# Burket's Oral Medicine

Thirteenth Edition

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# Preface

It is with great pleasure that we share this thirteenth edition of the classic text *Burket's Oral Medicine* with students, residents, and professional colleagues around the world. This edition reflects the scope of modern oral medicine in both the content and the international nature of many new contributors.

Two experienced editors with international reputations for clinical and academic excellence, Dr. Peter Lockhart and Dr. Stephen Challacombe, have been added as Editors to this new edition, which has contributed to expanding the scope of the text and the diversity of the authors.

As the volume and availability of both basic and clinical biomedical information are growing at an ever-increasing pace, we realize that today's students, teachers, and practitioners of oral medicine must broaden the scope of their knowledge to increase their competence as clinicians, academics, and researchers. The chapters from the 12th edition describing oral mucosal and salivary gland disease, orofacial pain, TMD, and dental management of medically complex patients have been expanded and updated. In addition, the 13th edition contains chapters not found in traditional books in this discipline, including chapters on clinical research, pediatric oral medicine, psychiatry and psychology, geriatric oral medicine, laboratory medicine, and appraising and interpreting the biomedical literature.

With more than 80 authors from across the globe, we have broadened the scope and approach to ensure that this text is highly relevant to teaching and practice in many different countries and clinical settings.

**Michael Glick, Martin S. Greenberg, Peter B. Lockhart, and Stephen J. Challacombe**

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# 1

# Introduction to Oral Medicine and Oral Diagnosis: Patient Evaluation

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Oral medicine, as defined by the American Academy of Oral Medicine, is "the specialty of dentistry responsible for the oral health care of medically complex patients and for the diagnosis and management of medically related disorders or conditions affecting the oral and maxillofacial region." Definitions vary in different parts of the world, but most include the diagnosis and nonsurgical management of oral mucosal and salivary gland disease, orofacial pain, and dental treatment of patients with medical disorders.

The overall goal for all oral healthcare professionals is to deliver and maintain optimal health for their patients. A recent definition was approved by the World Dental Parliament in 2016, which expanded the definition to include three different domains: disease and condition status, psychosocial status, and physiologic function.[1] The inclusion of a psychosocial status and physiologic function deviates from traditional definitions that mainly focused on the presence or absence of disease, and, further, it promotes the inclusion of patient values and preferences, as well as elevates the importance of subjective findings. This approach is more aligned with a person-centered care approach that emphasizes a patient's problem in the context of behavioral, socioeconomic, and environmental aspects, and their impact on the patient and on the care that needs to be delivered.[2–4] This definition has also been the underlying framework to establish outcomes that can be used to measure the oral status of an individual.[5]

Given the nature, complexity, and potential systemic implications for some oral conditions, coupled with an aging population with multimorbidities (multimorbidities do not identify an index disease, while comorbidities focus on an index disease and other diseases) and individuals taking numerous medications, all oral healthcare clinicians are required to enhance their knowledge of many aspects of medicine. Therefore, what previously was considered the purview of oral healthcare professionals with hospital-based

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training has become increasingly more important in general and specialty dental practice.

Advances in clinical practice are influencing many aspects of patient care, from our initial contact with a patient, through medical history-taking, diagnosis, and treatment options. For example, electronic health records (EHRs) allow for sharing health information among multiple clinicians caring for the same patient and can provide point-of-care algorithms for eliciting and using health information. Modern imaging techniques, such as computerized tomography scans (CTs) and magnetic resonance imaging (MRI), provide more detailed information and are a means to acquire more sophisticated data, but require enhanced training for accurate interpretation. Nevertheless, one of the most important skills for accurate diagnosis and management remains an experienced clinician with highly developed skills of listening and examination.

The initial encounter with a patient may influence all subsequent care. The skilled, experienced practitioner has learned to elicit the subjective (i.e., history-taking) and objective (e.g., clinical, laboratory) findings and other necessary information required for an accurate diagnosis. This process is an art, as well as a skill. Although mastering a patient evaluation can be assisted by specific clinical protocols, the experienced practitioner will add their own skills and experience to the diagnostic methodology.

A variety of accessible sources of healthcare information are now readily available to patients, and many will use this information to self-diagnose, as well as demand specific treatments. As a person-centered approach is encouraged, where a patient's preferences and values will influence care, the practitioner must listen to the patient to understand their needs, fears, and wishes and address them to arrive at an appropriate treatment plan that results in informed, scientific, and evidence-based choices. Furthermore, part of a shared decision-making approach includes the responsibility of the oral healthcare professional to educate their patient about the implications and consequences of a diagnosis and subsequent treatment. Creating an environment for effective communication between provider and patient has been shown to improve health outcomes.[6]

The process of obtaining, evaluating, and assessing a patient's oral and overall health status can arbitrarily be divided into seven major, sometimes overlapping, parts:

1) History and examination.
2) Establishing a differential diagnosis.
3) Obtaining necessary consultations, as well as appropriate laboratory tests, such as specific blood investigations, a biopsy, and imaging studies, all based upon the initial differential diagnosis.
4) Final diagnosis.
5) Formulating a plan of action.
6) Initiating treatment.
7) Follow-up assessment of response to treatment.

## INFORMATION GATHERING

An appropriate interpretation of the information collected through a medical history and patient examination achieves several important objectives. It affords an opportunity for:

- Gathering the information necessary for establishing a diagnosis for the patient's chief complaint.
- Assessing the influence of the patient's systemic health on their oral health.
- Detecting other systemic health conditions of which the patient may not be aware.
- Providing a basis for determining whether dental treatment might impact the patient's systemic health.
- Giving a basis for determining necessary modifications to routine dental care.
- Monitoring medical conditions of relevance to the maxillofacial condition.

### Medical History

Obtaining an appropriate and accurate medical history is a critical first step for all patient care. It begins with a systematic review of the patient's chief or primary complaint, a detailed history related to this complaint, information about past and present medical conditions, pertinent social and family histories, and a review of symptoms by organ system. A medical history also includes biographic and demographic data used to identify the patient.

There is no universally agreed method for obtaining a medical history, but a systematic approach will help the practitioner to gather all necessary information without overlooking important facts. The nature of the patient's oral health visit (i.e., initial dental visit, complex diagnostic problem, emergency, elective continuous care, or recall) often dictates how the history is obtained. The two most common means of obtaining initial patient information are a patient self-administered preprinted health questionnaire, or recording information during a systematic health interview without the benefit of having the patient fill out a questionnaire. The use of self-administered screening questionnaires is the most common method in dental settings. This technique can be useful in gathering background medical information, but the accurate diagnosis of a specific oral complaint requires a history of the present illness and other verbal information. While the basic information for a past medical history may be obtained by a questionnaire, a vital

part of the evaluation of a patient with a complex diagnostic problem is the history of the present illness, which is a combination of science and art and should be taken directly by the clinician.

The challenge in any healthcare setting is to use a questionnaire that has enough items to obtain the essential medical information, but is not too long to deter a patient's willingness and ability to fill it out. These questionnaires should be constructed in a manner that allows the clinician to query the patient about the most essential and relevant required information, yet provides a starting point for a dialogue with the patient about other pertinent information not included on the health form. Preprinted self-administered or online health questionnaires are readily available, standardized, and easy to administer and do not require significant "chair time." They give the clinician a starting point for a dialogue to conduct more in-depth medical queries, but are restricted to the questions chosen on the form and are therefore limited in scope. The questions on the form can be misunderstood by the patient, resulting in inaccurate information, and they require a specific level of reading comprehension. Preprinted forms cover broad areas without necessarily focusing on particular problems pertinent to an individual patient's specific medical condition. Therefore, the use of these forms requires that the provider has sufficient background knowledge to understand the reasons for the questions on the forms. Furthermore, the provider needs to realize that a given standard history form necessitates timely and appropriate follow-up questions, especially when positive responses have been elicited. An established routine for performing and recording the history and examination should be followed conscientiously.

