# Parameters of Care: Clinical Practice Guidelines for Oral and Maxillofacial Surgery (AAOMS ParCare 2023)

# PATIENT ASSESSMENT

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THIS SECTION IS 1 OF 11 CLINICAL SECTIONS INCLUDED IN AAOMS

PARCARE 2023, WHICH IS VIEWED AS A LIVING DOCUMENT APPLICABLE.

TO THE PRACTICE OF ORAL AND MAXILLOFACIAL SURGERY. IT WILL BE UPDATED AT DESIGNATED INTERVALS TO REFLECT NEW INFORMATION CONCERNING

THE PRACTICE OF ORAL AND MAXILLOFACIAL SURGERY.

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# **INTRODUCTION**

An appropriate preoperative patient assessment is a critical component of an oral and maxillofacial surgery practice. The proper method of obtaining and documenting a patient's medical history and physical examination findings, as well as appropriate diagnostic tests, is essential to ascertaining an accurate diagnosis and developing an effective treatment plan. In addition, a thorough patient evaluation provides the basis for determining patient-specific surgical and anesthetic risk, thereby minimizing morbidity and optimizing patient care. Several specific comorbid conditions require consideration by the Oral and Maxillofacial Surgeon.

The Oral and Maxillofacial Surgeon is trained to complete a thorough patient assessment. Therefore, this section will not describe how to perform an assessment but will organize the assessment process. The assessment process is divided into phases:

1) indications for surgery; 2) specific surgical goals; 3) factors that may affect surgical risks; and 4) outcome assessment. The patient assessment process described in this section establishes a foundation for patient assessment and management as described in subsequent sections of *ParCare 2023*.

Specific diagnostic techniques and physical assessment protocols are purposely not defined. It is not the intent of this document to dictate the exact methods for performing a patient assessment. The Oral and Maxillofacial Surgeon has the latitude to complete a patient assessment based on the clinical circumstances of the patient and/or institutional standards.

# **PREAMBLE**

The Oral and Maxillofacial Surgeon is responsible for an initial history and physical evaluation to determine the risk factors associated with the management of each patient. In some circumstances, the patient's physician may perform the history and physical examination, but it is the responsibility of the Oral and Maxillofacial Surgeon to ascertain whether the information is complete or whether further assessment is indicated based on the specific patient and planned procedure.

# GENERAL CRITERIA, PARAMETERS, AND CONSIDERATIONS FOR PATIENT ASSESSMENT

All surgery must be preceded by the patient's or legal guardian's consent, unless an emergent situation dictates otherwise. Emergent circumstances and the indications for treatment should be documented in the patient's record. Informed consent is obtained after the patient or the legal guardian has been informed of the indications for the procedure(s), the goals of treatment, the known benefits and risks of the procedure(s), the expected recovery period, alternative treatment options (including no treatment), and any patient- or procedure-specific factors that may affect the risk. The results of the informed consent process must be documented in the patient medical record. In general, an informed consent document is signed by the patient or guardian, but the OMS is well advised to document in the medical record that the informed consent process occurred and that the patient/guardian provided both verbal and written consent that they understand and are willing to proceed with treatment.

Non-English speaking or hearing/visually impaired patients may require a professional interpreter to obtain informed consent.

**DOCUMENTATION:** Documentation in a patient's medical record contains critical information and is governed by Health Insurance Portability and Accountability Act regulations. The Oral and Maxillofacial Surgeon is responsible for ensuring that all information contained in the medical record is accurate and complete. Additions, corrections, and/or deletions to the medical records should be clearly identified as to the individual making these changes and date of these changes.

Deletions are done with single line strikethrough with initials in written records or via tracking with electronic medical records.

AAOMS ParCare 2023 includes documentation of subjective and objective findings, diagnoses, and patient management interventions. The final judgment of a specific diagnostic test or the need for medical consultation must be made by the individual OMS according to unique circumstances presented by each patient. In instances when another health care provider assesses the patient health status preoperatively, such as a primary care physician, cardiologist, or pediatrician, the OMS must ensure that the documented assessment meets the parameters set forth in AAOMS ParCare 2023. Moreover, the Oral and Maxillofacial Surgeon is responsible for the patients' risk assessment and, ultimately, the decision to perform any surgical procedure(s). No other health care provider may assume this responsibility. There may be sound clinical causes to deviate from AAOMS ParCare 2023. When an Oral and Maxillofacial Surgeon deviates from a relevant parameter based on specific situations, document the reason for chosen course of action. Moreover, it should be understood that adherence to these parameters does not guarantee a favorable outcome.

