(s) and screen for secondary headache. An inadequate history is the probable cause of most misdiagnoses of the headache type [11; 18; 19].

It is important to focus on the following characteristics when interviewing a patient who presents with a headache [13; 20]:

Position/Location

- Where on the head does the pain occur?
- Is the headache unilateral or bilateral?
- Does the pain radiate anywhere (e.g., neck, back, jaw)?
- Is the face involved?

Quality/Character

- What does the headache feel like? Is it pounding, throbbing, aching, piercing, squeezing, etc.?

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- How intense is the headache on a scale of 1 to 10? Is it mild, moderate, severe, or incapacitating? Is it the worst headache one has ever had?

Frequency/Duration

- How often do the headaches occur?
- How long do they last?
- What time of day do the headaches occur?
- What time of year do the headaches occur?
- If the headaches are recurrent, what is the interval between headaches?
- What is the minimum, maximum, and usual duration?
- How long has this particular type of headache been affecting the patient?

Associated Factors

- Is there a fever?
- Any nausea, vomiting, congestion, flushing, arthralgia, depression, weight loss, etc.?
- Is there photophobia?
- Any neck stiffness?
- Any dental problems?

Aggravating Factors

- What makes the headache worse?
- Does head or body position make the headache better?
- Does coughing, sneezing, or bending affect the headache?
- Is the headache associated with menses?

Alleviating Factors

- What makes the headache better?
- Does ice or compression minimize the headache?
- Does a dark, cool room make it better?
- How does movement affect the headache?
- What types of medications have been tried? Have they been effective?

Environmental Exposures

- How does the environment affect the headache? For example, does exposure to bright light, loud noises, odors, cigarette smoke, temperature, foods, or alcohol affect the headache?
- Does the patient work around any metals or an industrial plant?

Associated Neurologic Symptoms

- Any visual, sensory, or motor abnormalities?
- Any dizziness or confusion?
- Any loss of consciousness?
- Is there any weakness?
- Does the patient exhibit ataxia?

Current and Past Medical History

- At what age did headaches first occur?
- What other medical conditions does one currently have (e.g., coronary artery disease, hypertension, depression, psychiatric disorder)?
- What are the current medications, including over-the-counter medications as well as supplements and herbal medicines? Is caffeine ingested on a regular basis?
- What medications have been recently terminated?
- Any recent trauma?
- Any recent falls?

Family History

- Does anyone else in the family have these types of headaches?
- Do any diseases or other medical conditions (e.g., cancer, stroke, diabetes, hypertension) run in the family?

Social History

- How are matters at home and at work?
- Is there any significant current stress?
- Are any illicit drugs used?
- Does the patient engage in unprotected sexual intercourse? In the past?

The above sample list of questions may seem daunting, especially in the context of a brief office visit. However, it is critical that a detailed history be obtained. It may be more efficient to have a questionnaire available for patients to fill out while they are waiting, or even prior to the office visit.

Upon further questioning, Mrs. T denies any fever, nausea, or vomiting. She denies depression or weight loss. She has not had visual disturbances. She does not recall any environmental exposures. Her current medications include metformin, lisinopril, simvastatin, and celecoxib. She remarks that her job is going quite well, and she does not feel particularly stressed from work. She works as a senior account manager at a consulting firm.

She has not had any change in medications and does not use any herbs or supplements. She drinks two cups of coffee a day, and there has been no recent change in her coffee consumption. There is neither family history of headaches nor family history of cancer. Both parents died of heart disease. She does note that she recently tripped and fell outside (almost a month ago) while playing with her grandson but denies any serious consequences from the fall other than a sore left wrist. She denies any residual weakness. She notes that she does not feel "quite 100%" but does not feel confused or "in a fog."

PHYSICAL EXAM

A thorough physical exam is necessary for all patients who present to either the physician's office or the emergency department with a headache. The goal of the history and physical

evaluation is to rule out findings that may suggest a headache of secondary pathology [13; 18; 19; 20; 21; 22]. All parts of the physical exam are important, but consider paying particular attention to the following:

- Vital signs: Carefully check blood pressure, respirations, heart rate, and temperature. Determine whether the patient is orthostatic.
- Skin: Observe color and texture, and carefully inspect for any rashes, petechiae, bruising, or lesions.
- Head, eyes, ears, nose, and throat (HEENT): Note the size, symmetry, and shape of the head. Inspect for bruises, masses, and/or nodules while palpating the head and neck. Palpate the temporal arteries. Be sure to auscultate for bruits over the scalp, eyes, and carotids. Assess the temporomandibular joint for clicking. Check for nuchal rigidity. Palpate the thyroid gland. Determine any decreased arterial pulsations. Check for sinus tenderness, especially frontal and maxillary areas.
- Eyes: Check visual function and extra-ocular movements, specifically looking for ptosis or miosis. Perform fundoscopy to evaluate disc margins, papilledema, and any evidence of retinal hemorrhages.
- Oral cavity: Check for decay, abscesses, loose teeth, etc.
- Cardiac: Listen carefully for murmurs or abnormal heart sounds.
- Extremities: Assess thoroughly range of motion.
- Neurologic: Assess all cranial nerves, muscle strength, reflexes, and cerebellar function. Consider performing the Mini-Mental Status Exam.

WARNING SIGNS OF SIGNIFICANT DISEASE

Although most headaches are benign, clinicians should be aware of the following "red flags" or warning signs that should prompt an immediate and exhaustive work-up and possible referral to an appropriate specialist for further assessment [5; 13; 20; 21; 23]:

- Onset in or after middle age (>50 years of age)
- Sudden onset, rapid time to peak headache intensity (i.e., seconds to five minutes)
- First or worst sudden, severe headache
- Accelerating pattern, progressively worsening
- Fever
- Seizure
- Change in level of consciousness
- Abnormal neurologic, physical, or systemic findings
- New headache in patients with cancer, immunosuppression, or pregnancy

On physical exam, Mrs. T's blood pressure is 135/82 mm Hg, heart rate is 78 BPM, respirations are 18/minute, temperature is 98 degrees, height is 5'5", and weight is 135 lbs. The physical exam is largely unremarkable. There are no masses appreciated, no petechiae noted, no sinus pain or tenderness, no scalp tenderness, and no neck stiffness. There are no visual defects and no focal neurologic deficits with the exception of minimal decrease in muscle strength in lower extremities bilaterally. She scored a 26 (maximum score: 30) on the Mini-Mental Status Exam, with some difficulty remembering three objects as well as performing serial 7s.

Given the patient's age and the fact that the headache has been persistent, a clinician should order a more extensive work-up. The patient seems to be dismissive of the minor fall, but this should be explored further. Although it would be easy to attribute this headache complaint to a tension-type headache, secondary causes should be excluded.

LAB STUDIES

In general, most headache diagnoses will be made based upon the history and physical exam [13; 20]. However, laboratory studies may aid in the diagnosis. For example, clinicians may want to measure basic serum chemistries, complete blood count with differential, erythrocyte sedimentation rate (ESR), liver function tests, and thyroid function tests. These tests will provide a general overview of the patient's health and help guide diagnosis and treatment choices.

A resting electrocardiogram (EKG) should be considered if the history or cardiac exam is abnormal or if the patient has signs of an arrhythmia. Some headaches may have a cardiac etiology, and some treatments for headaches may have an impact on cardiac function.

Mrs. T's laboratory tests are as follows:

Na 138; Cl 100; K 4.0; CO2 26; BUN 15; Creatinine 0.9; Glucose 125; Hgb 12.5; Hct 38; WBCs 5,000; Platelets 200,000; TSH 0.9; T3 120; ALT 30; AST 32; Alk phos 70; Total bili 1.0; LDH 120; GGT 22; ESR 35

EKG: normal sinus rhythm at 78 BPM; left axis deviation; evidence of old anterior infarct. No acute changes.

ELECTROENCEPHALOGRAM

Electroencephalogram (EEG) is not frequently used and not recommended in the routine work-up of headaches. It has minimal value in determining any structural causes of headaches. It may be useful, however, when patients present with encephalopathy, focal neurologic deficits, atypical aura symptoms, or altered consciousness [21; 22; 24].

LUMBAR PUNCTURE

In general, lumbar puncture is indicated when there is clinical suspicion of central nervous system (CNS) infection, cancer, hemorrhage, or conditions that result in a change in cerebrospinal fluid (CSF) pressure; it is not recommended in the routine evaluation of headaches [13; 21; 23]. Examples of indications include meningitis, encephalitis, idiopathic intracranial hypertension, meningeal carcinomatosis, or subarachnoid hemorrhage [5; 25]. If an intracranial mass lesion is suspected, or if the patient has papilledema on funduscopic exam, lumbar puncture should be deferred until after CT evaluation to reduce the possibility of cerebellar herniation [23; 25; 26].

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When lumbar puncture is performed, it is helpful to measure the opening pressure and perform a complete analysis of CSF, including glucose, protein, and differential blood count. In addition, opening pressure, supernatant color, and latex agglutination are sometimes useful. CSF examination is helpful in diagnosing subarachnoid bleeding, infection, and high and low CSF pressure syndromes [27]. It is important to avoid a traumatic tap. Such a tap, which leads to bleeding, could make it more difficult in establishing the diagnosis of subarachnoid hemorrhage [5]. In addition, the procedure itself may actually cause a headache [28; 29]. This usually occurs 48 to 72 hours following the procedure if too much fluid has been removed [30].

IMAGING

In general, routine neuroimaging, such as CT, MRI, MRA, or positron emission tomography (PET), of people with headaches and normal physical examinations has a very low yield and is not considered to be cost-effective. However, it is important to remain cognizant of the strengths and weaknesses of each imaging modality when considering and ordering such studies [31; 32]. MRI may be more sensitive than CT for identifying clinically insignificant abnormalities. However, MRI may not be more sensitive for identifying clinically significant pathology that is relevant to the cause of headache [22].

CT scans may be performed either with or without contrast. Unless there is a contraindication to the use of contrast agents, most scans are performed with contrast in the diagnostic work-up of headaches. A contrast-enhancing CT scan can be an effective test for identifying several serious lesions that may be causing headaches [33; 34].

CT is usually obtained in the setting of trauma or the abrupt onset of headache [27]. Primary indications include acute head trauma, suspected acute intracranial hemorrhage, mental status changes, headache, acute neurologic deficits, suspected intracranial infection or hydrocephalus, brain herniation, and suspected mass tumor. It may also be used in cases in which MRI is primarily indicated but unavailable, contraindicated, or delayed [34].

According to the American College of Radiology, the imaging mode of choice for patients who present with sudden onset of severe headache ("worst headache of one's life" or "thunderclap headache") that reaches maximal severity within one hour is CT without contrast.

(https://acsearch.acr.org/docs/69482/Narrative. Last accessed August 15, 2023.)

Level of Evidence: Expert Opinion/Consensus Statement

In general, CT scans are widely available, quickly performed, and well-tolerated by patients. The technology has been around for quite some time, and most patients are familiar with it [34]. In addition, there are "open" CT scanners that help minimize the feeling of claustrophobia some patients experience. This scan detects most space-occupying lesions such as brain tumors, subdural hematomas, and CNS abscesses. It can also show fluid from hydrocephalus and cerebral edema, and it can reveal bleeding and structural abnormalities such as some arteriovenous malformations. However, CT scanning can miss aneurysms, and it also does not provide adequate views of the sphenoid sinus. Adding "bone windows" on CT provides much better detection of skull fractures, especially as compared to plain films.

MRI is the diagnostic test of choice for most patients [27]. However, it is not as readily available as CT [34]. MRI is more sensitive for detecting lesions within the posterior fossa (specifically because of bony artifacts that limit CT's visualization), pituitary area, paranasal sinuses, and leptomeninges [34; 35]. It has also proven effective in identifying some otherwise occult tumors and infarcts. MRI is also more sensitive for detecting vascular abnormalities, although it is not as sensitive as CT in revealing early subarachnoid bleeding. In addition, special MRI images can evaluate problems with the orbit or optic nerve areas. When abnormalities of the cervical spine are suspected, MRI is the preferred imaging technique, especially compared to plain films. "Open" MRI scanners may be used to help diminish claustrophobia or to accommodate obese patients [34].

MRA is essentially an MRI of the blood vessels. MRA can be useful when suspecting circulatory causes of headache. For example, it provides increased sensitivity for unruptured aneurysms, as well as arterial stenosis. It is rarely useful, however, as a first-line study but rather helps to determine who may ultimately require an angiogram. This technology is not universally available. Many institutions also lack the appropriate staff for this procedure [32].

Plain films are rarely useful for diagnosing the etiology of headache unless CT and MRI are unavailable [34]. These films can demonstrate bony defects, such as fractures or other skeletal abnormalities, but usually there are other sources to obtain this data. In addition, the use of plain films for most cases of sinusitis is not usually cost effective in the work-up of headaches. In some institutions, nuclear medicine brain scans, or PET imaging scans, have been used with success as an ancillary procedure.

The choice of a specific imaging study depends on numerous factors, including clinical suspicion, availability of a given test, time necessary to perform the test, and the amount of time available to make a treatment decision. A patient should not undergo a test simply because it is available, but rather the information obtained from an imaging study should impact decision making. Ideally, one wishes to avoid additive tests,

such as a situation in which an MRI is a better study (e.g., for posterior fossa infarcts), but a CT is ordered because it is more rapidly available.

The U.S. Headache Consortium has issued guidelines relating to neuroimaging in patients with nonacute headache. The guidelines include three consensus-based general principles of management [22]:

- Testing should be avoided if the test results will not lead to a change in management.
- Testing is not recommended if the individual is not significantly more likely than anyone else in the general population to have a significant abnormality.
- Testing that normally may not be recommended as a population policy may make sense at the individual level, resources notwithstanding. For example, exceptions might be made for patients who are disabled by their fear of serious pathology.

The Consortium additionally has issued the following specific recommendations regarding neuroimaging [22]:

- Neuroimaging should be considered in patients with nonacute headache and an unexplained abnormal finding on the neurologic exam.
- Neuroimaging is not usually warranted for patients with migraine and normal neurologic examination. For patients with atypical headache features or patients who do not fulfill the strict definition of migraine, or have some additional risk factor(s), a lower threshold for neuroimaging may be applied.

Relating to CT and MRI, the panel did find that MRI appears to be more sensitive in finding white matter lesions and developmental and/or venous anomalies than CT. However, it noted that this difference had little clinical relevance, and thus did not make any recommendations on preferred testing methods in the evaluation of headaches [22].

PRIMARY HEADACHES

As noted earlier, there are three types of primary headaches: migraine, cluster, and tension-type (***Table 1***).

MIGRAINE HEADACHES

Migraine is the leading cause of recurrent headaches of moderate-to-severe intensity and the most frequent diagnosis in those who seek medical treatment. According to the 2016 Global Burden of Disease Study, an estimated 1 billion persons have a migraine headache each year and migraine is the second leading cause of disability worldwide; the affliction is greatest among girls/women between 15 and 45 years of age [6].

Migraine headache is a neurovascular condition triggered by neurologic stimuli that cause regional vasodilation, which in turn is interpreted by the brain as pain. It is important to realize that the event that initiates this cascade is not dilation of the blood vessels in the brain but rather a primary neural event. The exact neural event that is occurring is not completely understood, but it seems to involve the dysfunction of an ion channel in the brain stem that normally controls sensory input and exerts influences on cranial vessels [36]. It is now known that the trigeminal nerve and axonal projections to the intracranial vasculature (the trigeminovascular system) play a central role in the pathogenesis of migraine [192]. Neuronal afferent fibers, which innervate the meninges and its vessels, also project to areas within the brain. Activation of the trigeminovascular system releases vasoactive substances and inflammatory mediators, followed by further sensitization and then relay of nociceptive signals to cortical areas of the brain that subserve perception of pain [192]. Progress in understanding these components of pathogenesis has enabled development of mechanism-based, targeted therapies having increased clinical efficacy and fewer adverse effects. Migraine is believed to have a genetic basis; a family history of migraine is common, with the heritability estimated at 42% [3; 192].

Adults with migraine headache describe episodic attacks with pain of moderate-to-severe intensity that are often throbbing in quality, unilateral in position, and aggravated by physical exertion. Migraines are usually associated with nausea, vomiting, and sensitivity to light and sound. Nausea is the most common characteristic. The duration of these attacks, when not treated, may last anywhere from 4 to 72 hours [3].

The prevalence of migraine headache in developed countries is in the range of 16% to 25%, with women approximately two to three times more likely to have migraines than men [3; 6; 37]. The age-adjusted prevalence of migraine and severe headache in the United States has remained stable over two decades. According to a 2020 review of national health surveillance data, the prevalence of migraine is 15.9% among adults, highest among those 18 to 44 years of age (18.7%) [196]. The biological sex prevalence ratio also remains stable at 21% of women and 10.7% of men affected. The prevalence of migraine is highest among American Indian/Alaska Native individuals (22.1%) and lowest among Asian Americans (9.1%), compared with White, Black, or Hispanic individuals (15.6% to 16.3%),. The incidence of migraine attacks is highest among individuals 30 to 45 years of age, with declines thereafter for both biological sexes [3; 38].

During childhood, migraine is less common (1% to 4%) and equally prevalent among boys as girls. The prevalence of migraine increases during adolescence, predominantly among postmenarche girls. However, prevalence rates of migraine may be higher among children and adolescents than indicated by national health surveys. A systematic review of population-based studies found that the prevalence of migraine is 9.7% among female children and adolescents and 6% among male children and adolescents [197].

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CHARACTERISTICS OF PRIMARY HEADACHES			
Characteristics	**Migraine**	**Cluster**	**Tension**
Position	Unilateral	Unilateral	Bilateral
Quality	Throbbing, pulsating, pounding; moderate to severe	Burning, piercing, sharp; severe	Tightness, aching, pressure; mild to moderate
Radiation	None	None	None
Duration	4 to 72 hours	15 to 180 minutes	30 minutes to seven days
Triggers	Foods, oversleeping, stress, depression, decreased barometric pressure, hormonal variations, caffeine withdrawal	Alcohol, change in temperature, breezes on the face, a change in physical, mental, or emotional activity	Stress
Associated symptoms	Nausea, vomiting, photophobia	No nausea, vomiting, or photophobia	No nausea/vomiting; occasional photophobia or phonophobia
Therapies	Lifestyle modification, biofeedback, acupuncture, medications, exercise, consistent sleep schedule	100% oxygen, medications	Hot/cold packs, ultrasound, exercise, consistent sleep schedule, medications

Source: Compiled by Author *Table 1*

The social impact and economic burden of migraine are significant. The American Migraine Study II showed that 62% of patients with migraine experienced one or more severe headaches per month. More than half of respondents reported that severe headaches cause impairment of daily activities, forced bed rest, work absenteeism, and reduced work or school productivity by at least 50% [37]. The burden of migraine falls disproportionately on persons of lower socioeconomic status. Among respondents with migraine who participated in governmental surveys conducted 2009 to 2018, 38% were unemployed, 42% subsisted at or near the poverty level, 34% had received a high school (or less) education, and 18% were uninsured [196]. An estimated 4 million emergency department (ED) visits in the United States each year are for migraine/severe headache, and among girls/women 15 to 64 years of age, migraine is the third most common reason for ED visits [196]. These and other studies have also indicated that the economic burden of migraine, which totals more than $13 billion per year, results in part from misdiagnosis, underdiagnosis, and improper treatment [37; 38; 39; 40; 41].

A study published in 2003 has suggested using the following three questions to screen for migraine in patients who experience recurring headaches. A "yes" response to two of the questions can effectively identify patients who have true migraines [42]:

- Has a headache limited your activities for a day or more in the last three months?
- Are you nauseated or sick to your stomach when you have a headache?
- Does light bother you when you have a headache?

Although this set of questions has been validated, more studies are still necessary to determine its general applicability. It may be helpful, however, in identifying complicated cases. Additionally, the IHS has incorporated these elements into their guideline criteria for diagnosis of migraine. The diagnosis of migraine should be considered if a typical acute episode of headache is unilateral, pulsating ("throbbing"), and aggravated by physical activity [43].

Migraine is a syndrome with a range of neurologic and non-neurologic characteristics. The syndrome is classified into two major categories (***Table 2*** and ***Table 3***):

- Migraine without aura
- Migraine with aura

These were formerly referred to as "common" and "classic" migraines [43].