The oral healthcare professional has a responsibility to obtain relevant medical and dental health information, yet the patient cannot always be relied upon to know this information or to provide an accurate and comprehensive assessment of their medical or dental status.

All medical information obtained and recorded in an oral healthcare setting is considered confidential and may in many jurisdictions constitute a legal document. Although it is appropriate for the patient to fill out a history form in the waiting room, any discussion of the patient's responses must take place in a private setting. Furthermore, access to the written or electronic (if applicable) record must be limited to personnel who are directly responsible for the patient's care. Any other release of private information should be approved, in writing, by the patient and that approval retained by the dentist as part of the patient's medical record.

Given that medical status and medication regimens often change, a patient's health status or medication regimen should be reviewed at each office visit prior to initiating dental care. The monitoring of patients' compliance with suggested medical treatment guidelines and prescribed medications is part of the oral healthcare professional's responsibilities. The following strategies are common to nearly all methods of history-taking:

- Review available patient information prior to meeting the patient.
- Greet the patient; use the patient's name; ensure privacy; sit rather than stand, preferably at eye level; maintain eye contact as often as possible; listen carefully to the patient's concerns; do not rush the interview process.
- Do not concentrate chiefly on entering the information into an electronic health record, as this may distract you from listening to pertinent information.
- Use the patient's own words (in quotation marks) to describe the primary reason(s) to seek care/consultation; i.e., be absolutely clear about the patient's chief complaint(s).
- Use open-ended questions to encourage open dialogue with the patient. Although all information should be collected in a systematic fashion, the order is not as important as is initiating a dialogue with the patient about their health.
- Create a timeline of the reported patient-related events. An accurate chronology is an extremely important element to establish or deny a causative relationship.

The medical history traditionally consists of the following subcategories:

- *Identification*—name, date and time of the visit, date of birth, gender, ethnicity, occupation, contact information of a primary care provider (physician and, if applicable, dentist), referral source.
- *Chief complaint (CC)*—the main reason for the patient seeking care or consultation and the length of time these symptoms have been present, recorded in the patient's own words.
- *History of present illness (HPI)*—taking an effective HPI takes experience and is often the key to making an accurate differential diagnosis. It includes a chronologic account of events; state of health before the presentation of the present problem; description of the first signs and symptoms and how they may have changed; description of occurrences of amelioration or exacerbation; previous clinicians consulted, prior treatment, and degree of the response to previous treatment. For those who favor mnemonics, the nine dimensions of a medical problem can be easily recalled using OLD CHARTS (Onset, Location/radiation, Duration, Character, Habits, Aggravating factors, Reliving factors, Timing, and Severity).[7]
- *Review of systems (ROS)*—identifies symptoms in different body systems (Table 1-1). The ROS is a comprehensive and systematic review of *subjective* symptoms affecting different bodily systems. It is an essential component for

**Table 1-1** Review of Systems (ROS): A systematic approach to ascertain mostly subjective symptoms associated with the different body systems.

| |
|---|
| **General:** Weight changes, malaise fatigue, night sweats |
| **Head:** Headaches, tenderness, sinus problems |
| **Eyes:** Changes in vision, photophobia, blurring, diplopia, spots, discharge |
| **Ears:** Hearing changes, tinnitus, pain, discharge, vertigo |
| **Nose:** Epistaxis, obstructions |
| **Throat:** Hoarseness, soreness |
| **Respiratory:** Chest pain, wheezing, dyspnea, cough, hemoptysis |
| **Cardiovascular:** Chest pain, dyspnea, orthopnea (number of pillows needed to sleep comfortably), edema, claudication |
| **Dermatologic:** Rashes, pruritus, lesions, skin cancer (epidermoid carcinoma, melanoma) |
| **Gastrointestinal:** Changes in appetite, dysphagia, nausea, vomiting, hematemesis, indigestion, pain, diarrhea, constipation, melena, hematochezia, bloating, hemorrhoids, jaundice |
| **Genitourinary:** Changes in urinary frequency or urgency, dysuria, hematuria, nocturia, incontinence, discharge, impotence |
| **Gynecologic:** Menstrual changes (frequency, duration, flow, last menstrual period), dysmenorrhea, menopause |
| **Endocrine:** Polyuria, polydipsia, polyphagia, temperature intolerance, pigmentations |
| **Musculoskeletal:** Muscle and joint pain, deformities, joint swellings, spasms, changes in range of motion |
| **Hematologic:** Easy bruising, epistaxis, spontaneous gingival bleeding, increased bleeding after trauma |
| **Lymphatic:** Swollen or enlarged lymph nodes |
| **Neuropsychiatric:** Syncope, seizures, weakness (unilateral and bilateral), changes in coordination, sensations, memory, mood, or sleep pattern, emotional disturbances, history of psychiatric therapy |

identifying patients with a disease that may affect dental treatment or associated symptoms that will help determine the primary diagnosis. For example, a patient with skin, genital, or conjunctival lesions who also has oral mucosal disease, or a patient with anesthesia, paresthesia, or weakness who also presents with orofacial pain. The clinician records both negative and positive responses. Direct questioning of the patient should be aimed at collecting additional data to assess the severity of a patient's medical conditions, monitor changes in medical conditions, and assist in confirming or ruling out those disease processes that may be associated with patient's symptoms.

- *Past medical history (PMH)* (may not have been revealed in systems review)—general health; immunizations; major adult illnesses; any surgical operations (date, reason, and outcome); medications (prescribed medications, over-the-counter medications, supplements) and home remedies; allergies.
- *Personal and social history (SH)*—birthplace; marital status; children; habits (tobacco use, alcohol use, recreational drug use); occupation; religion (if it may have an impact on therapy); sexual history if relevant to complaint.
- *Family history (FH)*—health or cause of death of parents, siblings, and children. The FH should also include diseases important to the patient's chief compliant, including genetic disorders; and common diseases, such as cardiovascular diseases or diabetes mellitus.

## Patient Examination

The examination of the patient represents the second stage of the evaluation and assessment process. An established routine for examination decreases the possibility of missing important findings (signs).

A routine head and neck examination should be carried out at least annually or at each recall visit. This includes a thorough inspection (and when appropriate palpation, auscultation, or percussion) of the exposed surface structures of the head, neck, and face and a detailed examination of the oral cavity, dentition, oropharynx, and adnexal structures. Laboratory studies and additional special examination of other organ systems may be required for the evaluation of patients with orofacial pain, oral mucosal disease, or signs and symptoms suggestive of otorhinologic or salivary gland disorders, or signs or symptoms suggestive of a systemic etiology. A less comprehensive but equally thorough inspection of the face and oral and oropharyngeal mucosae should be carried out at each visit and the tendency to focus on only the tooth or jaw quadrant in question should be strongly resisted.

Each visit should be initiated by a deliberate inspection of the entire face and oral cavity prior to intraoral examination. The importance of this approach in the early detection of head and neck cancer cannot be overstated (see Chapter 7, Oral and Oropharyngeal Cancer).