AMERICAN SOCIETY OF ANESTHESIOLOGISTS PHYSICAL STATUS CLASSIFICATION SYSTEM: Based on a thorough patient assessment, an American Society of Anesthesiologists (ASA) physical status should be assigned to all surgical patients, according to the most recent guidelines set forth by the ASA (Appendix 1).

**PREOPERATIVE GUIDELINES:** Certain medical conditions and therapies, (eg, medication-related osteonecrosis of the jaw [MRONJ] or osteoradionecrosis), can increase the risk of poor wound healing, infection, or other serious complications including osteomyelitis and pathologic jaw fracture.

Prophylactic treatment strategies involving regular dental surveillance can reduce the incidence of postoperative complications in at-risk patients. At-risk patients are asymptomatic but have been previously treated with antiresorptive or radiation therapy (RT). (See AAOMS Position Paper on MRONJ for osteoradionecrosis details).

**PREOPERATIVE FASTING GUIDELINES:** All healthy patients without a risk of gastroparesis who will undergo a sedation or general anesthetic procedure should maintain a "nothing by mouth" (NPO) status (Appendix 2). The ASA recommends a 2-hour fasting period of clear liquids for all patients. The ASA recommends a fasting period for breast milk of 4 hours, and infant formula or nonhuman milk of 6 hours for neonates and infants. For solid foods in most adult patients, the ASA recommends fasting periods of at least 6 hours (light meal such as toast and clear liquid) and 8 hours (fatty or fried foods or meat). For infants and children, please see Appendix 2.

The preoperative use of gastric stimulants, gastric acid secretion blockers (histamine<sub>2</sub> receptor antagonist agents), antacids, antiemetic agents, and/or anticholinergic medications (to decrease the risk of pulmonary aspiration) is not routinely recommended. Their use should be based upon the individual patient assessment.

**PERIOPERATIVE ANTIBIOTIC THERAPY:** Patients with specific cardiac conditions, implantable devices, and joint replacement may require preoperative systemic antibiotics to reduce the risk of distant infections (see Appendix 4 and 5 for specific circumstances). The decision to employ prophylactic perioperative antibiotics is at the discretion of the treating surgeon and should be based upon the patient's clinical condition as well as other comorbidities. Subacute bacterial endocarditis (SBE) antibiotic prophylaxis and total joint replacement (TJR) antibiotic prophylaxis should be based upon the most recent guidelines set forth by the American Heart Association (AHA), American Dental Association (ADA), and AAO (see Appendices).

**DISCHARGE CRITERIA:** All patients who have had outpatient surgery using sedation or general anesthesia must meet minimal criteria to permit safe discharge from the office or outpatient surgical facility. Such criteria may include either the use of an Aldrete, modified-Aldrete Score, Post-Anesthesia Discharge Scoring System (PADSS or modified PADSS), or equivalent. Also see the *Anesthesia in Outpatient Facilities* chapter. In addition, the patient must arrive at the office or surgical facility with a responsible adult escort for discharge after surgery and anesthesia.

## SPECIAL CONSIDERATIONS FOR PEDIATRIC PATIENT ASSESSMENT

The child assessment begins with a careful history, followed by physical examination and radiographic and laboratory evaluation. However, much of the information may be provided by the parents or by both the patient and the parents depending on the maturity of the child. Informed consent for all children, who are considered minors, must be obtained from the parents or legal guardian. Oral and Maxillofacial Surgeons should include children in any discussions about their health and treatment, when appropriate. The Oral and Maxillofacial Surgeon must ascertain that the parent or adult giving the consent is the legal guardian. This is especially critical when the parents are divorced or if the child is living with guardian(s) other than the biologic parents. Emancipated adolescents who are legally responsible for themselves can make their own health care decisions and sign their own consent.

The Oral and Maxillofacial Surgeon must also be aware that the birth sex may not be how the child identifies at the time of care. Careful and thoughtful discussion with the pediatric patient and their parents is necessary to not only utilize the appropriate pronouns for the patient but may also direct the type of care provided. Certain standardized outcomes such as male versus female norms may need to be modified based on the patient's self-identification choice.