Migraines without aura are migraine headaches without an associated neurologic disturbance. Typical characteristics include headache of unilateral location, pulsating quality, moderate or severe intensity, aggravation by routine physical activity, and association with nausea and/or photophobia and phonophobia. These are the most common type of migraine, accounting for nearly 80% of migraines. They have a higher average attack frequency and are usually more disabling than migraine with aura [43].

Migraines with aura, seen in approximately 15% to 20% of patients with migraine, are preceded or accompanied by transient focal neurologic symptoms that usually develop gradually over 5 to 20 minutes and last for less than 60 minutes [43]. Aura symptoms may be sensory, motor, or visual but most commonly present as visual symptoms. The visual symptoms tend to manifest as scintillating scotomata, such as flashing lights, zigzags of light, and small blind spots [13]. On average, they last 20 to 30 minutes.

CRITERIA FOR DIAGNOSIS OF MIGRAINE WITHOUT AURA

At least five attacks with the following characteristics:

1. Episodic attacks of headache lasting 4 to 72 hours
2. At least two of the following headache characteristics:
   - Unilateral location
   - Throbbing or pulsating quality
   - Pain of moderate or severe intensity
   - Aggravated by or causing avoidance of routine physical activity
3. At least one of the following symptoms during headache:
   - Nausea
   - Vomiting
   - Photophobia
   - Phonophobia
4. Not better accounted for by another diagnosis

Source: [43] *Table 2*

CRITERIA FOR DIAGNOSIS OF MIGRAINE WITH AURA

At least two attacks not better accounted for by another diagnosis (particularly transient ischemic attack) fulfilling two criteria:

1. One or more of the following fully reversible aura symptoms:
   - Visual
   - Sensory
   - Speech and/or language
   - Motor
   - Brainstem
   - Retinal
2. At least two of the following four characteristics:
   - At least one aura symptom spreads gradually over five or more minutes and/or two or more symptoms occur in succession.
   - Each individual aura symptom lasts 5 to 60 minutes.
   - At least one aura symptom is unilateral.
   - The aura is accompanied, or followed within 60 minutes, by headache.

Source: [43] *Table 3*

Premonitory symptoms occur hours to a day or two before a migraine attack (with or without aura). They include various combinations of fatigue, difficulty in concentrating, irritability, neck stiffness, sensitivity to light or sound, nausea, blurred vision, yawning, and pallor. The IHS has recommended that the terms "prodrome" and "warning symptoms" be avoided because they are often mistakenly used to include aura [43]. Migraines with aura have been additionally subdivided into typical migraine, migraine with brainstem aura, hemiplegic migraine, and retinal migraine [43]. Additional types of migraines include episodic syndromes that may be associated with migraine, chronic migraine, complications of migraine, and probable migraine [43].

Familial hemiplegic migraine (FHM) is a type of hemiplegic migraine that is often earlier in onset than typical migraine, frequently beginning in the first or second decade. These attacks are characterized by visual disturbance, dysphasia, and severe unilateral weakness and may also be accompanied by unilateral numbness of the face, arms, and legs. The attacks tend to be prolonged and may last for hours or days [43; 44]. The diagnosis of FHM requires at least one affected first-degree or second-degree relative, and most individuals diagnosed with FHM have an affected parent [44]. Three subtypes of FHM have been identified: FHM1, FHM2, and FHM3 [44]. In approximately 50% of FHM1 families, chronic progressive cerebellar ataxia occurs independently of the migraine attacks.

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FHM is often mistaken for epilepsy and (unsuccessfully) treated as such [43]. Molecular genetic testing is available for the three genes known to be associated with FHM [44]. In many cases, FHM1 additionally has brainstem symptoms [43].

Sporadic hemiplegic migraine is migraine with aura including motor weakness but no affected first- or second-degree relative. Sporadic cases occur with approximately the same prevalence as familial cases and have similar clinical characteristics. Sporadic cases require neuroimaging and other tests to rule out other cause. A lumbar puncture is also necessary to rule out pseudomigraine with temporary neurologic symptoms. This condition is more prevalent in males and is often associated with transient hemiparesis and aphasia [43].

Migraines with brainstem aura (previously referred to as basilar migraines) occur in adolescence and young adulthood. The origin of the neural event is in the brain stem; as a result, the basilar artery dilates and causes a variety of bilateral aura symptoms. The aura of these migraines includes two or more of the following symptoms: diplopia, vertigo, tinnitus, hypoacusis, ataxia, and decreased level of consciousness [43]. These migraines are associated with a slightly increased risk of migrainous infarction when compared to other migraine types.

Retinal migraine is a type of migraine with aura associated with repeated attacks of monocular visual disturbance, including scintillations, scotomata or blindness [43]. Diagnosis is confirmed with a clinical visual field examination and/or the patient's drawing (made after clear instruction) of a monocular field defect.

Approximately 3% to 5% of patients with migraine experience an aura without headache. This presentation, formerly known as a "migraine equivalent," tends to occur in older individuals who have had a history of migraines with aura in their earlier years [45]. They predominantly occur in men of advanced age.

The symptoms of a migraine do not always end with resolution of the headache. Following a migraine, individuals tend to have continued symptoms. These symptoms are quite varied in scope and may manifest as impaired concentration, fatigue, irritability, listlessness, muscle weakness, anorexia, food cravings, and euphoria. Keep in mind that migraine headaches are quite heterogeneous and vary widely in scope. Not only do they vary from patient to patient, they even vary in the same individual [46].

Triggers

Many different factors work to trigger migraines. These factors vary greatly from one individual to another and often no precipitating events can be clearly identified. Trigger factors increase the probability of a migraine attack in the short term (i.e., usually in less than 48 hours) in a person with migraine. Some of the more common triggers include stress, sleep disturbances, depression, low barometric pressure, food, hormonal variations, and caffeine withdrawal. Some trigger factors have been reasonably well studied epidemiologically (e.g., menstruation) or in clinical trials (e.g., chocolate, aspartame); however, causal attribution in individual patients may be difficult [43].

For individuals who are not certain of what triggers their headaches, it may be helpful to recommend keeping a headache diary. This diary allows individuals to chronicle their headaches and document details, such as warning signs, time duration of headache, location of pain, intensity of pain, and treatment attempts/effects, along with details of their diet, sleep patterns, medications, stress, and menstrual cycle (if applicable). This is a useful tool in elucidating the relationship between events, environment, and migraines. The headache diary has been shown to improve diagnostic accuracy and allow a more precise judgment of medication consumption. It may also help in judging the quantity of two or more different headache types or subtypes, and it teaches the patient how to distinguish between different headaches.

Migraine headaches in premenopausal women often correlate with menses, when estrogen and progesterone levels precipitously drop. These same women, when on birth control pills, develop a similar headache pattern with initiation of their placebo pills, when estrogen and progesterone levels are low. It has been suggested that altering the schedule of birth control pills may significantly reduce the number and severity of the headaches; however, women who experience migraine with aura should not use a combined oral contraceptive pill [11; 47]. Despite the increased prevalence of headache and migraine in premenopausal women, migraine is underdiagnosed in this population [48].

EVIDENCE-BASED PRACTICE RECOMMENDATION

The Institute for Clinical Systems Improvement asserts that migraines occurring in association with menses and not responsive to standard cyclic prophylaxis may respond to hormonal prophylaxis with use of estradiol patches, creams, or estrogen-containing contraceptives.

(https://www.icsi.org/wp-content/uploads/2019/01/HeadacheES.pdf. Last accessed August 15, 2023.)

Level of Evidence: Expert Opinion/Consensus Statement

Approximately two-thirds of women with migraines experience headache improvement during pregnancy [49]. Usually, symptoms during the first trimester determine whether pregnant patients will experience relief—if symptoms resolve during the first trimester, patients usually remain headache-free throughout the pregnancy; if symptoms persist during first the trimester, they usually remain throughout the pregnancy [13]. In evaluating new-onset headache in a pregnant patient, clinicians should bear in mind that although migraine or tension headaches are common during pregnancy, secondary causes should be ruled out.

People who are prone to migraines also find that caffeine, which can acutely help with headaches, may work to precipitate

COMMON FOOD TRIGGERS	
Trigger	**Causal Factor**
Food	Chemical trigger
Cheese	Tyramine
Chocolate	Theobromine
Citrus fruits	Phenolic amines
Hot dogs, ham, cured meat	Nitrites, nitric oxide
Dairy products, yogurt	Allergenic proteins (casein)
Chinese food	Monosodium glutamate
Coffee, tea, cola	Caffeine
Artificial sweeteners	Aspartame
Wine, beer	Histamine, tyramine, sulfites
Source: Compiled by Author	*Table 4*

MIGRAINE DISABILITY ASSESSMENT SCALE (MIDAS)
• On how many days in the last three months did you miss work or school because of your headaches?
• How many days in the last three months was your productivity at work or school reduced by half or more because of your headaches?
• On how many days in the last three months did you not do household work because of your headaches?
• How many days in the last three months was your productivity in household work reduced by half or more because of your headaches?
• On how many days in the last three months did you miss family, social, or leisure activities because of your headaches?
• On how many days in the last three months did you have a headache?
• On a scale of 0–10, on average how painful were these headaches?
Source: [50] *Table 5*

headaches if it is withdrawn after a period of continuous daily use. Many different foods contain chemicals that may act to initiate the headache cascade (***Table 4***).

In addition to determining what may trigger a headache, it is important to have an understanding of the impact of a headache on an individual's quality of life and productivity. One way to get a fast yet effective understanding is with the use of the validated questionnaire called the Migraine Disability Assessment Scale (MIDAS) (***Table 5***) [50]. The MIDAS was developed to measure headache-related disability and improve communication between patient and physician about the functional consequences of migraine. Scores on the MIDAS have been highly correlated with physician judgments about the severity of illness and need for treatment. It may play a role in improving the care of patients with migraine and other types of headache [51].

Treatment Goals

The goals of both pharmacologic and nonpharmacologic long-term migraine treatment are to [52; 53]:

- Reduce attack frequency, severity, and disability
- Reduce reliance on poorly tolerated, ineffective, or unwanted acute pharmacotherapies
- Improve quality of life
- Avoid acute headache medication escalation
- Educate and enable patients to manage their disease to enhance personal control of their migraine
- Reduce headache-related distress and psychological symptoms

Behavioral and physical interventions are used for preventing migraine episodes rather than for alleviating symptoms after an attack has begun. Although these modalities may be effective as monotherapy, they are more commonly used in conjunction with pharmacologic management [52].

Nonpharmacologic Treatment for Migraines

The cornerstone of nonpharmacologic therapy for treating migraine headaches involves empowering patients with knowledge. Educating patients about their diagnosis allows them to have a better understanding of what is occurring and what factors may be contributing to their headaches. Patients should be involved in formulating a management plan. Regular re-evaluation of therapy is also important [38; 54].

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Migraine is a chronic neurologic disorder that may require patients to undergo some level of lifestyle change. Lifestyle modification is one of the most important aspects of nonpharmacologic therapy. Lifestyle modification includes dietary changes, stress management techniques, establishment of regular sleeping and eating habits, and moderate exercise. These may help ease both the severity and frequency of migraine headaches. After the early signs of headaches are identified, additional attempts may be made to further reduce symptoms.

As noted, patients' headaches are often precipitated by food triggers. Patient education includes teaching patients to recognize these triggers and then avoid them, which may help patients to become headache-free. A headache diary, as discussed previously, may help patients to identify these food triggers [20; 38]. Consultation with a nutritionist may help patients find alternative foods. In addition, patients should be counseled to maintain a regular diet and avoid skipping meals. Moreover, they should consume at least eight 8-ounce glasses of water daily [56].

It has been estimated that more than 85% of headache patients use complementary and alternative medicine (CAM) therapies. Some CAM techniques have been shown to be beneficial and effective in preventing migraine. Behavioral interventions (e.g., biofeedback, stress management, psychotherapy) should be part of the standard of care for a difficult migraine patient, especially when stress is a major trigger or when analgesics are being overused [13; 38]. Stress management techniques, including biofeedback and acupuncture, have been successful for some patients and have been recommended to help patients reduce the frequency and severity of migraine headache [11; 23]. These techniques are most successful with a motivated patient, especially one who is trying to avoid pharmacologic therapy. It should be considered, particularly for pregnant patients and those not easily treated with pharmacologic agents. However, it is time-consuming and requires a commitment on the part of the patient [20].

Acupuncture is another therapy with which some patients have found success. It may be used as preventive management in patients with migraine and tension headache but should be used with caution in patients with severe bleeding disorders, who are pregnant, or who wear a cardiac pacemaker [11; 23]. Available studies have suggested that acupuncture is at least as effective as, or possibly more effective than, prophylactic drug treatment, with fewer adverse effects [57]. It can be a valuable nonpharmacologic tool and should be considered a treatment option for patients willing to undergo this treatment [58; 59; 60].

Sleep disturbances are a well-known cause of headaches [61]. Insomnia has been identified as a risk factor for tension-type headache, and sleep problems have been reported as a trigger of headaches [62]. Therefore, it is important for patients to maintain regular sleep habits. This involves going to sleep and awaking at about the same time every day. It also includes avoiding stimulants around bedtime and trying to receive at least six to eight hours of sleep daily [13; 56]. Patients should avoid sleep fragmentation, if possible. Interestingly, patients with a family history of hypersomnia may also experience headache [63].

Moderate exercise has also been found to be helpful in decreasing headache frequency and intensity for some migraine patients [56; 64]. Exercise that decreases stress and concurrently improves cardiovascular fitness seems to be the most effective. Simply walking 30 minutes per day during a lunch hour or after work can make quite a difference in terms of decreasing headache frequency. Other migraine patients have found some relief with regular yoga classes, especially those that focus on breathing and relaxation. At a minimum, patients should be encouraged to engage in an exercise program, especially because exercise improves overall health. Ideally, patients should exercise 30 to 60 minutes, at moderate intensity, at least three times per week.

All patients who smoke should be encouraged to quit smoking. Nicotine is a well-known vasoconstrictor, and carbon monoxide is a vasodilator. Combined they can trigger the migraine process. Therefore, current smokers should be counseled to quit.

Often, a multidisciplinary approach can be effective for some patients and may lead to a decrease in migraine pain, frequency, and intensity; improved overall health status and quality of life; and improved functional status [65]. Treatment choices should be based on the severity and frequency of the headache as well as on associated symptoms and comorbidities [24].

Pharmacologic Treatment for Migraines

Unfortunately, even if a patient has some success with nonpharmacologic options, many will still need medications. Some data have suggested an enhanced effect with a combination of treatments [66].

The pharmacologic options for migraine headache fall into two main categories: acute attack treatment (also known as abortive treatment) and preventive therapies.

Acute Attack Treatments

The U.S. Headache Consortium has identified goals for the successful treatment of acute attacks of migraine [53]:

- Treat attacks rapidly and consistently without recurrence.
- Restore the patient's ability to function.
- Minimize the use of back-up and rescue medications.
- Optimize self-care and reduce subsequent use of resources.
- Be cost-effective for overall management.
- Have minimal or no adverse events.

To meet these goals, the Consortium has recommended that clinicians [52; 53; 54]:

- Educate migraine sufferers about their condition and its treatment; encourage patients to participate in their own management.
- Use migraine-specific agents (i.e., triptans, dihydroergotamine [DHE]) in patients with moderate or severe migraine or whose mild-to-moderate headaches respond poorly to nonsteroidal anti-inflammatory drugs (NSAIDs) or combinations such as aspirin plus acetaminophen plus caffeine. Note: The American Academy of Family Physicians/American College of Physicians-American Society of Internal Medicine has recommended the use of migraine-specific agents only when a first-line therapy of NSAIDs (e.g., aspirin, ibuprofen, naproxen sodium, acetaminophen-aspirin-caffeine combination) has failed.
- Select a non-oral route of administration for patients with migraine associated with severe nausea or vomiting.
- Consider a self-administered rescue medication for patients with severe migraine who do not respond to (or fail) other treatments.
- Guard against medication-overuse headache.

The goal of acute attack treatment should be for the patient to be pain-free within two to four hours. The patient should be able to return to full function after this time. In addition, the headache should not return within 24 hours of being pain-free. A stepwise approach is typically recommended [38]. This approach suggests that patients are to be treated with the safest, least expensive medication during the first migraine attack, and subsequently progress to more expensive medications for subsequent attacks, if the initial ones are not effective [53; 67]. As a general rule, medications used to alleviate the pain of a migraine attack should be taken early after onset, when the headache is still mild, if possible.

The American Headache Society (AHS), in cooperation with the American Academy of Neurology (AAN), publishes a periodic Consensus Statement designed to offer clinicians updated guidance in the use of established and approved therapies for the acute and preventive treatment of migraine [173; 198]. AHS updates, which are based on the expanded evidence base and emerging expert consensus concerning post-approval usage, provide practical recommendations but do not constitute formal practice guidelines [198]. AHS assessments published in 2015 are used in ***Table 6***, referencing individual pharmacotherapies for acute attack treatment [173]. Assessments were based on a review of clinical trials reported between 1998 and 2013, comparing the efficacy of various acute attack treatments versus placebo, but not the comparative efficacy of individual therapies. Where no new studies for a particular drug were found, classifications were based on previous AAN guidelines.

Acute attack pharmacologic options are used at the onset of the attack. They can be divided into nonspecific and specific drugs. The nonspecific therapies are single or combination analgesics. Routes of administration include oral, nasal, parenteral, and rectal. Appropriate situations for use, including potential side/adverse effects, drug-drug interactions, and patient-specific contraindications, should be addressed. Opioids are generally avoided, if possible, due to concerns about tolerance and dependence [54; 173].

The more common analgesics used include acetaminophen, NSAIDs (e.g., aspirin, ibuprofen, naproxen sodium), and narcotics (e.g., oxycodone, morphine sulfate) [38]. Acetaminophen-aspirin-caffeine combination may also be used to treat migraines. The evidence for efficacy is most consistent for aspirin, ibuprofen, naproxen sodium, and the acetaminophen-aspirin-caffeine combination. Acetaminophen alone has been found to be ineffective [53; 66; 173].

In the 2000 AAN guidelines, the NSAID diclofenac was considered "probably effective" for the acute treatment of migraine. Class I studies conducted since that time resulted in the agent being reassessed by the AHS as "effective" (Level A) [14; 176; 177].

The nonspecific therapeutic drugs may be used to relieve the pain through many different mechanisms, although most typically work by dulling pain receptors. These are usually considered first-line therapeutic options for many individuals who find these adequate in obliterating headaches [54]. In order to increase the likelihood of efficacy it is important that these are taken as early as possible in the headache cycle [38]. In addition, a large single dose tends to be more effective than repeated smaller doses. When any of these medications are used, many clinicians add an antiemetic or pro-motility agent to increase the chance of absorption, especially during an attack when nausea is a major component [53].

Over-the-counter analgesics are often effective in treating migraine. In an observational study of the impact of over-the-counter analgesics for migraines on a patient's quality of life, nearly 100 patients who used over-the-counter medications, such as acetaminophen-aspirin-caffeine combination, and who also received educational migraine materials over a four-month period completed a general health status questionnaire. At the end of the study, patients reported significant improvements in several quality-of-life measures and increased frequency of relief [69].

Ergotamines

The specific therapies include ergotamines and triptans. The ergotamines and triptans both work as vasoconstrictors. Ergotamine derivatives, although less expensive, are more nonspecific and tend to increase the likelihood of rebound headaches after their use [53; 67].