Examination carried out in the dental office (surgery) is traditionally restricted to that of the superficial tissues of the oral cavity, head, and neck and the exposed parts of the extremities. On occasion, evaluation of an oral lesion logically leads to an inquiry about similar lesions on other skin or mucosal surfaces or about the enlargement of other regional groups of lymph nodes. Although these inquiries can usually be satisfied directly by questioning the patient, the oral health professional may also quite appropriately request permission from the patient to examine axillary nodes or other skin surfaces, provided

that the examination is carried out competently and there is adequate privacy for the patient. A male oral health professional should have a female assistant present in the case of a female patient; a female oral health professional should have a male assistant present in the case of a male patient. Similar precautions should be followed when it is necessary for a patient to remove tight clothing for accurate measurement of blood pressure. A complete physical examination should not be attempted when facilities are lacking or when religious or other customs prohibit it, or when no chaperone is present.

The degree of responsibility accorded to the oral health professional in carrying out a complete physical examination varies among institutions, hospitals, states, and countries.

The examination procedure in a dental office setting may include any or all of the following six areas:

- Registration of vital signs (respiratory rate, temperature, pain level, pulse, and blood pressure).
- Examination of the head, neck, and oral cavity, including salivary glands, temporomandibular joints, and head and neck lymph nodes.
- Lesions of the oral mucosa should have a detailed description including location, size, color, ulceration and induration, and an assessment of the severity made. Detailed descriptions of specific diseases presenting as ulcers, blisters, or white or red lesions can be found in Chapters 3–7.
- Assessment of cranial nerves, particularly when the patient presents with nondental orofacial pain, weakness, anesthesia, or paresthesia.
- Examination of other organ systems, when appropriate.
- Ordering indicated laboratory studies.

## Consultations

### *Requesting Consultations from Other Clinicians*

The overall purpose of a consultation is to clarify issues or help with diagnosis or management. Oral medicine clinicians are involved with two major types of consultations: those that they initiate for their own patients as a request from another healthcare professional; and those in response to a request for help with a patient of another healthcare professional.

Consent from the patient is needed before a consultation is initiated. All verbal and written consultation should be documented in the patient's record. A consultation letter should identify the patient and contain a brief overview of the patient's pertinent medical history and a request for relevant and specific information. The written request should be brief and should specify the particular concern and items of information needed from the consultant (Box 1-1).

Patients who may need medical consultation include:

- Those with known medical problems who are scheduled for either inpatient or outpatient dental treatment and cannot adequately describe all of their medical problems.
- Those with abnormalities detected during history-taking, on physical examination, or through laboratory studies.
- Those who have a higher risk for the development of a particular medical problem (e.g., diabetes with increased risk of atherosclerotic cardiovascular disease).
- Those for whom additional medical information is required that may impact the provision of dental care or assist in the diagnosis of an orofacial problem.
- Those with an orofacial disorder, which may also affect other parts of the body. For example, oral lesions may also involve the skin and conjunctiva.
- Those who are being considered for a medication that may have an adverse effect on another medical problem, such as diabetes or hypertension, or drug interactions.

Requests for consultation should include the problem and the specific questions to be answered and should be transmitted to the consultant in writing. Adequate details of the planned oral or dental procedure, include, as appropriate:

- Estimated risk of clinically significant bleeding.
- Assessment of time and stress to the patient.
- Expected period of post-treatment disability.
- Details of the particular symptom, sign, or laboratory abnormality that gave rise to the consultation.

Medically complex patients may have a medical condition that suggests the need for an opinion from the patient's physician as to risks involved in an invasive or stressful dental procedure, too often referred to as "clearing the patient for dental care."[8] In many cases, the physician is provided with too little information about the nature of the proposed dental treatment (type of treatment, amount of local anesthetics, anticipated bleeding, etc.) to help in this regard. Physicians cannot be expected to understand the nature of dental procedures and they should not be asked to "clear" patients for dental treatment. They should be contacted for pertinent medical information that will help the oral healthcare provider make the decision as to the appropriateness of the dental treatment plan. The response of a given patient to specific dental interventions may be unpredictable, particularly patients with comorbidities and those taking one or more medications. A physician's advice and recommendation may be helpful in managing a patient, but the responsibility to provide safe and appropriate care lies ultimately with the clinician performing the procedure.[9] Another health professional cannot from a legal standpoint "clear" a patient for any dental procedure and thus a request for "medical clearance" should be avoided.[8]

**Box 1-1 Oral Medicine Inpatient Consultation**

**Patient:** BRADLEY, BOB **MRN:** 0002222222
**Age:** 36 years **Sex:** Male **DOB:** 5/4/1983
**Oral Medicine Resident:** Dr. Alexandra Howell

**Requesting Service:** Hematology **Attending Physician:** INPATIENT HEMATOLOGY
**Reason for Admission:** LEUKOCYTOSIS; THROMBOCYTOPENIA
**Date of Admission:** 01/24/2020 **Hospital Day:** 2

**Reason for Consult**: Hospital dentistry consult requested by Dr. Green for oral evaluation and to rule out oral infection prior to immunosuppressive chemotherapy.
**Source of History**: Patient and medical record.

**Chief Complaint:** Patient not aware of any problems with his mouth in the past 6 months. He denies active dental pain but says that his "enamel keeps chipping off."

**History of Present Illness:**
Patient is a 36 y/o male with past medical history of chronic acid reflux who presented to our Emergency Room on January 24 with right-sided abdominal & flank pain and decreased urine output. He was found to have an acute kidney injury with hyperkalemia. CT of his abdomen/pelvis showed hydronephrosis/hydroureter and splenomegaly. CBC revealed white blood cell count of 53.9, hemoglobin of 10, and platelets 29,000. He was transferred to the inpatient hematology service for further evaluation and management of acute T-cell ALL and tumor lysis.

**Health Status**
**Allergies**: None known
**Current Medications**:
allopurinol 300mg per 1 tablet ORAL daily
hydroxyurea (Hydrea) 1,000 mg per 2 capsules ORAL q8h
sevelamer (sevelamer carbonate 800 mg oral tablet) 800 mg per 1 tablet ORAL TIDWM (3 times a day with meals)
**Labs** from 01/25/2020: ANC = 3150; INR=1.2; aPTT = 32.8; ALT/AST = 26/28.

**Past Medical History**: No active or resolved past medical history items have been selected or recorded. Patient states he has not seen a dentist in 10+ years.

**Family History**: Cancer—mother. Diabetes mellitus—father.

**Extraoral examination:** No trismus or swelling noted. Significant lymphadenopathy in postauricular area bilaterally.

**Intraoral examination:** Very poor oral hygiene with heavy plaque and calculus. Rampant dental caries with several retained root tips and fractured teeth. Noted a draining sinus tract/fistula on the buccal gingiva of lower left first molar (root tip) with moderate swelling and erythema. Also noted possible sinus tract above tooth #8.

**Review/Management:** Reviewed soft tissue neck CT. Relevant dental findings include numerous dental caries and extensive periodontal disease with periapical lucencies involving the mandibular left second molar, mandibular left first molar, mandibular right first molar, and multiple maxillary and mandibular incisors. Multiple root tips, and grossly enlarged and erythematous gingiva.

**Impression:** Diagnosis: dental caries, root tips, and advanced periodontal disease. Multiple draining sinus tracts/fistulas of the buccal gingiva. Posterior auricular bilateral lymphadenopathy R>L, moderate sized.

**Recommendations:** Patient does have clear signs of active dental infection. Recommend patient be transported to the dental clinic by wheelchair for a comprehensive clinical examination, full mouth series of radiographs and a Panorex for full treatment planning. We have tentatively scheduled him for the dental clinic on Monday morning, 1/27/20 at 10:00 am, pending medical stability. Treatment recommendations will be available following our department case conference on Tues 1/28/20.

### *Responding to Consult Requests from Other Clinicians*

There are three major categories of oral medicine consultations:

- Diagnosis and nonsurgical treatment of orofacial disorders, including oral mucosal disease, temporomandibular and myofascial dysfunction, chronic lesions involving the maxilla and the mandible, orofacial pain, dental anomalies, maxillary and mandibular bone lesions, salivary gland disorders, and disorders of oral sensation, such as dysgeusia, dysesthesia, and glossodynia.
- Dental treatment of patients with medical problems that affect the oral cavity or for whom modification of standard dental treatment is required to avoid adverse events.
- Opinion on the management of dental disease that does not respond to standard treatment, such as rampant dental caries or periodontal disease in which there is a likelihood of a systemic etiologic cofactor.

In response to a consultation request, the diagnostic procedures outlined in this chapter may be followed, with the referral problem listed as the chief complaint and with supplementary questioning (i.e., history of the present illness) directed to the exact nature, mode of development, prior diagnostic evaluation/treatment, and associated symptomatology of the primary complaint. An examination of the head, neck, and oral cavity is important and should be fully documented, and the ROS should include an exploration of any associated symptoms and including pertinent negatives. When pertinent, existing laboratory, radiographic, and medical records should be reviewed and documented in the consultation record, and any additional testing or specialized examinations should be ordered.

A comprehensive consultation always includes a written report of the consultant's examination, usually preceded by a history of the problem under investigation and any items from the medical or dental history that may be relevant to the problem. A formal diagnostic summary follows, together with the consultant's opinion on appropriate treatment and management of the issue. Other previously unrecognized abnormalities or significant health disorders should also be communicated to the referring clinician. When a biopsy or initial treatment is required before a definitive diagnosis is possible, and when the terms of the consultation request are not clear, a discussion of the initial findings with the referring clinician is appropriate before proceeding. Likewise, the consultant usually discusses the details of their report with the patient, unless the referring dentist specifies otherwise. In community practice, patients are sometimes referred for consultation by telephone or are simply directed to arrange an appointment with a consultant and acquaint them with the details of the problem at that time; a written report is still necessary to clearly identify the consultant's recommendations, which otherwise may not be transmitted accurately by the patient. The details of an oral consultation must be documented on the patient's chart.

An important responsibility for hospital-based dentists is responding to consults from medical and surgical services. It is not at all uncommon for hospitalized patients to have routine maxillofacial problems (e.g., toothache) that have nothing to do with their reason for hospitalization. More commonly, patients may have a wide variety of problems that are directly related to their medical condition or its treatment (e.g., mucositis secondary to cancer chemotherapy) or require a dental exam to eliminate a possible source of infection during cancer chemotherapy.[9]

In hospital practice, the dental consultant is always advisory to the patient's attending physician; the recommendations listed at the end of the consultation report are suggestions and not *orders,* and are not implemented unless authorized by the attending physician. For some oral lesions and mucosal abnormalities, a brief history and examination of the lesion will readily identify the problem, and only a short report is required; this accelerated procedure is referred to as a limited consultation (Box 1-2).

Both custom and health insurance reimbursement systems recognize the need of individual practitioners to request the assistance of a colleague who may have more experience with the treatment of a particular clinical problem or who has received advanced training in a medical or dental specialty pertinent to the patient's problem. However, this practice of specialist consultation is usually limited to defined problems, with the expectation that the patient will return to the referring primary care clinician once the nature of the problem has been identified (diagnostic consultation) and appropriate treatment has been prescribed or performed (consultation for diagnosis and treatment).

## ESTABLISHING A DIFFERENTIAL AND FINAL DIAGNOSIS

Before establishing a final diagnosis, the clinician often needs to formulate a differential diagnosis based on the history and physical examination findings. The disorders included in the differential diagnosis will determine which laboratory tests, such as biopsies, blood tests, or imaging studies, are required to reach a final diagnosis.

**Box 1-2 Outpatient Oral Medicine Consultation**

Date: _____

To: John Doe MD

From: Robert Dent DMD

Patient Name and Date of Birth

The patient is a 19-year-old female sent for a consultation for evaluation of recurring oral ulcerations, which have been increasing in severity for the past 5 months.

The patient has a history of occasional oral ulcers since age 10 with 2 to 3 ulcers occurring 3 to 4 times yearly and lasting 8 to 10 days. Five months ago, she began to experience 5 to 10 ulcers each month lasting 2 to 3 weeks. Each episode has been treated with prednisone 30 mg once daily for 5 to 7 days. The lesions heal with this regimen, but recur in 3 to 4 weeks.

The patient denies conjunctival lesions, although on 2 occasions during the past 3 months she had a vaginal ulcer. She has acne-type facial lesions since taking prednisone monthly.

Her past medical history is remarkable for depression. She denies hospitalizations or surgery and has no known drug allergies.

She takes Lexapro for depression, but no medications other than prednisone for oral ulcers.

Her review of systems is remarkable for weekly episodes of intestinal cramping and diarrhea. She denies GI bleeding or black tarry stools. The remainder of the review of systems is noncontributory except for the skin and vaginal lesions noted above.

The family history is significant for her mother and maternal grandmother having a history of recurring oral ulcers during adolescence. Her father is of Japanese descent and her mother is Caucasian.

She is currently a college student and denies smoking or use of recreational drugs.

The examination showed multiple acne-like lesions of the skin of the face.

There was no cervical lymphadenopathy or salivary gland enlargement.

Cranial nerves II–XII were grossly intact.

The oral mucosa had 5 shallow ulcers 5 mm to 8 mm in diameter surrounded by inflammation: two involving the left lateral tongue, one on the dorsal tongue, and one involving the left buccal mucosa. No vesicles or white lesions were present.

Impressions

1) Recurrent aphthous ulcers; increasing in severity during the past 5 months
2) R/O Behçet's disease
3) R/O Lupus
4) R/O celiac disease
5) R/O blood dyscrasia

Plan:

1) Order the following laboratory studies: CBC, CMP, ANA, ESR, tTG-IgA
2) Dermatology consult for evaluation of skin and vaginal lesions, and pathergy test
3) Ophthalmology consult to rule out uveitis or retinal vasculitis suggestive of Behçet's disease
4) GI consultation
5) Biopsies of oral ulcer for routine histology and lupus band test
6) Begin treatment with Clobetasol propionate gel, 0.05% directly to lesions tid
7) If the above laboratory tests and consultations are normal and there is inadequate benefit from topical steroids, consider a trial of pentoxifylline or colchicine

The rapidity and accuracy with which a diagnosis or set of diagnoses can be achieved depend on the history and examination data that have been collected and on the clinician's knowledge and ability to match these clinical data with suspected disease processes. Experienced clinicians with a more extensive knowledge of physiology and maxillofacial disease, and a broader knowledge of the relevant literature, can more rapidly establish a differential and diagnosis. Such "mental models" of disease syndromes also increase the efficiency with which experienced clinicians gather and evaluate clinical data and focus supplemental questioning and testing at all stages of the diagnostic process.