The U.S. Headache Consortium reviewed the results from 23 controlled trials of ergotamine tartrate, ergotamine-containing compounds, and ergostine-containing compounds and has recommended the following regarding the use of ergot alkaloids and derivatives, all of which are supported by the recent AHS evidence assessment of migraine pharmacotherapies [53; 173]:

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AHS EVIDENCE ASSESSMENT OF ACUTE MIGRAINE PHARMACOTHERAPIES	
Drug Class	**Specific Agents and Doses**
Level A (Effective)	
Analgesics	Acetaminophen 1,000 mg (for non-incapacitating headache)
Ergots	DHE nasal spray 2 mg[a]
NSAIDs	Aspirin 500 mg[a] Diclofenac 50 mg, 100 mg Ibuprofen 200 mg, 200 mg Naproxen 500 mg, 550 mg[a]
Opioids	Butorphanol nasal spray 1 mg[a]
Triptans	Almotriptan 12.5 mg Eletriptan 20 mg, 40 mg, 80 mg Frovatriptan 2.5 mg Naratriptan 1 mg, 2.5 mg[a] Rizatriptan 5 mg, 10 mg[a] Sumatriptan (oral 25 mg, 50 mg, 100 mg[a]; nasal spray 10 mg, 20 mg; subcutaneous 4 mg, 6 mg) Zolmitriptan (nasal spray 2.5 mg, 5 mg; oral 2.5 mg, 5 mg[a])
Combinations	Acetaminophen/aspirin/caffeine 500 mg/500 mg/130 mg[a] Sumatriptan/naproxen 85 mg/500 mg
Level B (Probably Effective)	
Antiemetics	Chlorpromazine 12.5 mg IV[a] Droperidol 2.75 mg IV Metoclopramide 10 mg IV[a] Prochlorperazine 10 mg IV/IM[a]
Ergots	DHE 1 mg IV, IM, SC[a] Ergotamine/caffeine 1 mg/100 mg[a]
NSAIDs	Flurbiprofen 100 mg[a] Ketoprofen 100 mg Ketorolac 30–60 mg IV/IM
Other	Magnesium sulfate 1–2 g IV (for migraine with aura) Isometheptene 65 mg[a]
Combinations	Codeine/acetaminophen 25 mg/400 mg[a] Tramadol/acetaminophen 75 mg/650 mg
Level C (Possibly Effective)	
Antiepileptics	Valproate 400–1,000 mg IV
Ergots	Ergotamine 1–2 mg[a]
NSAIDs	Phenazone 1,000 mg
Opioids	Butorphanol 2 mg IM[a] Codeine 30 mg PO[a] Meperidine 75 mg IM[a] Methadone 10 mg IM[a] Tramadol 100 mg IV[a]
Steroids	Dexamethasone 4–16 mg IV
Other	Butalbital 50 mg[a] Lidocaine intranasal[a]

Table 6 continues on next page.

AHS EVIDENCE ASSESSMENT OF ACUTE MIGRAINE PHARMACOTHERAPIES *(Continued)*	
Drug Class	**Specific Agents and Doses**
Combinations	Butalbital/acetaminophen/caffeine/codeine 50 mg/325 mg/40 mg/30 mg[a] Butalbital/acetaminophen/caffeine 50 mg/325 mg/40 mg[a]
Level U (Conflicting or Inadequate Evidence)	
NSAIDs	Celecoxib 400 mg
Other	Lidocaine IV[a] Hydrocortisone 50 mg IV[a]
For an agent to be classified as Level A, it must be supported by at least two Class I studies (randomized controlled trials in the representative population). Level B requires one Class I study or two Class II studies (randomized controlled trials not meeting the standards of Class I), and Level C required one Class II study or two Class III studies (nonrandomized controlled studies). An agent was classified Level U when evidence to support its use was either conflicting or inadequate. [a]Based on 2000 American Academy of Neurology evidence review.	
Source: [173]	*Table 6*

- In the treatment of selected patients with moderate-to-severe migraine, ergot derivatives may be considered.
- Because of their inability to tolerate or take oral medication, patients with nausea and vomiting may be given DHE subcutaneous, IV, or intramuscular (IM). Initial treatment with DHE subcutaneous or IM is a reasonable choice when the headache is moderate-to-severe or an adequate trial of NSAIDs or other nonopiate analgesics has failed to provide adequate relief in the past. The use of DHE IM or subcutaneous may be considered in patients with moderate-to-severe migraine.
- DHE IV plus antiemetics is an appropriate treatment choice for patients with severe migraine.
- The use of DHE nasal spray is an appropriate treatment choice and should be considered for use in patients with moderate-to-severe migraine. Because of their inability to tolerate or take oral medications, patients with nausea and vomiting may be given intranasal DHE. Initial treatment with DHE nasal spray is a reasonable choice when the headache is moderate-to-severe or an adequate trial of NSAIDs or other nonopiate analgesics has failed to provide adequate relief in the past.

Triptans

The triptans are serotonin 5-HT1B/1D receptor agonists and act through three possible mechanisms: vasoconstriction of intracranial vessels, inhibition of neuropeptide release from the trigeminal nerve, and inhibition of central pain transmitters. The newer triptans have fewer side effects and are much less likely to cause rebound headaches as compared to their predecessors.

Although many of the serotonin 5-HT1B/1D receptors are located in the brain, some 5-HT1B receptors are located in the heart, as determined by anatomical studies using selective antibodies [70]. Triptans have been shown to constrict coronary arteries and prevent the release of pro-inflammatory neuropeptides [71]. In rarer circumstances, they may cause myocardial infarction [72]. Because of this, it is contraindicated to use these drugs in the setting of ischemic heart disease, uncontrolled hypertension, pregnancy, and cerebrovascular disease, such as ischemic stroke [36; 38; 53; 73]. They should also be avoided in the treatment of FHM and basilar migraine. Triptans should not be prescribed to patients who are also taking monoamine oxidase inhibitors (MAOIs), nor should they be given within 24 hours of use of ergotamines [73]. No evidence has supported the use of triptans during the aura phase of a migraine attack [53].

Several triptan drugs are available. The drugs may be taken orally as tablets or capsules, sublingually as quick-dissolving wafers, or intranasally as a spray. Sumatriptan is also available in subcutaneous injection form [71; 74].

The U.S. Headache Consortium has found that triptans are effective and relatively safe for the acute treatment of migraine headaches. They are an appropriate initial treatment choice in patients with moderate-to-severe migraine who have no contraindications for their use [52]. Patient-reported satisfaction with triptans is modest [75]. It is advisable to switch from one oral triptan to another if three migraine attacks have been treated without success [192].

Almotriptan: Almotriptan is available in oral form. It has the highest oral bioavailability of the triptans, with approximately 70% of the dose absorbed within the first hour [73; 76]. A meta-analysis of 53 randomized controlled trials demonstrated almotriptan 12.5 mg to be of comparable efficacy to sumatriptan 50 mg or 100 mg [77]. Side effects include dizziness, dry mouth, paresthesia, nausea, and somnolence [53; 73].

Eletriptan: Eletriptan is available in oral form. It has been suggested as one possible therapy for those patients who have a poor response to NSAIDs. In an open-label treatment study, 113 patients who suffered from migraines and did not experience a satisfactory response to NSAIDs were given eletriptan 40 mg for one migraine attack [78]. Headache, pain-free response,

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absence of associated symptoms, and functional response were assessed at 1, 2, 4, and 24 hours after receiving the medication. By four hours post-dose, the pain-free response rate was greater than 40% and relief of baseline symptoms was 82%. By 24 hours post-dose, only 24% of patients had headache recurrence. In a randomized double-blind study comparing eletriptan 40 mg to naratriptan 2.5 mg and placebo, 548 patients with migraines were evaluated [79]. At four hours post-dose, 67% of patients taking naratriptan experienced headache relief versus 80% for patients taking eletriptan and 44% for placebo. Patients taking eletriptan also used fewer rescue medications. Side effects include asthenia, dizziness, dysphagia, abdominal pain/discomfort, and chest tightness [53; 73]. Diagnosis should be re-evaluated if the first dose is ineffective.

Frovatriptan: Frovatriptan, available in oral form, appears to have the highest potency of the triptans and may be cerebroselective [76]. It has one of the lowest rates of headache recurrence after use. In a review of three randomized placebo-controlled trials involving almost 2,700 patients, patients using frovatriptan 2.5 mg experienced greater headache relief than placebo [80]. Side effects include fatigue, dizziness, flushing, dyspepsia, skeletal pain, and chest tightness [73].

Naratriptan: Naratriptan has the longest half-life of all the triptans. As a result, it may be particularly effective in reducing recurrence headaches in some patients. The use of naratriptan 2.5 mg was compared to naproxen 500 mg in a small, double-blind crossover study [81]. At six hours post-dose, naratriptan was more effective in relieving headache, nausea, and vomiting and did so more quickly than naproxen. Side effects include dizziness, drowsiness, malaise, paresthesias, and throat tightness [73].

Rizatriptan: Rizatriptan is one of the quickest acting oral preparations, typically reaching peak concentration in 1 to 1.5 hours. It is also available as an orally disintegrating wafer [73; 76]. In a study comparing rizatriptan 10 mg versus zolmitriptan 2.5 mg versus placebo, both drugs showed improvement in headache relief compared to placebo but there was no significant difference in symptom relief between the two drugs [82]. When taken orally, rizatriptan 10 mg is superior to sumatriptan 100 mg and naratriptan 2.5 mg on some, but not all, efficacy outcomes [71; 74]. Compared to sumatriptan 100 mg and naratriptan 2.5 mg, greater proportions of patients taking rizatriptan 10 mg have measurable pain relief one hour after taking medication and/or are completely pain-free after two hours. There is insufficient evidence to determine whether rizatriptan (or any triptan) is superior overall [71; 74]. Side effects include asthenia, dry mouth, nausea, paresthesia, dizziness, and chest discomfort. The wafer preparation contains phenylalanine [53; 73].

Sumatriptan: Sumatriptan is available in oral, subcutaneous, and intranasal preparations and in combination with naproxen [73]. It was the first triptan on the market and thus has been the most studied. Oral sumatriptan has been found to be significantly more effective than placebo at relieving migraine headache pain within two hours [83]. A systematic review of 61 studies involving 37,250 participants found that oral sumatriptan (100 mg) significantly improved headache relief compared to placebo [83].

Side effects include tingling/flushing, dizziness, fatigue, muscle pain or weakness, and chest discomfort [73]. There may be taste disturbance with the use of the nasal spray [53; 73]. Although sumatriptan is the most prescribed treatment for migraine, current formulations may be associated with limitations (e.g., difficulty taking oral medication) that can result in patients' delaying or avoiding treatment. Transdermal patches have proved effective for the delivery of sumatriptan. In 2013, the U.S. Food and Drug Administration (FDA) approved Zecuity, a sumatriptan iontophoretic transdermal system [84; 85]. In 2016, the manufacturer of Zecuity suspended sale of the drug pending an FDA evaluation of reports of burns and scars associated with the patch [86]. Additional novel formulations include needle-free injectable sumatriptan [75].

Zolmitriptan: Zolmitriptan is available in oral form, nasal spray, and orally disintegrating wafers [73]. In a randomized controlled trial of nearly 1,200 patients comparing oral zolmitriptan to placebo, zolmitriptan 2.5 mg was found to significantly decrease headache symptoms, resulting in headache relief in the majority of patients [87]. Of note, a dose response effect was observed, with lower doses resulting in fewer adverse events. In a randomized controlled trial comparing the use of zolmitriptan to sumatriptan of nearly 1,500 patients with migraines, there was no significant difference in headache relief [87]. Side effects include asthenia, nausea, paresthesia, dizziness, and chest discomfort. The use of the nasal spray can cause taste disturbances. The wafer preparation contains phenylalanine [53; 73].

The triptans are all closely related although they differ slightly in terms of half-life, oral bioavailability, and metabolism. Side effects vary but in general they are mild and include tingling, flushing, dizziness, somnolence, and the sensation of pressure in the head; their safety profiles are all quite similar [36]. Because sumatriptan was the first on the market and the most commonly prescribed, it is often used as a comparison in studies with newer triptans [53].

A comparative review of the safety and efficacy of the triptans has indicated that [71; 73; 74]:

- Indirect comparisons from placebo-controlled trials of oral triptans suggest that sumatriptan 100 mg, almotriptan 12.5 mg, eletriptan 40 mg, and zolmitriptan 5 mg all have similar efficacy, whereas frovatriptan 2.5 mg is probably inferior.
- Evidence remains inconclusive as to how the orally disintegrating wafer, nasal, and injectable forms of triptans compare in efficacy to the more conventional oral capsule or tablet forms.
- For the oral forms of eletriptan, naratriptan, rizatriptan, sumatriptan, and zolmitriptan, there are no differences in adverse effects (e.g., chest tightness, CNS symptoms); data are lacking for almotriptan and frovatriptan.

- For all the triptans, the safety of treating an average of more than four headaches in a 30-day period has not yet been established.

Note that, like NSAIDs, failure with one triptan does not imply that the patient will not find relief with another triptan. At least two medications in a class should be tried before the class of medications is considered unsuccessful in headache treatment. Ultimately, individuals will need to try the different triptans and determine what works best for them. One might also consider adding an NSAID to a triptan to potentially enhance effectiveness. The first combination product of a triptan and an NSAID (Treximet) was approved by the FDA in 2008. Treximet contains sumatriptan (85 mg) and naproxen sodium (500 mg) and has found to be more effective than placebo or either sumatriptan or naproxen sodium alone [38; 74].

Treating pregnant patients with migraines can be particularly challenging. In general, most medications should be avoided, and patients should be treated with behavioral intervention and nonpharmacologic measures. The triptans are considered FDA Pregnancy Risk Category C, which means risk to humans has not been ruled out [73].

Management of Acute Attack in the Emergency Department

Acute migraine attack results in 1.2 million visits to emergency departments in the United States each year [174]. While more than 20 different parenteral medications and combinations of medications are used to treatment acute migraine in U.S. emergency departments, fewer than 25% of patients experience sustained freedom from headache after treatment [175]. The ideal parenteral treatment should offer rapid, sustained freedom from headache, no short- or long-term sequelae, a rapid return to normal activities, and no adverse effects; however, no such treatment exists. This led the AHS to develop a guideline on the management of acute migraine in the emergency department, with the goal of determining which injectable medications should be considered first-line treatment for acute migraine in the emergency setting, and whether parenteral corticosteroids can prevent recurrence of migraine in adults discharged from the emergency department (***Table 7***) [175].

Other Medications

Although the triptans provide effective relief from migraine for many patients, a substantial number will be unresponsive. Calcitonin gene-related peptide (CGRP), a potent vasodilator widely distributed in the trigeminovascular system, is a signaling molecule that plays an important role in migraine pathogenesis [192]. Clinical studies have established that that migraine attacks develop in patients with migraine when they are exposed to CGRP (and other activating peptides), whereas study participants with no history of migraine report mild or no headache upon exposure [192]. These studies have led to the development of monoclonal antibodies and other small molecules (gepants) targeting the CGRP ligand or its receptor. Two CGRP receptor antagonists (ubrogepant and rimegepant) have proved to be beneficial and have received FDA approval for the treatment of acute migraine. Four CGRP monoclonal antibodies (erenumab, fremanezumab, galcanezumab, and ubrogepant) have been approved for prevention of migraine [192]. CGRP receptor antagonists and monoclonal antibodies have been tested in clinical trials and shown to be beneficial and safe, with an acceptable adverse effect profile [88; 89; 90; 91; 199]. At present, high costs and restricted availability limit the use of these agents to patients for whom NSAIDs and triptans are ineffective or have unacceptable side effects [192].

Selective serotonin reuptake inhibitors (SSRIs) block the passage of serotonin, a neurotransmitter, in brain cells and are typically used to treat depression. In view of research suggesting that serotonin may play a role in the genesis of headache pain, SSRIs have been tested for their potential benefit in preventing headaches. Results suggest, however, that SSRIs are no better than placebo for preventing migraine or tension-type headaches [92]. Additionally, the FDA has issued a public health advisory regarding the combined use of 5-hydroxytryptamine receptor agonists (triptans), SSRIs, or selective serotonin/norepinephrine reuptake inhibitors (SNRIs). A life-threatening condition called "serotonin syndrome" may occur when triptans are used together with an SSRI or an SNRI (***Table 8***). Symptoms may include restlessness, hallucinations, loss of coordination, tachycardia, rapid changes in blood pressure, increased body temperature, overactive reflexes, nausea, vomiting, and diarrhea. Serotonin syndrome may be more likely to occur when starting or increasing the dose of a triptan, SSRI, or SNRI. The FDA has requested that all manufacturers of triptans, SSRIs, and SNRIs update their prescribing information to warn of the possibility of serotonin syndrome when triptans and SSRIs or SNRIs are taken together [93].

In 2019, lasmiditan, a ditan, was approved for the treatment of migraine [73]. Lasmiditan is similar to a triptan but is a high-affinity, highly selective 5-HT1F receptor agonist. The selective targeting of the 5-HT1F receptor is hypothesized to decrease stimulation of the trigeminal system and treat migraine pain without causing vasoconstriction. In a phase 3 study, patients reporting being free of headache after two hours with lasmiditan 200 mg (32.2%) or 100 mg (28.2%) compared with placebo (15.3%). Patients who received lasmiditan were also significantly more likely to report alleviation of their most bothersome symptom compared with placebo [193]. Adverse events were mostly mild or moderate in intensity and included dizziness, fatigue, and sedation. Patients given a prescription for lasmiditan should be cautioned not to drive within eight hours after taking the medication [198].

Botulinum Toxin

Botulinum toxin type A (Botox) injections were discovered as a treatment for migraines after individuals who had injections for cosmetic purposes found that it lessened or obliterated their migraine headaches. These observations subsequently led to a series of clinical research studies designed to assess the value of botulinum toxin type A therapy for headache prevention; however, the results from these studies have been mixed [68; 94; 95; 96; 97].

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AHS RECOMMENDATIONS FOR MANAGEMENT OF ACUTE MIGRAINE IN THE ED			
Medication, Dose, Route of Administration	**Pharmacologic Category**	**Efficacy**	**Recommendation**
First-Line Treatment			
Acetaminophen, 1 g, IV	Analgesic	Possibly effective	May offer
Acetylsalicylic acid, 0.5–1.8 g, IV	NSAID	Likely effective	May offer
Chlorpromazine, 0.1–25 mg, IV	Antimanic, antipsychotic	Possibly effective	May offer
Diclofenac, 75 mg, IM	NSAID	Possibly effective	May offer
Droperidol, 2.5–8.25 mg, IM	Antiemetic	Likely effective	May offer
Haloperidol, 5 mg, IV	Antipsychotic	Likely effective	May offer
Ketorolac, 30–60 mg, IM/IV	NSAID	Likely effective	May offer
Metoclopramide, 10–20 mg, IV	Antiemetic	Highly likely to be effective	Should offer
Prochlorperazine, 10 mg, IV	Antiemetic	Highly likely to be effective	Should offer
Sumatriptan, 6 mg, SC	Triptan	Highly likely to be effective	Should offer
Valproic acid, 500–1,000 mg, IV	Anticonvulsant; antimanic	Possibly effective	May offer
Migraine Recurrence Prevention			
Dexamethasone, 8–24 mg, IV	Corticosteroid; antiemetic	Highly likely to be effective	Should offer

Source: [175] *Table 7*

MEDICATIONS IMPLICATED IN SEROTONIN SYNDROME
SSRIs
Citalopram Fluvoxamine Escitalopram Paroxetine Fluoxetine Olanzapine/fluoxetine Sertraline
SNRIs
Duloxetine Venlafaxine Sibutramine[a]
Triptans
Naratriptan Almotriptan Frovatriptan Sumatriptan Rizatriptan Eletriptan Zolmitriptan
Ditans
Lasmiditan
[a]Sibutramine, a drug approved for weight loss but not depression, is an SNRI and should therefore be used with caution with triptans and other serotonergic drugs.

Source: [93] *Table 8*

For example, a review of botulinum toxin studies was performed by the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. The Subcommittee examined evidence of the toxin's effectiveness for a variety of conditions, including migraine. According to the Subcommittee's report, the evidence indicated that botulinum toxin may be useful in the treatment of lower back pain but that it is probably not effective against episodic migraine and chronic tension-type headache. The report also stated that the available evidence was not strong or consistent enough to determine botulinum toxin's usefulness in the treatment of chronic daily headache (primarily, transformed migraine) [95; 96].

In a double-blind, randomized, placebo-controlled study, researchers compared the number of headache-free days experienced by patients four weeks prior to injections of botulinum toxin type A with the number of such days occurring four to eight weeks after treatment. The number of headache-free days increased for the study's placebo and nonplacebo groups, but the difference in increase between the two groups was not significant. The researchers did find, however, that when compared with the placebo group, the patients who received botulinum toxin type A injections experienced a significant reduction in the duration of their headaches [95]. Additionally, pooled results from two large trials indicated that treatment with up to five cycles of botulinum toxin type A at 12-week intervals was effective in reducing headache symptoms, decreasing headache-related disability, and improving health-related quality of life in patients with chronic migraine [97].