For effective treatment, as well as for health insurance and medicolegal reasons, it is important that a diagnosis (or diagnostic summary) is entered into the patient's record, following the detailed history and physical, radiographic, and laboratory examination findings. This may be a provisional diagnosis dependent on the results of investigation. When more than one health problem is identified, the diagnosis for the primary complaint is usually listed first. Previously diagnosed conditions that remain as actual or potential problems are also included, with the qualification "by history," "previously diagnosed," or "treated" to indicate their status. Problems that were identified but not clearly diagnosed during the current evaluation can also be listed with the comment "to be ruled out." Since oral medicine is concerned with problems that may be modified or linked to concurrent systemic diseases, it is common for the list of diagnoses to include both the oral problem such as a lesion or pain and systemic problems of actual or potential significance in the etiology or management of the oral problem. Items in the medical history that do not relate to the current problem and are not of major health significance usually are not included in the diagnostic summary. For example, for a presenting complaint of pain and swelling in the left side of the face in a 62-year-old female, a diagnosis list might read as follows:

| | | |
|---|---|---|
| Current: | 1) | Alveolar abscess, mandibular left first molar |
| | 2) | Rampant generalized dental caries secondary to radiation-induced salivary hypofunction |
| | 3) | Hyperglycemia; R/O diabetes |
| Previous | 4) | Carcinoma of the tonsillar fossa, by history, excised and treated with 65 Gy 2 years ago |
| | 5) | Cirrhosis and prolonged prothrombin time, by history |

A definite diagnosis cannot always be made, despite a careful review of all history, clinical, and laboratory data. In such cases, a descriptive term (rather than a formal diagnosis) may be used for the patient's symptoms or lesion, with the added word "idiopathic," "unexplained," or (in the case of symptoms without apparent physical abnormality) "functional" or "symptomatic." If a note is written prior to a definitive diagnosis, a clinician may list a descriptive term such as chronic oral ulcer with the diseases that must be "ruled out" (R/O) listed, from most to least likely. For example:

oral ulcer from chronic trauma
R/O squamous cell carcinoma
R/O granulomatous disease

The clinician must decide which terminology to use in conversing with the patient and whether to clearly identify this diagnosis as "undetermined." It is important to recognize the undiagnosed nature of the patient's problem and to schedule additional evaluation, by referral to another consultant, additional testing, or placement of the patient on recall for follow-up studies.

Unfortunately, there is no generally accepted system for identifying and classifying diseases, and diagnoses are often written with concerns related to third-party reimbursement and to medicolegal and local peer review, as well as for the purpose of accurately describing and communicating the patient's disease status. Within different specialties, attempts have been made to achieve conformity of professional expressions and language.

Some standardization of diagnoses has been achieved in the United States as a result of the introduction in 1983 of the diagnosis-related group (DRG) system as an obligatory cost-containment measure for the reimbursement of hospitals for inpatient care. However, groupings are mostly based on medical diagnoses, such as the *International Classification of Diseases, Tenth Revision* (ICD-11).[10] The DRG system is designed for fiscal use rather than as a system for the accurate classification of disease. It also emphasizes procedures rather than diseases and has a number of serious flaws in its classification and coding system. The ICD system, by contrast, was developed from attempts at establishing an internationally accepted list of causes of death and has undergone numerous revisions in the past 160 years since it was first suggested by Florence Nightingale; it is maintained by the World Health Organization. It relates to the various emphases placed on clinical, anatomic, biochemical, and perceived etiologic classification of disease at different times and different locations. However, the categories for symptoms, lesions, and procedures applicable to oral cavity conditions are limited and often outdated.

The patient (or, when appropriate, a responsible family member or guardian) should also be informed of the diagnosis, as well as the results of the examinations and tests carried out. Because patients' anxieties frequently emphasize the possibility of a potentially serious diagnosis, it is important to point out (when the facts allow) that the biopsy specimen revealed no evidence of a malignant growth, the blood test revealed no abnormality, and no evidence of

diseases, such as diabetes, anemia, leukemia, or other cancer, was found. Equally important is the necessity to explain to the patient the nature, significance, and treatment of any lesion or disease that has been diagnosed.

## FORMULATING A PLAN OF ACTION

### Medical Risk Assessment

Medical risk assessment of patients before oral or dental treatment offers the opportunity for greatly improving dental services for patients with complex health conditions. It requires considerable clinical training and understanding of the natural history and clinical features of systemic disease. It is hoped that revisions in dental pre-doctoral training will recognize this need and provide greater emphasis on both the pathophysiology of systemic disease and the practical clinical evaluation and management of medically complex patients.

The information gathering described above is also designed to help the oral health professional:

- Recognize a general health status that may affect dental treatment.
- Make informed judgments on the risk of dental procedures.
- Identify the need for medical consultation to provide assistance in ascertaining the presence of a systemic disease that may be associated with an oral pathology or that may adversely impact on the proposed dental treatment.

Reaching the end point of the diagnostic process and the formulation of a plan of action are usually not a simple process. In order to minimize any adverse events, an assessment of any special risks associated with a patient's compromised medical status that could be triggered by the planned anesthetic, diagnostic, or medical or surgical treatment procedure must be entered in the patient record, usually as an addendum to the plan of treatment. This process of medical risk assessment is the responsibility of all clinicians prior to initiating any treatment or intervention and applies to outpatient as well as inpatient situations.

A routine of initial history-taking and physical examination is essential for all dental patients, as even the apparently healthy individual may, on evaluation, be found to have a history or examination findings of sufficient significance to require a modification to the plan of treatment, a change to a medication, or deferring dental treatment until additional diagnostic data are available. To respect the familiar medical axiom *primum non nocere* (first, do no harm), all procedures carried out and all prescriptions given to a patient should be preceded by conscious consideration of the potential risk of the planned procedure. Establishing a formal medical risk assessment ensures a continuous evaluation process. A summary of the medical risk assessment, delineating potential risks from the proposed plan of action, should be entered in the patient record.

The Medical Complexity Status (MCS) was specifically developed for dental patients and has been used successfully for patients with medical problems ranging from nonsignificant to very complex diseases and conditions.[11] The MCS protocol is based on the premise that complications will rarely arise during provision of routine dental care in an outpatient setting to patients with stable or controlled medical conditions. However, modification of dental care may still be necessary in some circumstances and should be based on the level of the anticipated complication. The MCS classification and protocol, with examples, are described in more detail in Table 1-2.

### Modification of Dental Care for Medically Complex Patients

Although there are many different medical conditions that may require modification of dental care, and protocols for a wide variety of situations, the assessment of risk to medically complex patients follows similar guidelines. It is helpful to focus on the following three questions, which will change according to the severity of the underlying disease or condition:

- What is the likelihood that the patient will experience an adverse event due to dental treatment?
- What are the nature and severity of the potential adverse event?
- What is the most appropriate setting in which to treat the patient?

Each of these questions can be subdivided into smaller entities, which will facilitate the assessment of the patient.

The four major concerns that must be addressed when assessing the likelihood of the patient experiencing an adverse event are:

- Potential for impaired hemostasis from medications or disease.
- Potential susceptibility to infection, both maxillofacial and distant to the oral cavity (e.g., infective endocarditis).
- Drug actions and interactions.
- Patient's ability to tolerate the stress and trauma of the dental procedure.

Patients are designated to an MCS category at their initial dental visit, which may be modified during subsequent visits

their causes). The plan of treatment (similar to the diagnostic summary) should be entered in the patient's record and explained to the patient in detail. This encompasses the procedure, chances for improvement or cure (prognosis), potential complications and side effects, and number of appointments and expense. As initially formulated, the plan of treatment usually lists recommended procedures for the control of current disease as well as preventive measures designed to limit the recurrence or progression of the disease process over time. For medicolegal reasons, the treatment that is most likely to eradicate the disease and preserve as much function as possible (i.e., the ideal treatment) is usually entered in the chart, even if it is clear that compromises may be necessary to obtain the patient's consent to treatment.