It is generally recommended that use of botulinum toxin type A be restricted to patients who fail to respond to conventional preventative therapy or experience intolerable side effects from

such therapy. It is important to note that botulinum toxin type A is not FDA-approved for migraine treatment [73; 94]. Because its effects on a developing fetus are unknown, women who are pregnant should not receive botulinum toxin type A [73; 94].

EVIDENCE-BASED PRACTICE RECOMMENDATION

The American Academy of Neurology has stated that botulinum toxin type A injections should be offered as a treatment option to patients with chronic migraine (but not episodic migraine) to increase the number of headache-free days and reduce headache impact on health-related quality of life.

(http://n.neurology.org/content/86/19/1818.full. Last accessed August 15, 2023.)

Strength of Recommendation: A (Established as effective for the given condition in the specified population)

The mechanism of action of botulinum toxin type A is thought to be secondary to relieving pressure on certain nerves, such as branches of the trigeminal nerve, and thus reducing the release of neuropeptides. The actual process involves 20 to 30 injections in the forehead, temple, and neck. Side effects may include pain and bleeding at the site, exacerbation of the headache, and ptosis (eyelid droop) [73]. In those patients for whom it works, the effect typically lasts three to six months, at which time the headaches often return. This necessitates repeat injections every three to six months. This treatment is still considered to be experimental. Much more research is needed before this therapy can be considered effective.

Neuromodulation Devices

In recent years, there has been more research and development of neuromodulation devices for the treatment and prevention of headache disorders. Benefits of this type of device include proven efficacy, non-invasive nature, and very limited side effects. Due to the limited amount of time these devices have been available, ongoing research is needed to determine long-term safety and efficacy for headache disorders.

Cerena

In 2013, the Cerena transcranial magnetic stimulation (TMS) device was approved to treat migraine with aura. Patients use both hands to hold the device against the back of the head, then press a button to release a pulse of magnetic energy to stimulate the occipital cortex in the brain, which may stop or lessen the pain associated with migraine headaches. The maximum recommended dosage is one treatment in 24 hours [38].

Approval for Cerena was based on a study in which 39% of users were pain-free two hours post-treatment, compared with 22% of the control group. At 24 hours post-treatment, 34% of patients were pain-free, compared with 10% in the control group. However, studies and research on Cerena are limited [38].

Cefaly

In 2014, the first neuromodulation device received approval from the FDA for prevention of episodic migraines and received approval for acute treatment in 2017 [182; 183]. The Cefaly is a prescription external trigeminal nerve stimulation (e-TNS) device that is placed on the forehead. A self-adhesive electrode transmits electrical impulses to specific areas of the trigeminal nerve, generating an analgesic effect. The Cefaly device is used 20 minutes daily at a frequency of 60 Hz to prevent migraine or can be used for acute treatment during migraine with or without aura at a frequency of 100 Hz [183].

Results of a trial published in 2019 showed that patients using Cefaly as a preventive treatment for three months experienced a 16.21% reduction in headache days and a 30.81% decrease in acute medication intake compared with a group assigned to a sham device. Minor adverse events included skin irritation under the electrode and headache worsening with vertigo [184]. Another study published in 2019 examined the efficacy in acute treatment of migraine with or without aura. One hour after beginning the Cefaly treatment, 79% of patients achieved significant pain relief and 29% reported being pain free [185]. According to results of these and other studies, the Cefaly device is considered safe and effective for both prevention and acute treatment of migraine. In 2020, Cefaly was made available over the counter without the need for a prescription [194].

gammaCore

In 2017, the gammaCore device was cleared by the FDA for the acute treatment of migraine and cluster headache, and as a preventive treatment for cluster headache. This device is a handheld, non-invasive vagus nerve stimulator (nVNS) that produces mild electrical stimulation to the vagus nerve through the neck, thereby reducing and preventing pain [186]. Stimulation is controlled by the user, and treatment sessions consist of 2 to 3 two-minute stimulations. Patients that have a metallic device (e.g., a stent, bone plate, or bone screw) implanted at or near their neck should not use gammaCore.

A four-week study published in 2018 examined the effects of nVNS using the gammaCore device on episodic migraine headache with or without aura. Researchers found 12.7% of patients were pain free after 30 minutes of initiation of treatment (vs. 4.2% in the sham group) and 21% after 60 minutes (vs. 10%). The only adverse event was vertigo, seen in 1% of patients. Researchers indicate that nVNS is a safe treatment that may possibly decrease the risk of medication overuse in some patients [187].

Another study published in 2018 examined the effects of nVNS on episodic and chronic cluster headache over the course of two weeks. Compared with the sham group, 16.7% of patients with episodic cluster headaches achieved pain-free status at 15 minutes for greater than 50% of their attacks (vs. 6.8%), and 64.3% of patients reported significant improvement (vs. 15.4%). Comparison of patients with chronic cluster headaches were insignificant, with patients reporting free of

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pain at 8.8% (vs. 6.5% in the sham group) and patients with significant improvement at 29.4% (vs. 12.9%) [188].

Clinical trials for prophylactic treatment of cluster headaches using nVNS showed that there was a significantly greater reduction in the number of cluster attacks per week versus the control (5.9 vs 2.1, respectively). Forty percent of patients reported pain relief of 50% or greater, compared with 8.3% of the control group. nVNS also led to a reduction in the use of abortive medications. There was no change in cluster headache duration or severity of acute attacks reported in this trial [186].

Nerivio Migra

Nerivio Migra received FDA *de novo* clearance in 2019 for acute treatment of migraine with or without aura. It is a prescription trunk and limb electrical stimulator that is used on the upper arm. Electrical pulses are controlled through a smartphone for 30 to 45 minutes. This device is expected to be available in the United States in late 2019 [189].

A study of the efficacy of Nerivio Migra was published in 2019 and included patients who experience two to eight migraines per month. Two hours post-treatment with active stimulation, Nerivio Migra provided complete pain relief to 37.4% of patients (vs. 18.4% of sham participants), significant pain relief in 66.7% of patients (vs. 38.8%), and relief of most bothersome symptoms in 46.3% of patients (vs. 22.2%). For many, pain relief was sustained 48 hours post-therapy [190].

Relivion

In 2021, the FDA cleared Relivion, a transcutaneous electrical nerve stimulator that can be self-applied at home [195]. This device consists of a headset controlled by a smartphone app and delivers stimualtion to to six branches of the occipital and trigeminal nerves. It is is indicated for the treatment of migraine with or without aura in patients 12 years of age or older.

Preventive Therapies

The initiation of a preventive agent is a decision that can be made only when a variety of factors have been considered. For example, if an individual is using abortive medications more than two times per week with only moderate success, if there are more than two seriously disabling attacks per month, if there is failure of or contraindication to abortive treatments, if there is occurrence of uncommon features, or if there is a pattern being established of medication overuse, physicians should consider the initiation of a preventive medication [38; 113]. Additional factors that should be considered include the patient's preference, adverse events associated with treatments for acute migraine attacks, and how much treatment costs for acute attacks and migraine prevention [54]. Most treatment is effective within the first month.

Although the precise mechanism of action is unknown, it is believed that preventive therapies act on the CNS by raising the threshold of a migraine headache, producing "resistance" for the system to develop headaches. They also work by inhibiting the propagation of the migraine process early on.

MEDICATIONS AND STANDARD DOSES FOR MIGRAINE PREVENTION

Medication/Therapy	Standard Dose
Beta Blockers	
Propranolol[a]	160–240 mg daily
Timolol[a]	10–30 mg daily
Metoprolol	25–100 mg daily
Tricyclic Antidepressants	
Amitriptyline	10–150 mg daily
Antiepileptics	
Divalproex sodium[a]	250–1,000 mg daily
Topiramate[a]	25–100 mg daily
CGRP Antagonists	
Erenumab-aooe[a]	70 mg monthly
Fremanezumab-vfrm[a]	225 mg monthly
Galcanezumab-gnlm[a]	120 mg monthly
Neuromodulation Devices	
Cefaly[a]	100 Hz, for 20 minutes daily
gammaCore	50–60 Hz, for 4 to 6 minutes daily
[a]FDA-approved for migraine prevention	
Source: [73; 98; 178; 179; 180; 113]	*Table 9*

When considering preventive agents, keep in mind the following points [98; 113]:

- Start with the lowest possible dose.
- Give the medication an adequate trial, which typically is two to three months.
- Increase the dose slowly until either benefits or unacceptable adverse reactions are observed.
- Try to use long-acting formulations; these may help improve patient compliance.
- Choose an agent that may treat co- existing conditions, such as depression or hypertension.
- Encourage the patient to use a headache diary for better evaluation of effectiveness.

The proven and/or well-accepted drugs used for prevention of migraines include beta blockers (e.g., propranolol, metoprolol), tricyclic antidepressants, triptans, and antiepileptics (***Table 9***) [98; 113]. When antiepileptic drugs are used to treat or prevent migraine, the dose is typically much lower than the dose used to treat seizures. Also, divalproex sodium and topiramate are the only antiepileptic drugs approved by the FDA for migraine prevention [73]. Antiepileptic drugs have been shown to be effective in reducing the frequency of migraine attacks by 38% to 50% or more with antiepileptics than with an inactive placebo [99; 100; 101]. It should be noted that, although the drug may be beneficial, the FDA has issued a warning regarding

the risk of metabolic acidosis in patients receiving topiramate as well as a warning of increased risk of development of oral clefts in infants born to women treated with the drug during pregnancy [76; 102].

Gabapentin has demonstrated some effectiveness in the prevention of migraine; however, more research is needed to determine long-term effectiveness [98; 101; 103; 104]. The preventive treatments are often helpful but will not eradicate headaches altogether. Preventive therapy may reduce the frequency of migraines by 38% or more; such improvement is considered successful [36; 99; 100; 101; 105].

Newer mechanism-based therapies for migraine prevention include monoclonal antibodies targeting CGRP or its receptor. In 2018, the FDA approved three once-monthly parenteral agents for preventive treatment—erenumab-aooe, fremanezumab-vfrm, and galcanezumab-gnlm [178; 179; 180]. These CGRP antagonists are self-administered with an autoinjector. In 2023, the FDA approved atogepant, the only oral CGRP receptor-antagonist approved to prevent both episodic and chronic migraine. In a double-blind 12-week clinical trial, once-daily oral atogepant (60-mg dose) achieved a 61% reduction in the three-month average of migraine days per month, compared with 29% for placebo [200].

Physicians and other clinicians should also be cognizant that migraine sufferers often must try as many as five different medications (both acute and preventive) before they find one that is effective for their symptoms. It is important to be patient and not become frustrated during these trial periods.

Migraine in Children and Adolescents

The prevalence of migraine among children and adolescents may be as high as 6% to 10% [202]. Adolescents with migraine are reported to have high levels of disability, low health-related quality of life, and a tendency to inferior academic performance as compared with their peers. A longitudinal Canadian health survey, involving 61,000 subjects 12 to 19 years of age, found a strong, persistent association between migraine and perceived mental health in adolescents, including anxiety/mood disorders [202]. The authors recommended screening for symptoms of anxiety and depression in adolescents presenting with migraine. Clinical studies have found that prompt pharmacologic interventions (NSAIDs and/or triptans) for acute attacks plus self-management techniques and biopsychosocial approaches (e.g., biofeedback, relaxation or cognitive-behavioral therapy) constitutes the most effective strategy for managing pediatric/adolescent migraine [203].

In 2019, the AAN and AHS published practice guidelines for treatment of acute migraine in children and adolescents [191]. Ibuprofen oral solution (10 mg/kg) is the initial treatment option recommended to reduce pain and is more likely to be effective when administered early, within one hour of headache onset. The efficacy of triptans is less well established and triptans are less commonly prescribed in children than in adults. Four triptans have been approved by the FDA for treatment of migraine in adolescents (12 to 17 years of age): sumatriptan/naproxen, almotriptan, rizatriptan, and zolmitriptan nasal spray. When response to a triptan is less than satisfactory, ibuprofen or naproxen in combination should be offered to improve migraine relief. It is important to counsel patients and families on the cumulative duration limits of NSAID and triptan use to avoid adverse effects and overuse headache. AAN/AHS guidelines recommend that ibuprofen or acetaminophen use be limited to no more than 14 days per month, and triptan use limited to no more than 9 days per month [201]. Ergots and naproxen for acute migraine have not been studied in children [191].

CLUSTER HEADACHES

Cluster headache is among a group of five disorders called trigeminal autonomic cephalalgias, characterized by unilateral pain in the region of the trigeminal nerve. Cluster headache is defined as a primary type headache consisting of short (15 to 180 minutes), frequent (up to eight times per day), unilateral attacks of headache and facial pain with associated ipsilateral autonomic features and generalized restlessness [43; 53; 191]. Patients often experience delayed diagnosis and suboptimal treatment as cluster headache tend to be confused with migraine and trigeminal neuralgia. The term "cluster" refers to the recurring pattern of symptoms experienced by 80% of patients: symptomatic periods each year, typically in the same season, when the patient suffers headache attacks daily for one to three months at a time, then is symptom-free the remainder of the year [191].

When the disorder is active, the periodicity of cluster headache attacks may vary from every other day to eight times per day. Attacks are accompanied by one or more of the following symptoms: ipsilateral conjunctival injection and/or lacrimation, nasal congestion and/or rhinorrhea, ptosis and/or miosis, eyelid edema, forehead/facial sweating, forehead/facial flushing, or sensation of fullness in the ear (***Table 10***). Attacks occur in series lasting for weeks or months separated by remissions lasting for months to years [43].

Cluster headaches are divided into two subclasses: episodic and chronic [43]. The episodic cluster occurs at a rate six times higher than chronic cluster [106]. Episodic cluster headache attacks occur in periods lasting seven days to one year, separated by pain-free periods lasting one month or longer [43]. The chronic cluster headache occurs for more than one year without remission or with remissions lasting less than three months. Chronic cluster headache may arise de novo or evolve from the episodic subtype. Some patients may switch from chronic to episodic cluster headache [43].

The intensity of pain during a cluster attack is among the most severe in human experience. In an online survey of 1,604 patients with cluster headache, the pain intensity during an average attack was rated 9.7 on the 0–10 numerical scale, whereas the next highest pain was childbirth at 7.2 [191]. Cluster headaches are typically described as an excruciating burning or piercing pain. The pain comes on quickly and

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DIAGNOSTIC CRITERIA FOR CLUSTER HEADACHES
At least five attacks with the following characteristics: 1. Severe or very severe unilateral pain in the orbit, surrounding area, or both, lasting 15 to 180 minutes untreated 2. Either or both of the following: • At least one of the following signs on the side of the pain: – Conjunctival injection and/or lacrimation – Sensation of fullness in the ear – Nasal congestion and/or rhinorrhea – Facial and forehead sweating – Miosis and/or ptosis – Facial and forehead flushing – Eyelid edema • A sense of restlessness or agitation 3. Frequency of attacks from every other day to eight times a day 4. Not better accounted for by another diagnosis
Source: [43] *Table 10*

reaches its peak quickly. The location is typically retro-orbital and unilateral. Although patients rarely experience an aura, per se, some individuals report brief warning signs prior to the headache such as a "fuzzy" feeling in the head, spasm of the neck muscles, or a general feeling of discomfort. Interestingly, when a patient is in the throes of a headache, rather than resting and remaining still (as is the characteristic "migraine" behavior) the individual will likely be seen rocking, pacing, or even banging his or her head against a wall to somehow divert the pain. Each episode lasts from 15 minutes to three hours. Nausea and vomiting are rarely present [43; 107]. The pain is often so excruciating that it has been called the "suicide headache." Clinical reports have found an alarming rate of suicide ideation, as high as 55% to 64% [191]. The duration of episodic symptoms, frequency/periodicity, and restlessness exhibited during attacks distinguish cluster headache from more common headache disorders such as migraine.

The lifetime prevalence of cluster headache is estimated at 0.12% as determined by an analysis of 16 articles across four continents [191]. Men are more likely to get this type of headache than women with an approximate 3:1 ratio [43]. Cluster headaches tend to start in individuals 20 to 40 years of age and often remit by 55 years of age. They may be inherited in about 5% of cases [43]. Attacks often begin during sleep, implicating a disorder of circadian rhythm. An increased incidence of sleep apnea in patients with cluster headache suggests that periods of reduced oxygenation of key tissues may trigger an attack [106].

Although the symptoms for cluster headache are quite dramatic and for the most part pathognomonic, tumors (e.g., pituitary adenomas, meningiomas) and arteriovenous malformations in the vicinity of the internal carotid artery may induce symptoms that mimic cluster headache. For this reason, some guidelines recommend CT scan or MRI (with detailed views of the cavernous sinus and pituitary area) for all patients who present with this type of headache [108; 191].

Interestingly, there are apparent risk factors for cluster headache. Most individuals with cluster headaches are smokers, yet smoking cessation rarely, if ever, brings relief. A history of head trauma also seems to convey an increased risk of developing cluster headaches. Headache triggers include smoking, alcohol consumption, changes in temperature, breezes on the face, and changes in physical, emotional, or mental activity [43; 107].

The pathophysiology of cluster headache is poorly understood. Current understanding is derived from clinical observation, molecular changes, and imaging studies (PET scanning and functional MRI), which suggest that the trigeminovascular system, autonomic system, and hypothalamus are involved [191]. Neuromodulation of these three systems, using nerve stimulation techniques, has each shown promise in treating cluster headache. As indicated in the discussion of migraine, the trigeminovascular system uses pain signaling molecules such as CGRP. Blood levels of CGRP are increased during a cluster headache attack, and infusions of CDRP trigger attacks in patients with cluster headache [191]. During cluster headache attacks, activation of the cranial autonomic system includes both parasympathetic hyperactivity (lacrimation, conjunctival injection) and sympathetic inactivity (miosis, ptosis). The autonomic features involve a parasympathetic circuit that connects the superior salivary nucleus and sphenopalatine ganglion to the lacrimal and other glands of the face. Low-frequency stimulation of this network induces attacks, while oxygen gas has been found to have anti-nociceptive effects [191]. The cranial autonomic system connects with the trigeminovascular system and with the hypothalamus. The posterior hypothalamus is activated at the beginning of a cluster headache attack; however, the exact role of the hypothalamus in the pathogenesis of an attack is unclear.

TREATMENT OF CHRONIC CLUSTER HEADACHE		
Therapy	**Dosage and Route**	**Comments**
Verapamil	120 mg PO three times/day	–
Lithium	Start at 300 mg PO three times/day; use blood levels to achieve therapeutic dose	Need close monitoring of lithium levels; test 12 hours after last dose. Side effects include tremor and dysuria. Check thyroid and renal function before and during treatment.
Microvascular decompression	NA	Only used for intractable cases
Source: [73; 107; 109; 181]		*Table 11*

TREATMENT OF ACUTE CLUSTER HEADACHE		
Therapy/Drug	**Dosage and Route**	**Reported Adverse Effects**
Oxygen	100% oxygen at least 7 L/min over 15 minutes	None
gammaCore (non-invasive vagus nerve stimulator)	Stimulation level between 1–40 using device on side of neck over vagus nerve at maximum level tolerable for a treatment consisting of 3 two-minute stimulations applied consecutively at the onset symptoms; additional treatment may be administered if symptoms are not aborted; use for up to four attacks (or eight separate treatments) per day (for a total of up to 24 stimulations per day).	Local skin reactions, muscle contractions, dizziness
Triptans		
Sumatriptan	Up to 6 mg subcutaneously; may repeat in 24 hours OR 25–100 mg PO; repeat after two hours if significant relief not attained Maximum: 200 mg/day	Local skin reactions, fatigue, nausea, vomiting, dizziness, burning sensations, paresthesias
	20 mg nasal spray	None
Zolmitriptan	2.5 mg PO at onset (includes orally disintegrating wafer) Maximum: 10 mg/day	Chest pain, palpitation, dizziness, somnolence, vertigo, nausea, paresthesia, warm/cold sensation
	One nasal spray (5 mg) at onset	None reported
Intranasal dihydroergotamine	0.5 mg nasal spray bilaterally	Abuse potential; contraindicated in patients with cardiovascular disease
Intranasal lidocaine	1 mL of 4% lidocaine placed with a cotton swab bilaterally for 5 minutes	Unpleasant taste
Source: [73; 76; 107; 108; 111; 112; 188]		*Table 12*

Treatment of cluster headache involves a dual strategy of abortion (during the acute stage) and concurrent prophylaxis, which is initiated to suppress the expected recurrent headaches [109]. Patients with chronic cluster headache require long-term prophylaxis (***Table 11***). Patients with intractable headaches may require more aggressive intervention, including combination therapy or surgery [107; 110].