It is also unreasonable for the clinician to prejudge a patient's decision as to how much time, energy, and expense should be expended on treating the patient's disease or how much discomfort and pain the patient is willing to tolerate. Patient involvement in decisions regarding the treatment plan—shared decision-making—is necessary to help achieve a satisfactory outcome. Such an approach has been promulgated by the Institute of Medicine as "patient-centered care" and is defined as "Providing care that is respectful of and responsive to individual patient preferences, needs, and values, and ensuring that patient values guide all clinical decisions."[12]

The plan of treatment may be itemized according to the components of the diagnostic summary and is usually written prominently in the patient record to serve as a guide for the scheduling of further treatment visits. If the plan is complex or if there are reasonable treatment alternatives, a copy should also be given to the patient to allow consideration of the various implications of the plan of treatment that they have been asked to agree. Modifications of the ideal plan of treatment, agreed on by patient and clinician, should also be entered in the chart, together with a signed disclaimer from the patient if the modified plan of treatment is likely to be significantly less effective or unlikely to eradicate a major health problem.

Numerous protocols have been proposed to facilitate efficient and accurate preoperative assessment of medical risk. Many of the earlier guides were developed for the assessment of risks associated with general anesthesia or major surgery and focus on mortality as the dependent variable. All too often, these were adopted for risk assessment associated with invasive dental procedures performed under local or regional anesthesia. Of these, the most commonly used is the American Society of Anesthesiologists (ASA) Physical Scoring System (Table 1-3).[13] Although scores such as the ASA classification are commonly included in the preoperative evaluation of patients admitted to hospitals for dental surgery, they use relatively broad risk categories, and their applicability to both inpatient and outpatient dental procedures is limited. Importantly, the ASA score was developed for and is used to assess a patient's ability to tolerate general anesthesia and should therefore not be used to predict complications associated with dental surgery in the outpatient setting.

**Table 1-3** American Society of Anesthesiologists (ASA) physical status classification system.

| | |
|---|---|
| ASA I | A normal healthy person |
| ASA II | A patient with a mild disease |
| ASA III | A patient with a severe systemic disease |
| ASA IV | A patient with a severe systemic disease that is a constant threat to life |
| ASA VI | A declared brain-dead patient whose organs are being removed for donor purposes |

In the event of an emergency, precede the number with an "E."
Adapted from American Society of Anesthesiologists. *ASA Physical Status Classification System*. https://www.asahq.org/standards-and-guidelines/asa-physical-status-classification-system. Accessed September 22, 2020.

### Monitoring and Evaluating Underlying Medical Conditions

Several major medical conditions can be monitored by oral healthcare personnel.[14] Signs and symptoms of systemic conditions, the types of medications taken, and the patient's compliance with medications can reveal how well a patient's underlying medical condition is being controlled. Signs of medical conditions are elicited by physical examination, which includes measurements of blood pressure and pulse, or laboratory or other diagnostic evaluations. Symptoms are elicited through an ROS, whereby subjective symptoms that may indicate changes in a patient's medical status are ascertained. A list of the patient's present medications, changes in medications and daily doses, and a record of the patient's compliance with medications usually provide a good indicator of how a medical condition is being managed. The combined information on signs, symptoms, and medications is ultimately used to determine the level of control and status of the patient's medical condition.

## CLINICAL OUTCOMES AND ORAL DISEASE SEVERITY SCORING

All fields in medicine work toward evidence-based therapy. It is regarded as essential for the advancement of any field, including oral medicine, that there is continuous assessment of the results of treatment, so leading to progress in management. However, it is true that many treatments for oral

diseases are not evidence based, even those regarded as standard therapies. Until the last few years, there had been a lack of any method to routinely assess disease severity and thus to quantify responses to therapies. This led to the obvious need to devise and validate oral disease severity scores for a variety of conditions seen in routine clinical practice, which could also be used for assessing treatment responses. The accepted principle in medicine and surgery is that the response to therapy should be assessed in every single patient seen. This can be performed both from the perspective of the clinician (disease severity scores) and from the patient (patient-reported outcome measures or PROMs).

Disease severity scoring systems are tools that can help clinicians assess both the severity of the objective clinical findings as well as the subjective features of the disease, including its impact on patients' lives. There are three essential aspects that are important in defining the "intensity of the disease": clinical score measuring the level of inflammation, area, and specific clinical features (e.g., ulceration); subjective reporting of pain that the disease is inflicting; and a questionnaire relating to how the condition affects patients' functioning and their lives, known as oral health-related quality of life (OHRQoL).[15] There are now several validated and universally used tools for oral diseases that should be used at every patient visit.

### Oral Disease Severity Scoring

The benefits of a scoring system for mucosal disease severity are that (1) they can indicate the severity of disease; (2) they are needed to indicate the efficacy of any treatments; (3) they may distinguish between or reveal subgroups of activity; (4) they may assist in deciding to implement or withhold treatment; and (5) they are a routine clinical audit tool that can also be used for research.

Any such oral disease scoring systems (ODSS) much be objective, must be reproducible, should be easy to use, and should be widely applicable. Fortunately, such ODSSs have been created, validated, and are in use for recurrent aphthous ulceration, oral lichen planus pemphigus, mucous membrane pemphigoid, orofacial granulomatosis, and dry mouth assessment.[15–20] Although additional work is required before these scoring systems are universally accepted and utilized, the principle of assessing disease severity at each clinical consultation is regarded as good clinical practice. See Chapter 4 for more on oral disease severity scoring.

### Patient-Reported Outcome Measures and Oral Mucosal Disease

Alongside oral disease severity scoring, it is important to record PROMs. Whereas ODSSs are physician records of disease severity that allow clinical assessment of response to treatment, patient-reported outcomes record outcomes from a patient's perspective and are equally important in overall outcome success. On occasion, the PROMs score will demonstrate satisfaction at the outcome, even though the ODSS may be unchanged or vice versa. There are now simple, validated systems for PROMs[15] and it is appropriate for both to be recorded.

## THE DENTAL AND MEDICAL RECORD

The patient's record is customarily organized according to the components of the history, physical examination, diagnostic summary, plan of treatment, and medical risk assessment described previously in this chapter. Test results (diagnostic laboratory tests, radiographic examinations, and consultation and biopsy reports) are filed after this, followed by dated progress notes recorded in sequence. Separate sheets are incorporated into the record for the following: (1) a summary of medications prescribed for or dispensed to the patient; (2) a description of surgical procedures; (3) the anesthetic record; (4) a list of types of radiographic exposures; and (5) a list of the patient's problems and the proposed and actual treatment. This pattern of organization of the patient's record may be modified according to local custom and to varying approaches to patient evaluation and diagnostic methodology taught in different institutions.

In recent years, educators have explored a number of methods for organizing and categorizing clinical data, with the aim of maximizing the matching of the clinical data with the "mental models" of disease syndromes referred to earlier in this chapter. The problem-oriented record (POR) and the condition diagram are two such approaches; both use unique methods for establishing a diagnosis and also involve a reorganization of the clinical record.

### Problem-Oriented Record

The POR focuses on problems requiring treatment rather than on traditional diagnoses. It stresses the importance of complete and accurate collecting of clinical data, with the emphasis on recording abnormal findings rather than on compiling the extensive lists of normal and abnormal data that are characteristic of more traditional methods (consisting of narration, checklists, questionnaires, and analysis summaries). Problems can be subjective (symptoms), objective (abnormal clinical signs), or otherwise clinically significant (e.g., psychosocial) and need not be described in prescribed diagnostic categories. Once the patient's problems have been identified, priorities are established for further diagnostic evaluation or treatment of each problem.