The treatments of choice for acute cluster headache are oxygen, a triptan, or a combination of the two (***Table 12***). There has been some data suggesting the use of melatonin in patients who suffer from cluster headaches, especially those who have concomitant sleep disorders; however, the effectiveness of melatonin remains unclear because of conflicting studies [107; 108].

According to the Institute for Clinical Systems Improvement, oxygen inhalation is a highly effective treatment for cluster headaches when delivered at the beginning of an attack with a non-rebreathing facial mask (7–15 L/min). Most patients will obtain relief within 15 minutes.

(https://www.icsi.org/wp-content/uploads/2019/01/HeadacheES.pdf. Last accessed August 15, 2023.)

Level of Evidence: Expert Opinion/Consensus Statement

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PROPHYLAXIS OF EPISODIC CLUSTER HEADACHE			
Drug/Therapy	**Dosage and Route**	**Reported Adverse Effects**	**Comments**
gammaCore (non-invasive vagus nerve stimulator)	Stimulation level between 1–40 using device on side of neck over vagus nerve at maximum level tolerable for a prophylaxis treatment consisting of 2 two-minute stimulations; first daily treatment should be applied within 1 hour of waking; second treatment should be applied at least 7 to 10 hours later; additional treatment may be administered if symptoms are not aborted; use for up to four attacks (or eight separate treatments) per day (for a total of up to 24 stimulations per day).	Local skin reactions, muscle contractions, dizziness	Intended to be used as an adjunctive therapy; first FDA-cleared device
Galcanezumab-gnlm	Loading dose of 240 mg subcutaneous (SQ) injection, followed by 120 mg SQ monthly	Antibody development, injection site reaction	Given by patient self-injection, FDA-approved
Verapamil	120–160 mg PO three times/day	Hypotension, bradycardia, atrioventricular block, dizziness, fatigue, nausea, constipation	In doses of 360–480 mg/day, has been found to be effective in reducing attack frequency
Prednisone	100 mg PO/day, up to 500 mg IV (methylprednisolone or equivalent corticosteroid) titrated over five days	Increased appetite, insomnia, nervousness, hyperglycemia, dizziness, headache	Recurrences frequent toward the end of the taper; take concurrently with another prophylactic medication
Divalproex sodium	600–2,000 mg/day	Nausea, somnolence, dizziness, insomnia, anorexia, weakness, thrombocytopenia, alopecia, weight gain	Small studies indicate efficacy; use with caution in patients with renal or hepatic insufficiency; contraindicated in pregnant women
Topiramate	25 mg PO/day for seven days, then increase by 25 mg/day every week to maximum dosage of 200 mg/day	Paresthesias, cognitive effects, drowsiness, dizziness	Small studies indicate efficacy
Ergotamine	2–4 mg/day in divided doses	Vertigo, pruritus, nausea, paresthesias, weakness, cardiac valvular fibrosis, retroperitoneal or pleuropulmonary fibrosis, angina, myocardial infarction	Best for nocturnal attacks; should not be taken concurrently with sumatriptan May cause withdrawal symptoms if suddenly discontinued
Melatonin	10 mg PO at bedtime	None reported	May be useful in some patients; drug of third choice
Source: [107; 111; 186]			*Table 13*

Preventive therapies are usually initiated when the cluster headache series begins. Preventive medications include antidepressants, antiepileptics, ergotamine, and calcium channel blockers (***Table 13***). A possible new approach to preventive treatment of episodic cluster headache is monthly administration of injectable monoclonal antibodies against CGRP [191]. In a small placebo-controlled clinical trial of galcanezumab, at a dose of 300 mg administered subcutaneously, 71% of patients with episodic cluster headache who received active treatment had a 50% or greater reduction in the weekly frequency of attacks at week 3, compared with 53% of those who received placebo [55]. Longer and larger trials are required to determine the durability and safety of this approach.

TENSION HEADACHES

Tension headaches are among the most common headache type seen in practice today; however, it is the least studied of the primary headache disorders despite having the highest socioeconomic impact. The lifetime prevalence ranges from 30% to 78%, with a rate of 63% seen in men and 86% in women [21; 43].

DIAGNOSTIC CRITERIA FOR TENSION HEADACHE

A. Infrequent Episodic Tension Headache

1. At least 10 episodes occurring less than 1 day per month on average or less than 12 days per year
2. Duration from 30 minutes to seven days
3. At least two of the following pain characteristics:
   - Pressing or tightening (non-pulsating) sensation around the head
   - Mild-to-moderate severity
   - Bilateral location
   - No aggravation by walking, climbing stairs, or similar physical activity
4. No nausea/vomiting and no more than one photophobia or phonophobia
5. Not better accounted for by another diagnosis

B. Frequent Episodic Tension Headache

1. At least 10 episodes of headache occurring on 1 to 14 days per month on average for more than three months (≥12 and <180 days per year)
2. Duration from 30 minutes to seven days
3. At least two of the following pain characteristics:
   - Bilateral location
   - Pressing or tightening (non-pulsating) quality
   - Mild-to-moderate severity
   - No aggravation by routine physical activity such as walking or climbing stairs
4. No nausea/vomiting and no more than one of photophobia or phonophobia
5. Not better accounted for by another diagnosis

C. Chronic Tension Headache

1. More than 180 days of headache in a given year or at least 15 headaches per month for an average of greater than three months
2. Duration may be from hours or it may be continuous
3. At least two of the following pain characteristics:
   - Pressing or tightening sensation around the head
   - Mild-to-moderate severity
   - Bilateral location
   - No aggravation by walking stairs or similar physical activity
   - May include one of the following: nausea, photophobia, or phonophobia
4. No evidence of organic disease

Source: [43] *Table 14*

The etiology of tension headaches is multifactorial. Although once thought to be simply secondary to muscle spasm, it is now felt that other factors play important roles. In fact, although tension headaches may arise from sustained contraction of pericranial muscles, no correlation exists between muscle contraction and the presence of a tension headache. It seems that, just as in migraine headaches, tension headaches arise in part from centrally mediated neural dysfunction. This abnormality may in part be due to central sensitization in the trigeminal area [43; 67].

The IHS has categorized tension headaches into two categories: episodic and chronic (***Table 14***). Episodic tension-type headache is further divided into infrequent (i.e., episodes that occur less than once per month) and frequent subtypes. The infrequent subtype has little impact on the individual. Frequent sufferers, however, may encounter considerable disability that requires the use of expensive drugs and prophylactic medications. The chronic subtype is always associated with disability and high personal and socioeconomic costs [43].

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Episodic tension headaches are usually associated with a stressful event. They are of moderate intensity, typically are self-limited, and usually respond well to over-the-counter headache treatments. They are usually described as soreness, tightness, or a band-like pressure around the entire head. They are often accompanied by stiffness in the neck and shoulders [114].

IHS diagnostic criteria for infrequent episodic tension-type headache include at least ten episodes occurring on less than 1 day per month on average (i.e., less than 12 days per year), lasting from 30 minutes to 7 days, with at least two of the following characteristics: a pressing or tightening (non-pulsating) sensation around the head, mild-to-moderate severity, bilateral location, and no aggravation by walking stairs or similar routine physical activity. There is no nausea, but either photophobia or phonophobia may be present [43].

Chronic tension headaches generally have the same pain characteristics as episodic tension headaches, including phonophobia or photophobia. They occur more frequently, with an incidence of at least 15 headaches per month on average for greater than three months, or greater than 180 days in a given year. The headache may last hours, or it may be continuous [43; 53].

As with migraines, there are both nonpharmacologic and pharmacologic treatments. Nonpharmacologic measures tend to be more effective for tension headaches than for migraines or clusters. These measures include the use of hot or cold packs, ultrasound, electrical stimulation, improvement of posture, trigger point injections, regular exercise, and consistent sleep schedules [114]. Forward head posture and neck mobility have been associated with tension-type headache [115].

Tension headaches also tend to respond well to medications. Some commonly used medications that are effective include aspirin, acetaminophen, and NSAIDs in the standard prescribed doses [114]. Combination treatments with the above medications and caffeine, butalbital, and muscle relaxants are also effective. However, overuse of these medications, especially those containing caffeine, may lead to rebound headaches. The use of butalbital also may result in dependency, and for this reason, it is not recommended for prolonged use [53; 73]. In general, narcotics should be avoided because tension headaches are typically mild-to-moderate in pain intensity. Botulinum has also been suggested for the treatment of tension headaches; however, not all researchers agree that it should be used for chronic tension-type headache [11; 116]. As discussed, however, more study regarding efficacy and safety is required.

Some chronic tension headaches may not respond as well to the above modalities and may require preventive medication. Before preventive medication is initiated, it is important, as in the case with migraine headaches, to have the individual keep a headache diary to determine what factors, if any, are triggering the headache [114]. Use of nonpharmacologic measures may also be initiated. Some clinicians may try a drug-free holiday, whereby all headache drugs are stopped for at least two weeks. If none of these modalities prove effective, preventive medications may be helpful. The same preventive medications used for migraine are used for chronic tension headache. These tend to be helpful especially if the patient experiences both migraine and tension headaches.

OTHER PRIMARY HEADACHES

Primary Exercise Headache

As the name implies, primary exercise headache (formerly referred to as a primary exertional headache) is a headache that occurs with exertion, is benign in nature, and is unassociated with any structural lesions. On first occurrence of this headache type, it is mandatory to exclude subarachnoid hemorrhage (SAH) and arterial dissection [43; 117].

The headache is typically described as a diffuse, bilateral pain, throbbing in quality and acute in onset. It is precipitated by strenuous physical exercise. The headache lasts from five minutes to 48 hours and occurs particularly in hot weather or at high altitude [43; 117].

Primary exercise headache is believed to be vascular in origin. Strenuous physical activity increases intracranial venous sinus pressure, which leads to an increase in intracranial pressure and decreases blood flow. This results in the occurrence of the headache. Effective treatment includes ergotamines and NSAIDs. Indomethacin has been found effective in most cases [43; 117].

Hypnic Headache

Hypnic headaches are relatively brief (15 to 240 minutes), mild-to-moderate (severe pain is reported in 20% of patients), usually dull in quality, and bilateral in about two-thirds of cases. Hypnic headaches occur during sleep and are related to the REM stage. The headaches typically awaken patients from sleep, but there are few other associated symptoms [43]. They usually occur almost every night and may last for months until patients ultimately present for evaluation. These types of headaches primarily affect the elderly [118].

The etiology is considered idiopathic, and thus, the diagnosis is primarily one of exclusion. Other causes of headache associated with sleep, such as sleep apnea and drug withdrawal, should be excluded.

One of the most effective treatments for hypnic headaches includes the use of lithium; however, it is often limited by side effects and interactions and requires monitoring of plasma concentrations to avoid toxicity. Indomethacin, atenolol, prednisone, and caffeine have also been shown to be useful [43; 118].

Headache Associated with Sexual Activity

These headaches have been previously referred to as benign sex headaches, coital cephalalgias, benign vascular sexual headaches, or benign orgasmic headaches. They may be provoked by activities besides coitus and not necessarily with orgasm. Headache associated with sexual activity affects men more than women [119; 120].

Two subforms (preorgasmic headache and orgasmic headache) were previously described, but further research was unable to clearly delineate the two separate entities [43]. Therefore, headache associated with sexual activity is now a single diagnosis with variable presentation. The condition is characterized by at least two episodes of pain in the head and/or neck brought on by and occurring only during sexual activity [43]. The pain becomes more severe with increasing sexual excitement and/or may be experienced as abrupt explosive intensity just before or with orgasm. The duration of severe pain is from 1 minute to 24 hours; more mild presentations may last up to 72 hours [43].

Diagnosis cannot be made until secondary causes (e.g., SAH or arterial dissection) have been excluded. For most patients, these are self-limited disorders. Patients often can lessen the severity of an impending attack by ceasing the sexual activity. Frequent, recurrent episodes may require preventive strategies, such as propranolol or indomethacin [119].

SECONDARY HEADACHES

As noted, it is helpful to think of secondary headaches in terms of etiologic categories, such as vascular, traumatic, neoplastic, infectious, pressure, metabolic/toxic ingestions, and medication overuse. A secondary headache may be diagnosed when another disorder known to cause headache has been demonstrated; headache occurs in close temporal relation to the other disorder and/or there is other evidence of a causal relationship; and headache is greatly reduced or resolves within three months (this may be shorter for some disorders) after successful treatment or spontaneous remission of the causative disorder. The IHS has divided secondary headaches into subtypes attributed to specific causes [43]. ***Table 15*** shows a summary of several causes of secondary headache.

TRAUMATIC CAUSES OF HEADACHES

Epidural Hematoma

Epidural hematomas occur between the dura and skull, and thus separate the dura from the skull. In most cases, there is an associated skull fracture. Typically, there is a history of head trauma, although an epidural hematoma occurs in less than 2% of all serious head injuries. Epidural hematomas are not a frequent occurrence in the elderly, partly because as one ages, the dura becomes more firmly attached to the inner part of the skull [121].

Classically, there is a brief period of unconsciousness and then a return to a normal mental status. This is known as the "lucid interval." Roughly 10% to 33% of patients demonstrate the classic presentation of a lucid interval, and alterations in the level of consciousness may have a variable presentation. After a period of hours, the hematoma expands and pushes the dura inward. Signs of rising intracranial pressure manifest as a severe, diffuse, constant headache, which develops within minutes to 24 hours after development of the hematoma [121]. Other symptoms may include papillary dilatation, hemiplegia, and eventually obtundation. Often there is weakness on the side of the body opposite the hematoma [121].

Hemorrhages usually occur in the temporal fossa from middle meningeal artery tears; they may also occur in the posterior fossa as a result of a transverse sinus tear. Posterior fossa epidural hematoma may exhibit a rapid and delayed progression from minimal symptoms to even death within minutes. Overall mortality has been estimated to be as high as 50%, so prompt evaluation and treatment is critical [43].

With respect to diagnosis through neuroimaging, in the acute setting, unenhanced CT scan is more useful than MRI imaging. Epidural hematomas have a characteristic white lenticular shape adjacent to the bone, while focal hypodense or isodense areas on CT indicate active bleeding. Because the temporal fossa is often involved, one must be careful that bony artifacts do not obscure a hemorrhage [121].

Subdural Hematoma

As the name implies, subdural hematomas occur between the surface of the brain and the dura. The source of bleeding is the venous system (i.e., bridging veins) as opposed to the arterial system. Because the subdural space is continuous, these types of hemorrhage may have significant mass effect. Subdural hematomas are more common than epidural hematomas. They tend to evolve more slowly based on the slower rate of venous bleeding compared to arterial hemorrhage. As a result, there may be a progression of symptoms over two to four weeks; the rate of progression depends upon the severity of the injury [122].

Patients often present with a mild persistent headache. There may be drowsiness and confusion, although focal neurologic signs are often absent. Symptoms may be followed by a brief lucid interval with subsequent deterioration. Subdural hematomas are seen in approximately 15% of all head traumas. Automobile accidents are a typical cause of subdural hematomas [122].

Different types of subdural hematomas should be differentiated according to their temporal profile. In acute and subacute hematomas, which usually occur after obvious head trauma, headache is frequent (11% to 53% of cases) but commonly overshadowed by focal signs and disorders of consciousness. In chronic subdural hematomas, headache is more frequent still (up to 90%) and, though moderate, may be the leading symptom [122]. The diagnosis can be difficult because the causative head trauma is often trivial and may have been forgotten by the patient [43].

Subdural hematomas are more common in the elderly than epidural hematomas, and patients on anticoagulants are at increased risk of developing a subdural hematoma. Chronic subdural hematoma should always be considered in an elderly patient with a progressive headache, particularly if there is some cognitive impairment and/or mild focal signs [43; 122; 123].

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CHARACTERISTICS OF SECONDARY HEADACHES					
Type of Headache	**Position**	**Quality**	**Radiation**	**Duration**	**Therapy**
Subarachnoid hemorrhage	Diffuse	Sharp	Neck, back	Several days	Surgery, hypertension management, volume expansion
Giant cell arteritis	Temporal area, unilateral or bilateral	Soreness/ burning	No	Days to weeks	High-dose steroids
Arterial dissection	One-sided, nonthrobbing pain in the eye	Pounding	Neck	Days	Anticoagulants, stenting, surgery
Stroke	Diffuse	Dull	No	Hours	Supportive
Epidural hematoma	Diffuse	Severe	No	Hours to days	Surgery
Dental	Occipital, temporal	Squeezing	No	Varies	Dental referral for care
Subdural hematoma	Diffuse	Mild	No	—	Diuretics, anticonvulsants, surgical evacuation
Brain tumor	Diffuse or unilateral	Mild ache	No	—	Surgery, radiation, chemotherapy
Meningitis	Diffuse	Mild to moderate	Neck	—	Rest, fluids, electrolyte balance, antibiotics
Encephalitis	Diffuse	Dull	No	—	Rest, fluids, electrolyte balance, antiretrovirals
Sinusitis	Sinus area	Heavy fullness	No	Duration of illness	Antibiotics
Abscess	Hemicrania	Moderate to severe	Neck	—	Evacuation, antibiotics

Source: [43] *Table 15*

Patients with suspected subdural hematoma should undergo CT scanning. CT scan findings depend on the age of the hemorrhage but typically demonstrate an abnormality in the entire hemisphere, causing a shift of the midline structures. Early on, there are hyperdense areas demonstrated on CT, followed by isodense areas after a week and hypodense areas after a month [122; 123].

Prompt treatment is critical because mortality can reach 60%. Treatment may include diuretics to reduce swelling. Because there is a high frequency of seizures, antiepileptics are frequently used to either control or prevent seizures. For more serious hematomas, surgical evacuation may be necessary. The long-term prognosis is actually worse than that for epidural hematomas [122; 123; 124].

Upon further history taking, it becomes clear that Mrs. T did experience a significant fall a few weeks ago, even though she minimized it when mentioning it. Sequelae are present. Therefore, a contrast-enhanced CT should be ordered.

The CT scan demonstrated hypodense areas in both hemispheres, consistent with subdural hematoma. There was no evidence of mass effect. The subdural hematoma is likely a result of the fall approximately one month earlier. Mrs. T was admitted to the hospital for observation and given diuretics and anticonvulsants. Her clinical course was good with resolution of the hematoma without the need for surgery.

VASCULAR HEADACHES

Subarachnoid Hemorrhage

Typically, headache due to an SAH is described as a sharp pain that usually involves the entire head. Patients classically describe it as the "worst headache of their life." It often radiates into the neck and even into the back. There is usually nausea and vomiting. In general, there are no focal neurologic deficits early on, but as it progresses, there may be loss of consciousness and altered mental state. Seizures during the acute phase occur in 10% to 25% of patients [125].

The course of this headache is abrupt in its onset and maximum intensity at its origin; it is typically incapacitating in its severity. It is exacerbated by neck and head movements. It usually remains severe for several days and then gradually diminishes [43]. An often-overlooked aspect is that the acute headache may be preceded days to weeks earlier by a similar but less severe headache due to slow bleeding. Therefore, a high index of suspicion is necessary for accurate diagnosis [125].

The headache results most often (approximately 80% of cases) from rupture of an aneurysm, although this condition may also result from trauma, arteriovenous malformations, venous thrombosis, blood dyscrasias, cocaine use, amphetamine use, and a variety of metabolic conditions [43; 125]. Types of aneurysms include berry aneurysms, fusiform aneurysms, atherosclerotic lesions, and mycotic aneurysms from septic emboli. Approximately 80% of nontraumatic SAHs are due to a ruptured berry aneurysm; rupture of arteriovenous malformations is the second most identifiable cause (10%) [126]. The initial pain is actually produced by tearing and distortion of the blood vessel and its adjacent arachnoid membrane. The incidence of headache in ruptured aneurysms is 90% [122].