These decisions (or assessments) are based on likely causes for each problem, risk analysis of the problem's severity, cost and benefit to the patient as a result of correcting the problem, and the patient's stated desires. The plan of treatment is formulated as a list of possible solutions for each problem. As more information is obtained, the problem list can be updated, and problems can be combined and even reformulated into recognized disease categories.

The POR is helpful in organizing a set of complex clinical data about an individual patient, maintaining an up-to-date record of both acute and chronic problems, ensuring that all of the patient's problems are addressed, and ensuring that preventive as well as active therapy is provided. Furthermore, the POR facilitates interprofessional communication and is a foundation for collaborative practice and teaching.[21,22] It is also adaptable to computerized patient-tracking programs. However, without any scientifically based or accepted nomenclature and operational criteria for the formulation of the problem list, data cannot be compared across patients or clinicians. An additional concern that has been put forward is the reliance on a POR to "automatically" generate a diagnosis.[23] Although the POR will allow for a systematic approach to delineate specific problems, clinicians need to be able to synthesize findings into an appropriate diagnosis.[24]

Despite these shortcomings, two features of the POR have received wide acceptance and are often incorporated into more traditionally organized records: the collection of data and the generation of a problem list. The value of a problem list for individual patient care is generally acknowledged and is considered a necessary component of the hospital record in institutions accredited by the Joint Commission on Accreditation of Healthcare Organizations. Furthermore, the use of a problem-oriented approach may enhance the utilization of and satisfaction with EHRs.[25]

## SOAP Note

The SOAP note concept, as well as POR, was initially proposed by Dr. Lawrence ("Larry") Weed in the 1960s and has ever since been a mainstay in teaching and clinical care.[26,27] The purpose of this type of documentation was to provide a clinician with a systematic and structured method—a checklist—to record patient findings. The SOAP note is also used for communication between healthcare professionals and as a teaching aid.

The four components of a problem—Subjective, Objective, Assessment, and Plan—constitute the SOAP mnemonic for organizing progress notes or summarizing an outpatient encounter (see Box 1-3). The components of the mnemonic are as follows:

- *S or Subjective*—the patient's experience, complaint, symptoms, and medical history (a brief review of the chief complaint, HPI, PMH, ROS, current medications, and allergies).
- *O or Objective*—the general clinical examination (physical examination, vital signs); review of laboratory data, imaging results, other diagnostic data; review of documentation from other healthcare providers; and a focused evaluation of the chief complaint or the area of the procedure to be undertaken.

**Box 1-3 SOAP Note: Example: A progress note placed in a patient's chart after an oral medicine evaluation**

*Date* _____

**S**—The patient is a 32-year-old women with a history of multiple sclerosis and recent increasing loss of visual acuity and muscle weakness, with sudden onset of severe but brief episodes of pain involving the left mandibular region. She was admitted by Neurology for evaluation and treatment with intravenous methylprednisone and interferon.

**O**—Touching lower left lip or gingiva in the region of the mental foramen triggers brief electric shock-like pain.
Extraoral exam reveals no lymphadenopathy, major salivary gland tenderness, or enlargement.
Intraoral exam shows no mucosal lesions or masses in the area of the left mandible. Teeth are not tender to percussion and no dental caries, fractured teeth, or removable prosthesis noted.
Panoramic radiography of the left mandible showed no dental or bony pathology.
A recent MRI of the brain, reviewed with radiology, demonstrated a demyelinating plaque involving the left trigeminal nerve root.

**A**—Trigeminal neuralgia secondary to multiple sclerosis, no evidence of an oral source for her pain.

**P**—Current plan includes a trial of carbamazepine or oxcarbazepine.

*Signature*_____

- *A or Assessment*—a synthesis of the subjective and objective findings to arrive at a diagnosis (problem list and differential diagnosis) for the specific problem being addressed.
- *P or Plan*—the need for additional information (e.g., laboratory tests, consultations); referrals; treatment recommendation; patient education for the purpose of shared decision-making.

The SOAP note is a useful tool for organizing progress notes in the patient record for routine office procedures and follow-up appointments. It is also quite useful in a hospital record when a limited oral medicine consultation must be documented. However, in order for other healthcare professionals to more easily retrieve the most relevant information, it might be better to reorganize and document the SOAP note as an ASOP note (Assessment, Plan, Subjective, Objective). One significant drawback with the SOAP framework is the lack of a temporal or time component. This can be remedied by including a time component before consecutive SOAP notes. For example, "The present SOAP note is recorded 14 days following the last SOAP note. During this time the following changes have occurred: ...."

## Confidentiality

Patients provide dentists and physicians with confidential dental, medical, and psychosocial information, on the understanding that the information (1) may be necessary for effective diagnosis and treatment; (2) will remain confidential; and (3) will not be released to other individuals without the patient's specific permission. This information may also be entered in the patient's record and shared with other clinical personnel involved in the patient's treatment, unless the patient specifically requests otherwise. Patients are willing to share such information with their dentists and physicians only to the extent that they believe that this contract is being honored.

There are also specific circumstances in which the confidentiality of clinical information is protected by law and may be released to authorized individuals only after compliance with legally defined requirements for informed consent (e.g., psychiatric records and confidential HIV-related information). Conversely, some medical information that is considered to be of public health significance is a matter of public record when reported to the local health authorities (e.g., clinical or laboratory confirmation of reportable infectious diseases such as syphilis, hepatitis, or AIDS). Courts may also have the power to subpoena medical and dental records under defined circumstances, and records of patients participating in clinical research trials may be subject to inspection by a pharmaceutical sponsor or an appropriate drug regulatory authority. Dentists are generally authorized to obtain and record information about a patient to the extent that the information may be pertinent to the diagnosis of oral disease and its effective treatment.

Conversations about patients, discussion with a colleague about a patient's personal problems, and correspondence about a patient should be limited to those occasions when information essential to the patient's treatment has to be transmitted. Lecturers and writers who use clinical cases to illustrate a topic should avoid mention of any item by which a patient might be identified and should omit confidential information. Conversations about patients, however casual, should never be held where they could possibly be overheard by unauthorized individuals, and discussion of patients with nonclinical colleagues, friends, family, and others should always be avoided and should never include confidential patient information.

## Informed Consent

Prior consent of the patient is needed for all diagnostic and treatment procedures, with the exception of those considered necessary for treatment of a life-threatening emergency in a comatose patient.[28] In dentistry, such consent is more often implied than formally obtained, although written consent is generally considered necessary for surgical procedures (however minor), for the administration of general anesthetics, and for clinical research.

Consent of the patient is often required before clinical records are transmitted to another dental office or institution. In the United States, security control over electronic transmission of patient records has since 1996 been governed by the Health Insurance Portability and Accountability Act (HIPAA). The creation and transmission of electronic records are an evolving process that is mainly dependent on technological advances and fast movement of the integration of electronic patient information.[29]

There may also be specific laws that discourage discrimination against individuals infected with infectious diseases, such as HIV, by requiring specific written consent from the patient before any HIV-related testing can be carried out and before any HIV-related information can be released to insurance companies, other practitioners, family members, and fellow workers.[30] Oral healthcare professionals treating patients whom they believe may be infected with HIV must therefore be cognizant of local law and custom when they request HIV-related information from a patient's physician, and they must establish procedures in their own offices to protect this information from unauthorized release. In response to requests for the release of psychiatric records or HIV-related information, hospital medical record departments commonly supply the practitioner with the necessary additional forms for the patient to sign before the records are released. Psychiatric information that is released is usually restricted to the patient's diagnoses and medications.