The prevalence of SAH increases with age in a linear relationship. The mean age is 50 years [125; 126; 127]. On physical examination, the patient is typically in severe pain. The pain is sometimes referred to as a "thunderclap" headache [126]. Symptoms of meningeal irritation, such as nuchal rigidity and pain, back pain, and bilateral leg pain, occur in as many as 80% of patients with SAH but may take several hours to manifest [126]. Focal neurologic deficits, such as facial droop or weakness in a specific extremity, are present in 25% of patients. However, if the hemorrhage is associated with ischemic stroke it will likely involve the brain parenchyma, which may lead to hemiparesis, aphasia, or visual field abnormalities. Loss of consciousness is transient [43; 125].

Patients with suspected SAH should undergo CT scanning without contrast or MRI (flair sequences) [43; 122]. The CT typically demonstrates blood localized to the basal cisterns or extended into the ventricles [122]. Unenhanced CT detects SAH in about 90% of cases; however, sensitivity drops to 80% after three days. As a result, a normal CT does not exclude a small SAH [125].

If the CT is negative, equivocal, or technically inadequate, a lumbar puncture should be performed [43]. Most cases not detected on CT are identified on lumbar puncture by red blood cells (RBCs) that do not clear in three samples of CSF. A decrease in RBCs from the first to the last tube represents an artificially bloody tap, whereas an increase count in RBCs suggests SAH. The fluid is then centrifuged and examined for xanthochromia. Xanthochromia is often characterized as a yellow-tinged supernatant, although it may also be pink or orange. It represents enzymatically derived breakdown products, oxyhemoglobin, methemoglobin, and bilirubin, of in vivo red blood cells. It is always seen within 12 hours of SAH but is absent after a traumatic tap. Its presence may be helpful in the diagnosis [43]. Of note, blood in the CSF after a traumatic tap will also result in an artificial increase in white blood cells (WBCs). WBCs will increase by one for every 500 to 1,000 RBCs in the CSF. This assumes a normal WBC count, which is typically the case in SAH [126]. Ultimately, angiography may be necessary to determine aneurysm size and location, as well as to determine surgical or medical management. Treatment options include a surgical clip, management of hypertension, and volume expansion [124; 126]. In 2013, the FDA approved a new oral nimodipine solution for the treatment of patients with SAH from ruptured intracranial berry aneurysms. The solution is administered enterally (e.g., oral, nasogastric tube, gastric tube route) within 96 hours of the SAH at a starting dose of 20 mL every four hours for 21 consecutive days [73; 128].

SAH is a serious condition. Prompt diagnosis of SAH is critical because 50% of patients die following SAH, often before arriving at hospital, and 50% of survivors are left disabled [43; 125].

Giant Cell Arteritis

Giant cell (temporal) arteritis is systemic large and medium-sized vessel vasculitis. Most often, it involves the external carotid arteries [43; 129]. This headache typically begins as an intermittent soreness or burning discomfort and steadily escalates over several weeks or months to become a constant, well-localized pain. On rare occasions, it can be explosive. Many patients report that the pain is worse at night. Although the pain is usually unilateral, it may also be bilateral. Pain is classically confined to the temples. Between 70% to 90% of patients with giant cell (temporal) arteritis complain of headache [53; 129].

The typical presentation is a new-onset headache in patients older than 50 years of age. Incidence is higher in females than males (ratio 3.7:1), as well as in persons of northern European descent. It represents the most common vasculitis in adults. Nearly 50% of patients with polymyalgia rheumatica also have giant cell arteritis [129].

On exam, the affected scalp artery is sometimes prominent. It may be tender and is often pulseless. The scalp itself is usually tender as well. Depending upon the progression, visual field defects and decreased acuity may be noted, although the patient does not usually exhibit focal neurologic deficits. Typically, the headache occurs in someone who is febrile, has malaise, and feels aches in the back and shoulders. Jaw claudication (pain on chewing food) occurs commonly and is virtually pathognomonic for this condition when present during talking or chewing [129].

Giant cell arteritis involves not only the arteries of the scalp causing headache, but also other vessels, including those supplying the eye and occasionally the brain. Nearly half of patients with giant cell arteritis develop blindness, if untreated, due to ischemia of the optic nerve or retina. Because blindness can be prevented by immediate steroid treatment, prompt and accurate diagnosis is critical [43; 129].

Laboratory studies often show patients to have an elevated erythrocyte sedimentation rate (ESR), typically >80 mm/hour. (In general, a normal rate would be less than or equal to the patient's age, divided by two.) Given the lack of sensitivity and specificity of this test, however, a normal ESR does not exclude the diagnosis [129]. Platelets may also be elevated, as well as liver function tests (especially alkaline phosphatase). These are nonspecific but may provide more information to make a clinical diagnosis [129].

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Diagnosis is confirmed by biopsy of the temporal artery, which should be performed as an outpatient procedure within one week after the initiation of corticosteroid therapy [129]. The biopsy demonstrates skip lesions, which are due to the disease's segmental process. When ocular symptoms exist, emergency medical treatment is necessary. High-dose corticosteroids are an effective treatment. Headache usually resolves or greatly improves within three days of high-dose steroid treatment [43; 129]. A maintenance dose of prednisone may be required to be administered for one to two years in some patients [129].

Arterial Dissection

Arterial dissection may cause headache. Dissection of the cervical carotid or vertebral artery typically causes sudden, nonthrobbing pain around the eye, piercing pain in the neck, and a "pounding" one-sided headache. Headache with or without neck pain may be the only manifestation of cervical artery dissection. It is by far the most frequent symptom (55% to 100% of cases), and it is also the most frequent inaugural symptom (33% to 86% of cases). Headache and facial and neck pain are usually unilateral, severe, and persistent, averaging four days in duration. However, it has no constant specific pattern and may sometimes be misleading [43]. The headache is often mistaken to be due to migraine or tension. However, the time, course, and associated symptoms are considerably different.

The cause of arterial dissection is multifactorial and may involve some sudden neck movement, causing hyperextension or significant pressure in the area. This may be a result of trauma; however, cases of dissection have been reported after patients cough or sneeze, undergo spinal manipulation, shave a beard, or place their necks in the sink at beauty salons. Underlying arteriopathies, alone or in combination with the mechanical forces, account for most of the pathophysiology [130]. Therefore, it is important to determine what a patient was doing when the headache occurred.

The dissection may begin when the rotation/hyperextension of the neck causes a small lesion in the lining of an artery. This causes bleeding, which then leads to the formation of a clot. Over time, the clot expands restricting blood flow to the brain [130].

Dissection is more common in patients younger than 50 years of age. It accounts for nearly a quarter of all strokes in that age range [130]. Diagnosis is confirmed by Duplex scanning, MRI, MRA, and/or helical CT and, ultimately, arteriography. Several of these investigations are commonly needed as any of them may be normal. Once detected, the majority of patients survive, and most dissections heal without surgery. Treatment includes the use of anticoagulants (heparin followed by warfarin for three to six months), stenting, and bypass surgery on rare occasion [43].

Stroke

Headache, migraine, and stroke are common and can be temporally related, but a direct causal association has not been definitively proven in clinical studies. Headache may be coincidental with stroke (also referred to as cerebrovascular accident or stroke syndrome), including both ischemic and hemorrhagic stroke, or it may be a consequence of stroke. Headache or migraine may increase the risk of stroke [131]. Results of the Women's Health Study, presented at the 2013 International Headache Congress, reported that migraine with aura is a strong risk factor for any type of stroke [132; 133; 134]. Headaches associated with stroke are typically reported as dull but diffuse (35%) [135]. They are not localized to a particular side. In addition, headache presentation of a stroke is more common in patients younger than 40 years of age [135]. Headache is more likely to occur in combination with other signs and symptoms of stroke [132]. Depending upon the type of stroke, there may be a focal neurologic deficit, such as aphasia or dysarthria. Young patients should be evaluated carefully to avoid misclassification of stroke as a complicated migraine [135].

Diagnostic work-up necessitates a CT scan or MRI to identify the location of the stroke. Treatment focuses on preventing further ischemia and bleeding [132; 135]. For ischemic strokes, recombinant tissue plasminogen activator may be given within 3 to 4.5 hours of symptoms. Aspirin and other antiplatelet medications are also frequently used. For hemorrhagic stroke, most care is supportive, unless there is a large hematoma, in which case surgery may be necessary [124].

NEOPLASTIC CAUSES OF HEADACHES

Brain tumors are either primary or metastatic, and both types may have headaches as a symptom. Primary brain tumors arise from CNS tissue and account for approximately 50% of all cases of intracranial neoplasms; most do not metastasize. The remainder of brain neoplasms are caused by metastatic lesions. Gliomas, meningiomas, acoustic neuromas, and pituitary adenomas account for 95% of all primary brain tumors [136].

Estimates of the annual incidence rate of primary brain tumors range from 7 to 19.1 cases per 100,000 population. Metastatic tumors to the brain are more common, affecting more than 200,000 patients per year in the United States. Brain tumors are the second most common cancer in children, comprising 15% to 25% of all pediatric malignancies [136]. The most common primary tumors that metastasize to the brain are lung, breast, melanoma, and kidney [137]. Although the overall incidence remains low, it is increasing. This increase appears to be independent of improved diagnostic capabilities. However, it could be due to the aging population; approximately 60% of brain tumor patients are 50 to 70 years of age. Men are slightly more affected than women [136; 137].

Headache (42%) and seizure (21%) are the two most common presenting symptoms of brain tumors [137]. The headache is generally described as a dull ache and nonpulsating. It may be localized to one area early on, but often it is generalized. It tends to be mild and intermittent, but it is recurrent. Over a period of days, weeks, or months, it becomes more persistent and more intense. This is because most brain tumors tend to grow slowly over time and cause progressive symptoms. Headache is often a late complaint, not an isolated finding, and the worst presenting symptom in only one-half of patients. Most

headaches in patients with brain tumors are nonspecific and resemble tension-type headaches. New onset of headaches in middle-aged or older patients is cause for concern as is a change in any patient's headache pattern [136].

The headache is typically associated with nausea. Depending upon the type, size, and location of the tumor, there may also be neurologic, visual, and/or hearing impairment. The location of the headache reliably indicates the side of the head affected, but it does not indicate the precise site of the tumor. The cause of the headache is a progressively enlarging mass causing displacement of, or traction on, pain-sensitive intracranial structures, producing a worsening headache [136; 137].

Headaches are more common with posterior fossa tumors [136]. Colloid cysts of the third ventricle may produce explosive paroxysmal headaches that last minutes to several hours and may be brought on or alleviated by sudden changes in position. This occurs because they produce position-dependent intermittent obstruction.

Diagnosis is made by contrast-enhanced CT or MRI. MRI is most helpful for identifying tumors in the posterior fossa [136]. Scans should then be followed by histologic analysis (hence the phrase "tissue is the issue" in oncology). Depending upon several factors, including tumor type, degree of any metastasis, and comorbidities, treatment options include surgery, radiation, and/or chemotherapy.

INFECTIOUS CAUSES OF HEADACHES

In general, headaches related to infections tend to be painful, accompanied by nausea, and gradual in onset. Infections may be bacterial, viral, or fungal. The most common types of infections that cause headaches are meningitis, encephalitis, sinusitis, and brain abscess.

Meningitis

Meningitis is an inflammation of the meninges. The etiology of the meningitis may be bacterial, viral, or fungal.

Bacterial meningitis causes an abrupt diffuse headache associated with a high fever, altered consciousness (most commonly lethargy), focal neurologic deficits, and nuchal rigidity [43]. The severity of the headache and the acuteness of the infection are directly proportional. Focal neurologic deficits and papilledema are uncommon. Classically, a patient would show Kernig sign (i.e., resistance to knee extension following flexion of hips and knees) and Brudzinski sign (i.e., rapid flexion of the neck elicits involuntary flexing of the knees in a supine patient). However, a prospective study of 297 adults with suspected meningitis documented very low sensitivities for these signs (5% for Kernig sign; 5% for Brudzinski sign) indicating that their absence should not defer the performance of lumbar puncture [138]. In general, whenever the diagnosis of meningitis is strongly considered, a lumbar puncture should be promptly performed [139]. Laboratory studies reveal a CSF with more than 100 WBCs per mL and a protein level >100 mg/dL. CSF cell counts above 2,000/mL, a protein above 100 mg/dL, and a CSF-serum glucose ratio of <0.40 are all 99% specific for bacterial meningitis [139]. Treatment with antibiotics is usually empiric but may be modified by gram stain results. Typical organisms are *Haemophilus influenzae*, *Neisseria meningitidis*, and *Streptococcus pneumoniae*.

Viral meningitis causes a less severe headache that may develop over several days with a low-grade fever. The headache is usually frontal or retro-orbital. Other symptoms may include fever, irritability, nausea, vomiting, stiff neck, rash, or fatigue within the previous 18 to 36 hours. Meticulous history taking is essential and should include evaluation of exposure to ill contacts; mosquitoes, or ticks; outdoor activity in areas of endemic Lyme disease; travel history; history of medication use, including intravenous drug use; and risk of sexually transmitted disease [140]. Diagnosis may be made with the assistance of a CSF viral culture or the absence of a positive bacterial culture. Most cases of viral meningitis are caused by enteroviruses, such as coxsackieviruses and echoviruses. Herpes viruses and human immunodeficiency virus (HIV) may also cause viral meningitis. Therapy consists of bed rest, analgesics, fluids, and other conservative treatment [140].

Fungal meningitis gives a more chronic picture and may not be associated with fever or fever may be below normal. The headache is temporal, frontal, or retro-orbital. It becomes more frequent and severe over time and may be accompanied by irritability, nausea, vomiting, stiff neck, and hallucinations. Diagnosis is made by CSF analysis (fungal stain and culture, increased CSF pressure, elevated protein, decreased glucose [45% of blood glucose], and leukocytosis [40–400/mm^3—mostly mononuclear cells]). The most common organism is *Cryptococcus neoformans* [139]. *Blastomyces* and *Coccidioides* may also cause fungal meningitis. The most common treatment is with amphotericin B, an intravenous therapy. Rarely, treatment may also consist of oral antifungal drug therapy [141].

Encephalitis

Encephalitis is an inflammation of the brain parenchyma. Encephalitis may be due to either infectious or noninfectious causes. Noninfectious causes include toxins, tumors, and connective tissue disorders.

Viral encephalitis is the most common infectious type. Examples include herpes, arboviruses, HIV, and cytomegalovirus. Typically, there is acute onset of low-grade fever, altered consciousness, vomiting, and sometimes seizures. There is often disorientation and some speech disturbances. Encephalitis may occur as a secondary complication after the administration of certain vaccines or during the course of an acute illness, such as measles. Dull, diffuse headache may also be present, although it is neither common nor prominent as a symptom. When present, the headache typically does not radiate. Headache is not as common a symptom as in meningitis [142].

Most cases of encephalitis are mild and benign in nature, with symptoms resolving over one to two weeks. When neurologic symptoms are present, it may take up to two months for symptoms to completely resolve. If associated with HIV, such infections may be life-threatening.

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CSF examination is critical to establish the diagnosis and reveals moderate monocytosis and erythrocytosis with a variably elevated protein level. EEG is sensitive but not specific, and contrast CT is only 60% sensitive. It may be used, however, to evaluate acute disease progression and to follow up on complications. MRI is more sensitive than CT scan [142]. MRI with gadolinium enhancement is the preferred imaging study. One should keep in mind certain seasonal and geographic issues when differentiating specific etiologic agents.

Depending upon the etiology, treatment is mostly supportive (e.g., rest, fluid, electrolyte balance). For some conditions, antiretrovirals are available [142].

Sinusitis

Although the term "sinus headache" is widely used, sinus headaches are uncommon. Sinusitis causes headache or facial pain when mucosal swelling and purulent inflammatory debris obstruct the sinus ostium, interrupting drainage and raising pressure within the sinus cavity. This occurs most often in two clinical settings: acute bacterial superinfection (purulent sinusitis) complicating conditions that impede sinus drainage (e.g., viral upper respiratory infection, nasal allergy, polyps, deviated septum); recurring chronic sinusitis complicated by fixed mucosal damage, inadequate mucociliary transport, and retained secretions/inflammatory debris.

The paranasal frontal, ethmoid, and sphenoid sinuses are contiguous with the intracranial vault. Congestion or inflammation combined with inadequate drainage in any one of these sinuses may cause headache. The location and character of headache pain is determined by the sinus involved. The floor of the frontal sinus forms a portion of the roof of the orbit; frontal sinusitis causes pain (headache) above the eye over the region of the skull, accompanied by local tenderness and occasionally slight edema of the eyelid. This headache often occurs mid-morning and is aggravated by bending forward. The ethmoid sinus air cells are variable in number and occupy the bony area between the nasal cavity and the medial wall of the orbit. Headache associated with anterior ethmoid sinusitis is referred to the parietal region of the head, while posterior ethmoiditis causes pain in the mastoid and occipital regions. The sphenoid sinus is located behind the orbit, where the roof of the sphenoid sinus forms the pituitary fossa at the base of the brain. Sphenoid sinusitis produces a deep retro-orbital pain and coronal headache that can be severe and unremitting.

The cardinal clinical features of acute rhinosinusitis are nasal congestion/obstruction, purulent nasal discharge, and pain (regional facial pain and/or headache), Patients may exhibit low-grade fever, though this is more common in children [43]. Regional pain is often described as a deep, dull, heavy sensation of pressure or fullness that sometimes may be throbbing. Bending forward, shaking or flexion of the head, coughing, and sneezing exacerbate the pain. Sinus headache is seldom associated with nausea and, except for sphenoiditis, does not reach the same pain intensity of cluster headache or migraine. The diagnosis of sinusitis is most often made by careful clinical assessment, including sinus transillumination for suspected frontal or maxillary disease. In select cases, plain radiographs of the face ("sinus views") are helpful, as they may show clouding or air-fluid levels in the involved sinus [144]. Diagnosis may be facilitated by Gram stain and culture of purulent discharge directly from the sinuses; however, this technique is not commonly performed in the primary care office setting. Neuroimaging is usually reserved for evaluation of persistent, recurrent, or complicated cases. A CT scan is highly sensitive and is the neuroimaging modality of choice in evaluating sinusitis, particularly cases of chronic sinus disease [144]. MRI is generally preferred for the evaluation of sphenoid sinus disease, and for suspected intracranial extension of infection (e.g., orbital cellulitis, abscess).

Treatment of sinusitis is designed to promote drainage, relieve pain, and treat suspected bacterial infection. A systemic and/or topical decongestant should be administered. The most common offending bacterial pathogens are streptococcal species (group A and *S. pneumoniae*) and *Hemophilus influenzae*; therefore, a common choice is amoxicillin or amoxicillin/clavulanate for 10 to 14 days. The use of local corticosteroids may offer the allergic individual added relief when nasal symptoms are prominent [145].

It is important to note that more than 90% of self- or physician-diagnosed sinus headaches meet the IHS criteria for migraine or probable migraine [145; 146]. In those patients with migraine, the most common reasons for misdiagnosis include headache triggers, pain location, and associated features commonly attributed to sinus headache. The clinician should be aware of these unique presentations of migraine so that a correct diagnosis can be made, and effective treatment instituted [145]. Additionally, a portion of patients with self-diagnosed sinus headache suffer from a headache type that is unclassifiable by the IHS criteria. These headaches are characterized by bilateral maxillary pressure, mild-to-moderate pain intensity, cranial autonomic symptoms, and the complete absence of migraine features [145].

Brain Abscess

Brain abscesses are quite uncommon; however, when they do occur, they are life-threatening. They may originate from a contiguous site of infection (e.g., sinusitis, dental infections, otitis media), hematogenous spread, or trauma. In at least 15% of cases, the source of the infection is unknown [43; 146; 147]. They occur usually in the first three decades of life. They are also more prevalent in immunocompromised patients [146].