## TELEHEALTH/TELEDENTISTRY

Telehealth has been defined as "communication and information technologies [used] to provide or support long-distance clinical health care, patient and professional health-related education, public health, and health administration."[31] Although sometimes used interchangeably, several designations, such as telemedicine, mHealth, and eHealth, have been used to described how to interact and provide care when there is no direct physical contact—remotely—between providers and patients. According to some definitions, telehealth refers to a broad scope of remote healthcare services that may include nonclinical services, while telemedicine specifically refers to remote clinical services.[32] mHealth is usually employed to describe technology used by patients to capture their own health data with the help of apps on devices such as smartphones and tablets, while eHealth mostly refers to utilizing the internet and similar technology.

One of the major drawbacks for the utilization of teledentistry in oral medicine is the inability to perform a clinical examination that includes components such as touch and palpation. In telemedicine there are already armamentaria that aim to overcome these types of limitations. For example, there exist electronic stethoscopes, dermatoscopes, and scales, as well as tele-ophthalmoscopes, video-otoscopes, and digital endoscopes.[33] However, studies have been performed where individuals can take pictures with their smartphones and share these images with a specialist who can make differential diagnoses and determine the need for additional studies, such as biopsies. This technology has enabled early detection of oral cancer, as well as HIV-associated lesions, among individuals in areas without immediate access to specialists.[34,35] Another study using a mobile telemedicine system to diagnose oral mucosal lesions remotely showed a high degree of accuracy, demonstrating the potential for future use of this technology in oral medicine.[36]

The need to develop better, more reliable, and validated technology for oral medicine purposes will enhance our ability to provide care to individuals not only in remote areas, but also during circumstances where person-to-person interactions are being discouraged due to, for example, a pandemic. The Covid-19 pandemic has substantially increased the routine use of telemedicine by many clinicians, including oral medicine specialists. It is expected that as these clinicians become experienced using telemedicine, its use will continue to expand in clinical practice.

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# 2

# Overview of Clinical Research

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Evidence-based practice uses current scientific evidence to guide clinical decision-making. In dentistry, this practice integrates the dental professional's clinical expertise, the patient's needs and preferences, and the most current, clinically relevant evidence.[1] Oral health clinical research seeks to improve the evidence base to allow dental professionals and patients to make informed clinical care decisions. The purpose of this chapter is to provide a brief overview of types of research involving human subjects and the features of good clinical research, including ethical and regulatory considerations.

## DEFINITIONS OF HUMAN SUBJECTS AND CLINICAL RESEARCH

The US Department of Health and Human Services (Title 45 Code of Federal Regulations (CFR) Part 46)[2] defines a human subject as "a living individual about whom an investigator (whether professional or student) conducting research: obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens." Research involving human subjects must be reviewed by the overseeing Institutional Review Board (IRB), or an equivalent ethics committee or board in countries outside of the US, to seek approval or determination of exemption prior to enrolling research participants. Human subjects research includes all research in which investigators interact directly with subjects to collect research data, including survey research, and research utilizing existing data/biospecimens from human subjects if at least one member of the research team has the ability to link data/biospecimens to identifiable information.[3] For human subjects research utilizing existing data/biospecimens, an IRB or equivalent ethics committee will make a determination about whether the study would be exempt or non-exempt depending upon the role of the study team member who has access to identifiable information.

*Burket's Oral Medicine*, Thirteenth Edition. Edited by Michael Glick, Martin S. Greenberg, Peter B. Lockhart, and Stephen J. Challacombe.

Human subjects are also sometimes referred to as "participants," and both terms will be used throughout this chapter.

"Clinical research" can be broadly defined as patient-oriented research. Many types of studies are included under this definition, including studies of human disease mechanisms, natural history studies of disease, epidemiologic studies, prognostic studies, studies of technologies or procedures used to diagnose, prevent, or treat human diseases, outcomes research, and health services research. Clinical research can be broadly categorized as observational or interventional research. In observational studies, participants are identified as belonging to study groups and are assessed for biomedical or health outcomes. Participants may receive diagnostic, preventive, therapeutic, or other types of interventions as "standard of care," but the investigator does not assign the participants to a specific group. Interventional research, or clinical trials, involves prospective assignment of participants to one or more interventions to test the effect of the intervention(s) on the disease or condition. "Intervention" includes anything that can alter the course of a disease, such as a pharmaceutical agent, a medical device, a surgical technique, a behavioral intervention, or a public health program. Clinical research studies, whether observational or interventional, require approval by an IRB or equivalent ethics board/committee and provision of informed consent by the study participants.

## STUDY DESIGNS

Several types of designs are available to study diseases and conditions and collect research information. The study designs described below are commonly employed in clinical research.

### Case Report and Case Series

A case report (singular) or case series (plural) is a description of one or several individuals with a disease or condition of interest. A case report can offer insights into diagnosis and management of a disease or condition by providing details about the patient's clinical presentation, diagnostic work-up, differential diagnoses, final diagnosis, management, and current disposition. Examples include descriptions of: orofacial manifestations of a patient with a systemic disease and strategies to manage the disease, unusually shaped teeth in a child or children with a genetic syndrome, or an adult presenting with orofacial pain from an unusual source such as a metastatic tumor and the diagnostic approach to determine the pain etiology. The description should be complete enough for use by another clinician who may evaluate a similar case. If the study is a case series, the same diagnostic criteria should be used to group the cases together for a report.

Case series can be very valuable in the description of new diseases or conditions. A good example is the large case series describing 63 cases of osteonecrosis of the jaw (ONJ) associated with the use of bisphosphonates.[4] While the report of this emerging clinical condition suggested a relationship to use of bisphosphonate medication, an obvious limitation of this study design is the lack of a population of individuals without the disease or condition, or a "control" group. Other limits of a case series include the fact that most data are obtained via a retrospective review of existing clinical records. This introduces the potential for recall bias as the researchers are "looking back" at events and extracting record information, which often is a mixture of complete and incomplete facts. Also, the information is recorded for clinical care and not research purposes. Therefore, clinicians will use varying methods to evaluate patient outcomes, such as a non-healing extraction site. If the patients were evaluated as part of a research study, the study team would use a predefined set of criteria to determine study inclusion and judge clinical outcomes and would collect a predefined set of information from the patients such as current and past medications.

### Cross-Sectional Studies

Cross-sectional studies are employed frequently in clinical research. Research participants are evaluated at one time point and are not followed over time, creating a dataset that is a "snapshot" of the condition under study. Prevalence studies use cross-sectional designs that describe the population under study, derive a representative sample of that population and define the characteristics under study to establish the prevalence of a disease or condition in a population.[5] For example, the prevalence of oral human papillomavirus (HPV) infection in unvaccinated men and women has been estimated through the National Health and Nutrition Examination Survey (NHANES) 2009–2016.[6] The NHANES study uses a statistically representative sample of the civilian non-institutionalized US population. Many factors must be considered when designing a cross-sectional prevalence study. First, it is not usually feasible to examine an entire population of individuals with a disease or condition. Therefore, the sample being examined should represent the entire population at risk and not only those most severely affected. In the example of ONJ, patients with small non-healing affected sites that healed in two to three months without any intervention should be included as well as those with large lesions that persisted for months, to represent the entire spectrum of the disease. Second, all research participants should be evaluated using the same, standardized methods (read "Outcome Assessment" below). Prevalence studies require very large sample sizes and, therefore, may need to be conducted at more than one