A moderate-to-severe headache, frequently hemicranial, is a common complaint (70%) [147]. The level of pain remains constant and may be aggravated by straining [43]. Often, there is nuchal rigidity. Frontal lobe abscesses tend to present with headache more often than other regions. In more than half of the cases, patients present with fever, altered mental status, nausea, and vomiting. There may also be papilledema and seizures [146; 147].

The time course of an abscess is reflected in the symptoms and usually progresses over one to two weeks [147]. Diagnosis is aided by CT, MRI, and nuclear medicine studies. In general, MRI provides better brain parenchymal differentiation than CT and shows the edema from the abscess in better detail [147]. The abscess is also better demonstrated because the routine brain MRI generally is multiplanar, as opposed to the routine CT, which is usually axial. However, MRI may not be useful in an acutely ill patient [146]. MR spectroscopy and some nuclear medicine studies may also be helpful to differentiate abscess from brain tumor [146]. Diffusion weighted MR may also give early indication of an infarction because this may be part of the sequelae of the abscess. Lumbar puncture is contraindicated due to its poor diagnostic yield and possible risk of herniation of the cerebellar tonsils [146; 147].

The typical treatment is evacuation/drainage and an antibiotic regimen based on cultures. The most common organisms are *Staphylococcus aureus*, *Streptococcus*, *Bacteroides* species, and *Enterobacter*. Occasionally, intracranial tuberculosis or fungal infections may present as an abscess. Therefore, cultures for acid-fast bacilli and fungi should be done in all cases [43; 146].

PRESSURE HEADACHES

Hypertension

High blood pressure is an infrequent cause of headaches. In general, it does not become a cause of headaches until diastolic blood pressure exceeds 120 mm Hg [43; 148]. The association between blood pressure and headache is most clearly manifested in patients with systolic blood pressure greater than 200 mm Hg [148]. Whether moderate hypertension predisposes to headache at all remains controversial, but there is some evidence that it does [43].

Headaches associated with high blood pressure usually appear in the morning. Typically, the headache eases as the patient gets up and about [43; 148]. It is usually dull, although sometimes throbbing, and is either diffuse or bioccipital in location. Infrequently, it is bifrontal in location. As blood pressure increases, there is often nausea, vomiting, and visual disturbances. As elevation of blood pressure progresses further, seizures and confusion may develop.

Malignant hypertension occurs when there is evidence of end-organ damage. On funduscopy, one will see papilledema and retinal hemorrhages. A diagnosis of malignant hypertension is based on the association of severely elevated blood pressure (e.g., >130 mm Hg) with severe hypertensive retinopathy [149]. The average age at diagnosis is 40 years, although a wide range of ages has been observed. Men are affected more often than women and Black individuals more often than White individuals [150; 151]. Despite progress in the overall management of hypertension, the prevalence of malignant hypertension has remained stable over the past 30 to 40 years [149].

Routine screening consists of a chest radiograph, which is useful for assessment of cardiac enlargement, pulmonary edema, or involvement of other thoracic structures. Other tests (e.g., head CT scan, transesophageal echocardiogram, renal angiography) may be indicated if directed by the initial workup. An EKG is an essential part of the evaluation to screen for ischemia, infarct, or evidence of electrolyte abnormalities or drug overdose [151]. Treatment consists of slowly reducing pressure. Too rapid a decline may cause cerebral hypoperfusion and coronary insufficiency. Recommendations advise reduction of mean arterial pressure by 25% over the first 24 to 48 hours [151]. Nitroprusside has been the drug of choice [151].

It is important not to misdiagnose the normal reactive hypertension that follows an ischemic stroke as hypertensive encephalopathy. In addition, a sudden increase in blood pressure may be the result of illicit drugs, such as cocaine or methamphetamine; this sudden increase may cause a headache [151]. Patients using MAOIs who ingest tyramine may also exhibit a precipitous rise in blood pressure that will cause a headache.

Idiopathic Intracranial Hypertension

Idiopathic intracranial hypertension (IIH) (formerly referred to as pseudotumor cerebri or benign intracranial hypertension) is characterized by increased intracranial pressure without evidence of a tumor, obstruction, infection, or encephalopathy [43; 152]. The etiology is unknown [153]. Although benign, it is not without morbidity.

Most patients present with papilledema (although IIH without papilledema has been observed), progressive visual loss, sixth-nerve palsies (10% to 40%), and headache [43; 152]. Headache is the most common symptom and is usually pulsatile and of mild severity. It is usually chronic in duration and can either be bilateral or unilateral; the most common presentation is bifrontotemporal. Overall, the patient appears in relatively reasonable health, although there may be some gastrointestinal upset [153; 154].

Incidence is greatest in young obese females. Risk factors include corticosteroid use, pregnancy, large doses of vitamin A, adrenal and parathyroid disease, and venous sinus thrombosis [43; 153].

The diagnosis is one of exclusion. Brain MRI with gadolinium enhancement is the study of choice for most patients with IIH because it provides sensitive screening for hydrocephalus, intracerebral masses, meningeal infiltrative or inflammatory disease, and dural venous sinus thrombosis. MR venography may be useful for patients who are at greater risk for dural venous sinus thrombosis. Brain CT scan is less expensive than MRI and is adequate to rule out larger tumors or lesions, but it is not as sensitive as MRI for meningeal infiltration and/or dural venous sinus thrombosis. On lumbar puncture, CSF pressure is elevated with a low protein level [153].

This condition may resolve spontaneously, although it may take several months to a year to completely resolve. Analgesics typically are given for the headache. Acetazolamide, or other diuretics, may be considered as well as serial lumbar punctures to drain fluid. Corticosteroids are sometimes used if there is

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impending visual loss. In rare circumstances, surgery consisting of lumboperitoneal shunting may be performed when the condition is refractory [153].

METABOLIC/TOXIC CAUSES OF HEADACHES

Carbon Monoxide

Numerous toxins may cause headache as a sequela. Carbon monoxide is one of the more common causes of poisoning and represents the most frequent cause of toxin-induced death. This poisoning most commonly occurs when there is inadequate or faulty ventilation. Examples of sources include car exhausts, propane heaters, and gasoline-powered generators [153; 155; 156; 157].

Patients typically present with headache, altered mental status (most commonly confusion), nausea, chest pain, and dizziness. Cherry-red discoloration of the skin and lips has been described but is a rare manifestation. The acuity and time of exposure determine the degree of symptoms [43]. High levels may cause loss of consciousness and death [153; 155; 156].

High clinical suspicion is necessary as this condition mimics other illnesses with nonspecific symptoms, including significant myocardial damage. A complete blood count and arterial blood gas analysis are helpful in aiding the diagnosis. Often, there is a metabolic acidosis with an anion gap; in addition, there may be neutrophilia. Diagnosis is made through measuring venous or arterial carboxyhemoglobin, which will be elevated (>2% nonsmokers, >9% smokers). Treatment involves 100% oxygen. Some patients may need to undergo hyperbaric treatment. In severe cases of poisoning, there may be residual brain damage [158].

Lead Poisoning

Lead poisoning is uncommon in adults. In general, it takes years of exposure before symptoms become apparent. Whereas children usually become exposed due to lead-based paint in old homes, adults can develop lead poisoning through occupational exposures [159].

Symptoms include headache, which generally is diffuse and nonspecific, irritability, confusion, mood disorders, and sleep problems. As levels become toxic, patients develop ataxia and convulsions [159].

Diagnosis is based on symptoms and blood or urine tests for lead. Treatment involves chelation therapy in severe cases, as well as removal of the source of exposure [159].

OTHER CAUSES OF SECONDARY HEADACHES

Syringomyelia

Syringomyelia is an uncommon presentation of headache. It is a condition in which a cyst forms within the spinal cord, either congenitally or due to trauma, malignancy, infection, or hemorrhage. In most cases, the disorder is related to a congenital abnormality of the brain called a Chiari malformation. This malformation occurs during the development of the fetus and causes the lower part of the cerebellum to protrude from its normal location in the back of the cranium into the cervical portion of the spinal canal [160].

The cyst, or syrinx, gradually expands and elongates over time, eventually resulting in destruction of the cord's center. As a result, patients may present with a variety of symptoms, although they typically present with headache, back pain and stiffness, and numbness of the extremities [160]. Symptoms usually begin between 25 and 40 years of age; they are more common in men than women and may worsen with straining (e.g., heavy lifting) or any activity that causes CSF pressure to fluctuate [160].

Signs of the disorder tend to develop slowly, although sudden onset may occur with coughing or straining. In addition, there are often long periods of stability. The preferred imaging modality is MRI, which shows dilation of the central canal and may reveal contributing factors (e.g., a tumor). The usual treatment when significant symptoms are present is surgery, which involves drainage of the syrinx. If not treated surgically, syringomyelia may lead to progressive weakness in the arms and legs, loss of hand sensation, and chronic, severe pain [160].

In the absence of symptoms, syringomyelia is usually followed by observation over time. Patients are advised to avoid activities that involve straining [160].

Dental and Myofascial Causes

There may be times when referral to a dentist is appropriate for headache management. Disorders of the teeth usually cause toothache and/or facial pain; those causing headache are rare. Pain from the teeth may be referred, however, and cause diffuse headache. The most common cause of headache is periodontitis or pericoronitis as the result of infection or traumatic irritation around a partially erupted lower wisdom tooth [43].

Myofascial pain dysfunction (MPD) syndrome (formerly called temporomandibular joint or TMJ syndrome) originates in the muscles that move the jaw. Symptoms include dull, aching pain in and around the ear, which may radiate to the side of the scalp, back of the head, or down into the neck. Usually, the source of pain is an overuse of the masticatory musculature through parafunction. The most common dental parafunctional habits are bruxism and clenching. The patient is often unaware of the habit, which may take place while asleep [161].

Initial therapy is directed at relief of muscle spasms and involves use of heat, massage, a soft and non-chewy diet, muscle relaxing, and pain-reducing medications. For many patients, one or two weeks of such treatment is sufficient to eliminate the symptoms. Early treatment is important to prevent shifting of the jaw and arthritic changes in the jaw joint [161].

Cervicogenic Headache

Cervicogenic headache is often a sequela of head or neck injury but may also occur in the absence of trauma [162]. With this type of headache, the pain is perceived to be in the head but is

actually referred from the cervical spine. Typically, the pain may be characterized as insidious in nature and unilateral in position [163]. The parietal and occipital areas are most commonly affected. The pain is usually constant and may last for days to weeks. It is aggravated by neck movements. On exam, there is usually cervical paraspinal tenderness. The source of pain is usually the cervical ligaments or intervertebral discs [162].

The mean age of patients with this condition is 43 years, and it is four times more prevalent in women than in men [162; 163]. Diagnostic criteria have been established, but the presenting characteristics of cervicogenic headache are often difficult to distinguish from primary headaches disorders, such as tension-type headache [43; 162]. Additionally, there are significant differences, especially with respect to quality of life. In a study comparing responses on a medical outcomes questionnaire for patients with cervicogenic headache, episodic tension-type headache, and patients with migraine without aura, domain scores for physical functioning for patients with cervicogenic headache were lower than the tension-type and migraine groups [164].

Diagnostic imaging cannot confirm the diagnosis of cervicogenic headache but may lend support to its diagnosis. Successful treatment requires a multifaceted approach, including using pharmacologic, nonpharmacologic, manipulative, anesthetic, and occasionally surgical interventions. Medications alone have proven to be ineffective or, at best, to provide only modest benefit [162; 163].

Medication Overuse

Medication overuse headache, also known as rebound headache, results from misuse of drugs, most notably over-the-counter analgesics or migraine medications. It is most common in patients with frequent migraine attacks or tension-type headaches [165]. Chronic tension-type headache is less often associated with medication overuse; however, episodic tension-type headache has commonly become a chronic headache through overuse of analgesics [43]. The headache is caused by frequent use of anti-headache medications for more than 15 days per month. Evidence suggests that this occurs sooner with triptan overuse than with ergotamine overuse [43; 166]. The mean period of time that elapses before this type of headache evolves ranges from one to two years for the triptans, three to five years for ergotamines, and up to 5 to 10 years for over-the-counter analgesics [167]. The pathophysiology of this syndrome remains unknown.

The diagnosis of medication-overuse headache is clinically extremely important because patients rarely respond to preventative medications while overusing acute medications [43]. Treatment is withdrawal from the medication. If tapered, this may take more than two weeks, depending on the medication. Improvement should occur within two months after cessation of overuse in order for the diagnosis to be definite [43]. This is followed by prophylactic treatment of the primary headache [165; 166].

Herbal Medications

It is important to consider the use of herbal medications as a possible cause of headaches. Approximately 38% of adults in the United States use at least one herbal medicine [168]. Many patients do not admit use to physicians, either because they do not consider them to be a "medication," because they do not need a prescription to obtain them, or because they are embarrassed to admit they use a medication that most physicians do not consider scientific. Herbal medications that have been reported to cause headaches include valerian root, ginkgo biloba, and ginseng [169].

ACUTE VERSUS CHRONIC

Although chronic headache is a term often used by patients, as well as some clinicians, it is no longer a recognized diagnosis. Patients either have a chronic primary headache or a chronic secondary headache. Chronic daily headache occurs in approximately 4% to 5% of the population [170; 171]. The overwhelming majority of chronic headaches are primary headaches, typically migraine or tension. Chronic headache is not a separate syndrome. The general time frame for chronic is when the headache occurs on more than 15 days of each month, whether or not the patient is taking any medication.

REFERRAL

One of the most important decisions in managing patients with headaches, especially chronic headaches, is when to continue care and when to refer care. In general, most patients with benign headaches can be managed by primary care physicians and other clinicians. There are several factors involved when one should consider referral to a specialist. These include, but are not limited to:

- Minimal physician expertise in headache management
- Unable to determine diagnosis
- Failure of the patient to respond to appropriate treatment
- Worsening symptoms
- Development of rebound cycles
- Dependence on opioids
- Significant comorbidities

When one or more of these conditions exist, referral to a specialist should be considered. Specialists typically are neurologists, although some are internists and family practitioners who focus their clinical practice on headache management. Headaches represent the most common reason for neurology visits [172]. Therefore, physicians should not view referral as failure on their part.

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EVIDENCE-BASED PRACTICE RECOMMENDATION

The decision to seek a specialty consultation will depend upon the practitioner's familiarity and comfort with headache and its management. The Institute for Clinical Systems Improvement recommends considering specialty consultation when:

- The diagnosis cannot be confirmed.
- Etiology cannot be diagnosed or warning signals are present.
- Headache attacks are occurring with a frequency or duration sufficient to impair the patient's quality of life despite treatment or the patient has failed to respond to acute remedies or is in status migrainosus.

(https://www.icsi.org/wp-content/uploads/2019/01/HeadacheES.pdf. Last accessed August 15, 2023.)

Level of Evidence: Expert Opinion/Consensus Statement

MEDICO-LEGAL ISSUES

With rising malpractice premiums, the threat of malpractice remains high on the minds of many healthcare professionals. With respect to headaches, physicians are fearful of missing that rare brain tumor or other catastrophic cause of headache. When such a misdiagnosis occurs, a malpractice claim may ensue. Any malpractice action falls under tort law.

Tort law allows injured persons to recover damages through the civil (i.e., noncriminal) judicial system. It is important to note that injury is a necessary but not sufficient requirement for recovery and most injuries do not give rise to a legal action. In the context of medical malpractice suits, the most relevant aspect of tort law is negligence as that is the claim most plaintiffs raise. A common claim for headache management is "failure to diagnose."

Not all bad outcomes, however, support a claim for negligence. There are several necessary components to negligence, all of which must be present for a plaintiff to prevail. First, the defendant must have owed some duty to the plaintiff to adhere to a specific standard of conduct and protect the plaintiff from unreasonable risk of injury. In the context of the doctor-patient relationship, this duty is for the physician to meet the standard of care for his or her profession. Generally, the standard of care is the knowledge and skill held by a member of the profession in the same community or a similar community. The standard of care for specialists is somewhat higher as it is based on the knowledge and skill held by specialists.

Second, the defendant must have breached this duty by deviating from the standard of care. Such a deviation may be either an act or an omission. Finally, this breach of duty must be the actual and proximate cause of the plaintiff's injury. This means that a physician might make a clear medical error but if that error proves harmless and does not actually cause any injury to the patient, there is no legitimate claim for negligence.

In order to minimize malpractice, physicians and other clinicians should document their actions and thought processes in the medical record. In addition, it is imperative that physicians keep up to date on the management of the conditions that they treat. If one has little expertise in headache management and the patient's condition is not improving, one should then consider referral.

CONCLUSION

Headaches represent one of the most common medical conditions and are a frequent reason for physician visits. They produce a significant socioeconomic cost in terms of lost work and decreased quality of life. In general, most headaches will be benign; however, there should be a thorough history and physical exam each time a patient presents with headaches. Most headaches will be primary in origin (i.e., migraine, tension, cluster), but secondary causes need to be excluded. Physicians should be aware of the warning signs that warrant an immediate and thorough work-up and realize that a patient may have more than one headache disorder. Various imaging modalities, such as CT, MRI, and PET, exist but should be used prudently, based on clinical presentation and clinical suspicion of disease.

Numerous treatment modalities exist to treat the various headache syndromes. Therapies for primary headaches include both pharmacologic and nonpharmacologic interventions. Preventive therapies also should be explored for patients with repeat headaches. Finally, primary care physicians and clinicians should know when to refer patients to a specialist.

ADDITIONAL SOURCES OF INFORMATION

American Migraine Foundation
https://americanmigrainefoundation.org

American Headache Society (AHS)
https://americanheadachesociety.org

Help for Headaches
http://www.headache-help.org

International Headache Society
https://ihs-headache.org

National Headache Foundation
https://headaches.org

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

COURSE TEST - #50214 DIAGNOSING AND MANAGING HEADACHES

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 August 31, 2026.

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AGD Subject Code: 200.

This course meets the Dental Board of California's requirements for 10 units of continuing education.

Dental Board of California course #10-3841-00401.

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1. All of the following statements regarding the epidemiology of headaches are true, EXCEPT:
- *A) Women have a greater incidence of headaches than men.*
- *B) Three-fourths of adults experience some type of headache each year.*
- *C) About 25% of patients with headache seek medical attention.*
- *D) More than $2 billion is spent annually on over-the-counter medications to treat headache.*

2. People tend to seek medical care for headaches when they experience
- *A) increased frequency.*
- *B) persistent symptoms.*
- *C) an unusually intense headache.*
- *D) All of the above*

3. How much do headaches cost in direct and indirect expenditures annually?
- *A) $12 billion*
- *B) $14 billion*
- *C) $16 billion*
- *D) $18 billion*

4. Secondary headaches account for what percentage of headaches?
- *A) 5%*
- *B) 10%*
- *C) 15%*
- *D) 20%*

5. Which of the following is considered a "red flag" when assessing the patient with headaches?
- *A) Gradual onset*
- *B) Accelerating pattern*
- *C) Normal systemic findings*
- *D) Onset around 20 years of age*

6. The use of electroencephalogram (EEG) is
- *A) useful when patients present with encephalopathy.*
- *B) not recommended for routine work-up of headaches.*
- *C) of limited value in determining structural causes of headache.*
- *D) All of the above*

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7. All of the following statements regarding imaging for patients with headache are true, EXCEPT:
- *A) Most patients tolerate CT scans easily.*
- *B) MRI is preferred for cervical spine lesions.*
- *C) Most CT scans for headache are done with contrast.*
- *D) CT scans are more sensitive than MRI for posterior fossa lesions.*

8. The U.S. Headache Consortium developed which of the following management principles for neuroimaging in patients with nonacute headache?
- *A) Testing should be completed even if the test results will not lead to a change in management.*
- *B) Testing that may not normally be recommended as a population policy may make sense at the individual level.*
- *C) Testing is recommended even if the individual is not significantly more likely than anyone else in the general population to have a significant abnormality.*
- *D) All of the above*

9. A migraine aura without headache
- *A) is the most common type of migraine.*
- *B) most commonly occurs in young women.*
- *C) is often described as the worst pain one can experience.*
- *D) predominately occurs in older individuals with a history of migraine with aura.*

10. Which of the following factors may act as a trigger for migraine headaches?
- *A) Stress*
- *B) Caffeine withdrawal*
- *C) Low barometric pressure*
- *D) All of the above*

11. All the following statements regarding the acute treatment of migraine are true, EXCEPT:
- *A) Triptans are contraindicated in the setting of ischemic heart disease.*
- *B) Ergotamine derivatives tend to increase the likelihood of rebound headaches.*
- *C) Opioids are among the most commonly used class of drugs in treating migraine.*
- *D) Both the triptan and ergotamine classes of drugs work to alleviate migraine headaches, in part, by their vasoconstrictive properties.*

12. Which of the following is TRUE regarding cluster headaches?
- *A) The pain is often bilateral.*
- *B) They may induce lacrimation.*
- *C) Bilateral conjunctival injection may occur.*
- *D) They are commonly mild to moderate in pain intensity.*

13. Which of the following statements is TRUE regarding tension headaches?
- *A) Tension headaches are more common in men.*
- *B) Tension headaches are solely due to muscle spasm in the head and neck region.*
- *C) The lifetime prevalence for tension headaches ranges from 30% to 78%.*
- *D) Tension headaches are the most extensively studied of the primary headaches.*

14. Which of the following medications should be avoided for the treatment of tension headaches?
- *A) Aspirin*
- *B) NSAIDs*
- *C) Narcotics*
- *D) Acetaminophen*

15. All of the following are considered etiologic categories for secondary headaches, EXCEPT:
- *A) Tension*
- *B) Metabolic*
- *C) Neoplastic*
- *D) Traumatic*

16. Which of the following statements is TRUE regarding epidural hematomas?
- *A) Posterior fossa is most often involved.*
- *B) MRI is more useful than unenhanced CT.*
- *C) Characteristic white lenticular shapes are observed on CT.*
- *D) All of the above*

17. Subdural hematomas
- *A) are typically caused by metastases.*
- *B) often present with focal neurologic signs.*
- *C) are more common than epidural hematomas.*
- *D) evolve more quickly than arterial hemorrhage.*

18. Which of the following may be used as a treatment for a subdural hematoma?
- *A) Diuretics*
- *B) Antiepileptics*
- *C) Surgical evacuation*
- *D) All the above*

Test questions continue on next page ➞

19. Which of the following characteristics is commonly associated with a subarachnoid hemorrhage (SAH)?
- A) *Dull pain*
- B) *Mild severity*
- C) *Early focal deficits*
- D) *Radiation of pain to the neck and back*

20. The mean age for an SAH is
- A) *30 years of age.*
- B) *50 years of age.*
- C) *70 years of age.*
- D) *80 years of age.*

21. Giant cell (temporal) arteritis typically presents with
- A) *fever.*
- B) *hyperactivity.*
- C) *ache in neck.*
- D) *All of the above*

22. Headache with a stroke is
- A) *atypical.*
- B) *usually unilateral.*
- C) *indicative of a hemorrhagic stroke.*
- D) *more common in patients younger than 40 years of age.*

23. Cerebrospinal fluid (CSF) analysis of patients with encephalitis demonstrates
- A) *monocytosis.*
- B) *erythrocytosis.*
- C) *decreased protein.*
- D) *Both A and B*

24. An individual with sinusitis usually presents with all of the following, EXCEPT:
- A) *Fever*
- B) *Nausea*
- C) *Leukocytosis*
- D) *Purulent nasal discharge*

25. Which of the following would best aid in the diagnosis of a brain abscess?
- A) *MRI*
- B) *CT scan*
- C) *MR spectroscopy*
- D) *Lumbar puncture*

26. All of the following are true regarding syringomyelia, EXCEPT:
- A) *It results in numbness of the extremities.*
- B) *It is an uncommon presentation of headache.*
- C) *It is most often related to a congenital abnormality of the brain.*
- D) *It usually becomes symptomatic between 45 and 60 years of age.*

27. All of the following are true regarding rebound or medication overuse headache, EXCEPT:
- A) *It has a well-understood pathophysiology.*
- B) *Treatment is withdrawal from the medication.*
- C) *It is caused by frequent use of analgesics or migraine medications.*
- D) *It is most common in patients with frequent migraine headaches or chronic tension headaches.*

28. All of the following are true regarding chronic headaches, EXCEPT:
- A) *Chronic headache is not a separate syndrome.*
- B) *Most chronic headaches are primary headaches.*
- C) *Chronic daily headache occurs in 10% of the population.*
- D) *Headaches occur on more than 15 days of each month, whether or not the person is taking any medications.*

29. Which of the following factors should trigger referral to a headache specialist?
- A) *Failure of the patient to respond to appropriate treatment*
- B) *Dependence of the patient on opioids for headache management*
- C) *Minimal expertise of the primary physician regarding headache management*
- D) *All of the above*

30. Which of the following statements regarding medico-legal issues in headache management is TRUE?
- A) *Physicians are fearful of missing a catastrophic cause of headache.*
- B) *A common claim for headache management is "failure to diagnose."*
- C) *Injury is a necessary but not sufficient requirement for recovery of damages.*
- D) *All of the above*

Be sure to transfer your answers to the Answer Sheet located on the envelope insert.
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AIRWAY MANAGEMENT: BASICS FOR HEALTHCARE PROVIDERS

#50010 • 5 CE Credit Hours • $45

Purpose: Gaining control of the airway in a compromised patient is absolutely crucial. The purpose of this course is to provide dental professionals with the clinical knowledge needed to rapidly and effectively assess the patient's airway and intervene efficiently to begin to ventilate the patient in distress.
Faculty: Richard E. Haas, BSN, MSN, EdM, PhD, CRNA (Retired), LTC US Army Nurse Corps (Retired)
Audience: This course is designed for dental professionals involved in monitoring and maintaining patients' airways.
AGD Subject Code: 142

ORAL CANCER AND COMPLICATIONS OF CANCER THERAPIES

#50683 • 5 CE Credit Hours • $45

Purpose: Problematic oral changes can affect more than oral health, and dental professionals should consider individuals' oral health in their overall patient care plans. The purpose of this course is to define oral cancer and briefly explain its diagnostic criteria as well as discuss the changes experienced within the oral environment after the treatments for oral and systemic cancers are initiated.
Faculty: Mark J. Szarejko, DDS, FAGD
Audience: This course is designed for all dental professionals, including dentists, dental hygienists, and dental assistants.
AGD Subject Code: 730

HIPAA PRIVACY AND SECURITY

#51140 • 5 CE Credit Hours • $45

Purpose: The purpose of this course is to provide information that will allow dental professionals to more easily comply with the Privacy and Security Rules defined by HIPAA.
Faculty: Carol Shenold, RN, ICP
Audience: This course is designed for all dental professionals.
AGD Subject Code: 566

WHAT HEALTHCARE PROFESSIONALS SHOULD KNOW ABOUT EXERCISE

#51724 • 5 CE Credit Hours • $45

Purpose: The purpose of this course is to supply the information necessary for dental professionals to provide practical advice for patients beginning an exercise program.
Faculty: John J. Whyte, MD, MPH
Audience: This course is designed for all dental professionals working with adult patients who are overweight or obese and should begin an exercise program.
AGD Subject Code: 150

PROMOTING THE HEALTH OF GENDER AND SEXUAL MINORITIES

#51793 • 5 CE Credit Hours • $45

Purpose: More individuals who identify as gender and sexual minorities and their families want culturally appropriate information as well as support and referral. The purpose of this course is to provide dental professionals with strategies that promote cultural competency when treating and caring for these patients, supporting the concept of patient-centered care.
Faculty: Leslie Bakker, RN, MSN
Audience: This course is designed for all members of the dental team, including dentists, dental hygienists, and dental assistants, working in all practice settings.
AGD Subject Code: 750

CARPAL TUNNEL SYNDROME

#51953 • 3 CE Credit Hours • $27

Purpose: The purpose of this course is to provide dental professionals with awareness of carpal tunnel syndrome, based on specific signs and symptoms and appropriate diagnostic tests, and of interventions available to treat and/or prevent the condition.
Faculty: Charlene H. Grafton, RN, BS, MS, CCM
Audience: This course is designed for dental professionals who may encounter patients with carpal tunnel syndrome or who are at risk for carpal tunnel syndrome themselves.
AGD Subject Code: 149

ORAL AND MAXILLOFACIAL INFECTIONS

#54033 • 5 CE Credit Hours • $45

Purpose: The purpose of this course is to emphasize to dental professionals the importance of quickly identifying and treating oral and maxillofacial infections.
Faculty: Mark J. Szarejko, DDS, FAGD
Audience: This course is designed for all dental professionals involved in the identification and treatment of oral and maxillofacial infections.
AGD Subject Code: 310

ORAL MANIFESTATIONS OF SEXUALLY TRANSMITTED INFECTIONS

#54072 • 5 CE Credit Hours • $45

Purpose: The purpose of this course is to introduce dental professionals to the pathophysiology of STIs, their oral manifestations, systemic complications, available treatment options, and any modifications required for dental treatment.
Faculty: Mark J. Szarejko, DDS, FAGD
Audience: This course is designed for all dental professionals.
AGD Subject Code: 148

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Course Availability List *(Cont'd)*

NUTRITION AND ORAL HEALTH
#54121 • 6 CE Credit Hours • $54
Purpose: The purpose of this course is to provide clinicians with a better understanding of the impact of nutrition on dental health and care.
Faculty: Mark J. Szarejko, DDS, FAGD
Audience: This course is designed for all dental professionals.
AGD Subject Code: 150

MULTIDRUG-RESISTANT MICROBIAL INFECTIONS
#54214 • 5 CE Credit Hours • $45
Purpose: In spite of a growing understanding and application of effective control measures, the problem of multidrug-resistant microbial infection remains a ubiquitous and complex issue for communities and hospitals. Each decade seems to usher in a new generation of common bacterial pathogens that have become resistant to available medications, resulting in ongoing excess morbidity, mortality, and healthcare costs. The purpose of this course is to provide an overview of the basics of antimicrobial resistance mechanisms and to review the classes of multidrug-resistant pathogens currently prevalent in healthcare facilities and the community, including guidelines for prevention and options for therapy.
Faculty: Carol Shenold, RN, ICP; John M. Leonard, MD
Audience: This course is designed for dental professionals involved in the treatment and care of patients with infections.
AGD Subject Code: 148

MEDICAL EMERGENCIES IN THE DENTAL SETTING
#54354 • 5 CE Credit Hours • $45
Purpose: Patients, those who accompany them, or members of the dental staff can be stricken suddenly and without warning by any of a variety of medical emergency issues. The purpose of this course is to provide all members of the dental staff with the training necessary to provide immediate assistance to a patient that experiences any problem that constitutes a medical emergency.
Faculty: Mark J. Szarejko, DDS, FAGD
Audience: This course is designed for all members of the dental profession, including dentists, dental hygienists, and dental assistants.
AGD Subject Code: 142

VIRAL DISEASES: ORAL INVOLVEMENT AND COMPLICATIONS
#54984 • 5 CE Credit Hours • $45
Purpose: The purpose of this course is to provide dental professionals with a review of several viral organisms and the effect they have directly and indirectly upon dental treatment, oral health, and systemic health.
Faculty: Mark J. Szarejko, DDS, FAGD
Audience: This course is designed for all dental professionals involved in evaluating and maintaining patients' oral health.
AGD Subject Code: 148

ANALGESICS IN DENTISTRY
#55044 • 5 CE Credit Hours • $45
Purpose: The purpose of this course is to describe new reports and new information on analgesics for the dental professional to use in determining the best pharmacotherapeutic approach in those situations requiring oral analgesics.
Faculty: Richard L. Wynn, BSPharm, PhD
Audience: This course is designed for all dental professionals.
AGD Subject Code: 200

MEDICATION USE IN DENTISTRY
#55253 • 5 CE Credit Hours • $45
Purpose: As the number of medications and range of uses grow, dental prescribing has become increasingly complex. The purpose of this course is to provide dental professionals with the knowledge necessary to effectively prescribe and to monitor the effects of commonly used drugs.
Faculty: Mark J. Szarejko, DDS, FAGD
Audience: This course is designed for all dental professionals.
AGD Subject Code: 010

DENTAL ETHICS: A BRIEF REVIEW
#57424 • 2 CE Credit Hours • $18
Purpose: The purpose of this course is to provide dental professionals with a review of ethics and ethical theoretical systems that pertain to their profession. The content of this course is not intended as legal advice for patients or practitioners.
Faculty: William E. Frey, DDS, MS, FICD; Michele Nichols, RN, BSN, MA
Audience: This course is designed for all dental professionals.
AGD Subject Code: 555

CANNABINOID OVERVIEW


#58010 • 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 various cannabinoids.
Faculty: Chelsey McIntyre, PharmD
Audience: This course is designed for dental professionals whose patients are taking or are interested in taking cannabinoid products.
AGD Subject Code: 149

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	55290	Responsibilities & Requirements of Prescribing Schedule II Opioid Drugs / 2 CE Credit Hours	$18
	58030	Getting to the Point: Acupuncture and Acupoint Therapies / 4 Credit Hours	$36
	51234	OSHA and Healthcare Facilities / 5 CE Credit Hours	$45
	50214	Diagnosing and Managing Headaches / 10 CE Credit Hours	$90

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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.**

#51293 THE CALIFORNIA DENTAL PRACTICE ACT—2 CE CREDIT HOURS

Please refer to pages 26–27.

Expiration Date: 01/31/25 *May be taken individually for $18*

	A	B	C	D		A	B	C	D
1.	❍	❍	❍	❍	6.	❍	❍	❍	❍
2.	❍	❍	❍	❍	7.	❍	❍	❍	❍
3.	❍	❍	❍	❍	8.	❍	❍	❍	❍
4.	❍	❍	❍	❍	9.	❍	❍	❍	❍
5.	❍	❍	❍	❍	10.	❍	❍	❍	❍

#55290 REQUIREMENTS OF PRESCRIBING SCHEDULE II OPIOID DRUGS—2 CE CREDIT HOURS

Please refer to pages 59–60.

Expiration Date: 01/31/27 *May be taken individually for $18*

	A	B	C	D		A	B	C	D
1.	❍	❍	❍	❍	6.	❍	❍	❍	❍
2.	❍	❍	❍	❍	7.	❍	❍	❍	❍
3.	❍	❍	❍	❍	8.	❍	❍	❍	❍
4.	❍	❍	❍	❍	9.	❍	❍	❍	❍
5.	❍	❍	❍	❍	10.	❍	❍	❍	❍

#51234 OSHA AND HEALTHCARE FACILITIES—5 CE CREDIT HOURS

Please refer to pages 93–94.

Expiration Date: 01/31/26 *May be taken individually for $45*

	A	B	C	D		A	B	C	D
1.	❍	❍	❍	❍	11.	❍	❍	❍	❍
2.	❍	❍	❍	❍	12.	❍	❍	❍	❍
3.	❍	❍	❍	❍	13.	❍	❍	❍	❍
4.	❍	❍	❍	❍	14.	❍	❍	❍	❍
5.	❍	❍	❍	❍	15.	❍	❍	❍	❍
6.	❍	❍	❍	❍	16.	❍	❍	❍	❍
7.	❍	❍	❍	❍	17.	❍	❍	❍	❍
8.	❍	❍	❍	❍	18.	❍	❍	❍	❍
9.	❍	❍	❍	❍	19.	❍	❍	❍	❍
10.	❍	❍	❍	❍	20.	❍	❍	❍	❍

#58583 INFECTION CONTROL FOR DENTAL PROFESSIONALS: THE CA REQ.—2 CE CREDIT HOURS

Please refer to pages 43–44.

Expiration Date: 01/31/25 *May be taken individually for $18*

	A	B	C	D		A	B	C	D
1.	❍	❍	❍	❍	6.	❍	❍	❍	❍
2.	❍	❍	❍	❍	7.	❍	❍	❍	❍
3.	❍	❍	❍	❍	8.	❍	❍	❍	❍
4.	❍	❍	❍	❍	9.	❍	❍	❍	❍
5.	❍	❍	❍	❍	10.	❍	❍	❍	❍

#58030 ACUPUNCTURE AND ACUPOINT THERAPIES—4 CE CREDIT HOURS

Please refer to pages 74–76.

Expiration Date: 10/31/25 *May be taken individually for $36*

	A	B	C	D		A	B	C	D
1.	❍	❍	❍	❍	11.	❍	❍	❍	❍
2.	❍	❍	❍	❍	12.	❍	❍	❍	❍
3.	❍	❍	❍	❍	13.	❍	❍	❍	❍
4.	❍	❍	❍	❍	14.	❍	❍	❍	❍
5.	❍	❍	❍	❍	15.	❍	❍	❍	❍
6.	❍	❍	❍	❍	16.	❍	❍	❍	❍
7.	❍	❍	❍	❍	17.	❍	❍	❍	❍
8.	❍	❍	❍	❍	18.	❍	❍	❍	❍
9.	❍	❍	❍	❍	19.	❍	❍	❍	❍
10.	❍	❍	❍	❍	20.	❍	❍	❍	❍

50214 DIAGNOSING AND MANAGING HEADACHES—10 CE CREDIT HOURS

Please refer to pages 132–134.

Expiration Date: 08/31/26 *May be taken individually for $90*

	A	B	C	D		A	B	C	D
1.	❍	❍	❍	❍	16.	❍	❍	❍	❍
2.	❍	❍	❍	❍	17.	❍	❍	❍	❍
3.	❍	❍	❍	❍	18.	❍	❍	❍	❍
4.	❍	❍	❍	❍	19.	❍	❍	❍	❍
5.	❍	❍	❍	❍	20.	❍	❍	❍	❍
6.	❍	❍	❍	❍	21.	❍	❍	❍	❍
7.	❍	❍	❍	❍	22.	❍	❍	❍	❍
8.	❍	❍	❍	❍	23.	❍	❍	❍	❍
9.	❍	❍	❍	❍	24.	❍	❍	❍	❍
10.	❍	❍	❍	❍	25.	❍	❍	❍	❍
11.	❍	❍	❍	❍	26.	❍	❍	❍	❍
12.	❍	❍	❍	❍	27.	❍	❍	❍	❍
13.	❍	❍	❍	❍	28.	❍	❍	❍	❍
14.	❍	❍	❍	❍	29.	❍	❍	❍	❍
15.	❍	❍	❍	❍	30.	❍	❍	❍	❍

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2. How much time did you spend on this activity, including the test questions?
3. Would you recommend this course to your peers?
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5. Did the course content demonstrate the author's knowledge of the subject?
6. Was the course content free of bias?
7. Before completing this course, did you identify the necessity for education on the topic to improve your professional practice?
8. Have you achieved all of the stated learning objectives of this course?
9. Has what you think or feel about this topic changed?
10. Did evidence-based practice recommendations assist in determining the 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?

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1. ☐ New ☐ Review	1. ☐ New ☐ Review	1. ☐ New ☐ Review	1. ☐ New ☐ Review	1. ☐ New ☐ Review	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	5. ☐ Yes ☐ No	5. ☐ Yes ☐ No
6. ☐ Yes ☐ No	6. ☐ Yes ☐ No	6. ☐ Yes ☐ No	6. ☐ Yes ☐ No	6. ☐ Yes ☐ No	6. ☐ Yes ☐ No
7. ☐ Yes ☐ No	7. ☐ Yes ☐ No	7. ☐ Yes ☐ No	7. ☐ Yes ☐ No	7. ☐ Yes ☐ No	7. ☐ Yes ☐ No
8. ☐ Yes ☐ No	8. ☐ Yes ☐ No	8. ☐ Yes ☐ No	8. ☐ Yes ☐ No	8. ☐ Yes ☐ No	8. ☐ Yes ☐ 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. ☐ Yes ☐ No	10. ☐ Yes ☐ No	10. ☐ Yes ☐ No	10. ☐ Yes ☐ No
11. ☐ Yes ☐ No	11. ☐ Yes ☐ No	11. ☐ Yes ☐ No	11. ☐ Yes ☐ No	11. ☐ Yes ☐ No	11. ☐ Yes ☐ No
12. ☐ Yes ☐ No	12. ☐ Yes ☐ No	12. ☐ Yes ☐ No	12. ☐ Yes ☐ No	12. ☐ Yes ☐ No	12. ☐ Yes ☐ No

#51293 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? _____

#58583 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? _____

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