Several important aspects of the patient assessment and treatment are distinct to children. The OMS must navigate the child/parent dynamic in regards to the psychological, physical impact of treatment. The surgeon must be the advocate for the minor patient and ensure that all concerned parties understand the procedure, the risks, the benefits, and alternative treatment options. Therapeutic decisions are also affected by the patient's chronologic age and stage of psychological, physical, and dental development. These factors can alter the indications and timing of treatment and must be considered in the final assessment of the pediatric patient. The surgeons must consider the effects of the child's growth on the ultimate outcome of treatment.

Pregnancy status should be assessed in female patients of childbearing age. When evaluating pediatric patients who have congenital or developmental anomalies, a thorough family history and the existence of similar conditions in other relatives or siblings may provide additional useful information. In addition, determining exposure to known teratogens during pregnancy or in the early developmental years is a key component in the evaluation of children who exhibit growth abnormalities.

When performing the physical examination, it is critical to remember the differences between children at various ages compared to adults with regard to anatomy and physiology. For example, children have an epiglottis longer and less rigid

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than their adult counterpart and the larynx is more anteriorly and superiorly positioned. Children are more susceptible to hypothermia due to greater body surface area to mass ratio. The autonomic system of a very young child is immature therefore cardiac output is dependent on heart rate.

Oral and Maxillofacial Surgeons are in a unique position to identify child abuse and neglect because a majority of physical signs of abuse occur in the head and neck region. Dentists and physicians are mandated by state laws to report such suspected or confirmed cases of child abuse or neglect. The physical and behavioral diagnostic signs of physical abuse, physical neglect, and sexual abuse include precociousness, unusual redness/tenderness in the oropharyngeal areas, inability to open the mouth, poor hygiene, and wounds and/or fractures in various stages of healing, especially in the younger population, warrant further questioning. The Board of Trustees of AAOMS supported AMA Opinion 2.02 on "Physicians' Obligations in Preventing, Identifying, and Treating Violence and Abuse" adopted in November 2007 and issued in June 2008, supporting the pivotal role of the Oral and Maxillofacial Surgeon in identifying and treating victims of violence and abuse.

#### PATIENT ASSESSMENT

This section addresses the assessment of the patient's medical history and physical status in all patient care settings, including the documentation of examination findings. The results of the patient assessment are used as a foundation for subsequent clinical sections throughout the remainder of this book.

#### I. Indications for Patient Assessment

- A. Presentation of a patient to an Oral and Maxillofacial Surgeon for evaluation, diagnosis, continuing care, and/or treatment
- B. Referral to an Oral and Maxillofacial Surgeon for a second opinion regarding diagnosis and management
- C. Planning for inpatient or outpatient surgery or procedure
- D. Scheduled follow-up visit for assessment of outcomes resulting from a treatment, surgery, or procedure
- E. Return of a patient for new condition, evolving condition, and continuing evaluation

## II. Specific Goals for Patient Assessment

- A. Perform a problem-focused, age- and ASA-appropriate medical history and physical examination based upon both the history of present illness and the observations of the Oral and Maxillofacial Surgeon
- B. Establish an accurate diagnosis
- C. Determine the need for care or treatment
- D. Identify factors affecting risk to determine patient ability to undergo safe treatment, surgery, and/or anesthesia
- E. Establish the rationale for care, treatment, or surgery of diagnosed conditions
- F. Develop care or treatment recommendations and alternative treatment options, including no treatment
- G. Document findings and recommendations and assign an ASA physical status (Appendix 1)
- H. Provide preoperative patient instructions for planned surgery
- I. Identify new or previously unrecognized conditions and determine the need for further assessment (eg, laboratory or radiographic) or consultation (eg, with primary care physician or specialist), treatment, surgery, or procedure and perioperative management (eg, autologous blood products)
- J. Document outcomes and recommendations for further care or treatment
- K. Confirm or refute an established diagnosis as a second opinion
- L. Confirm appropriateness of a planned operation or procedure
- M. Perform an informed consent discussion: Inform the patient/guardian of the findings, diagnosis, treatment options, and risks and benefits of each treatment option, including no treatment
- N. Psychologically prepare the patient for surgery by providing reassurance and review of perioperative expectations
- O. Obtain documentation for predetermination of insurance coverage benefits using current International Classification of Diseases (ICD-10) and Current Procedural Terminology (CPT) codes and guidelines
- P. If you are an out-of-network provider, ensure all disclosures to the patient, including obtaining patient consent where needed, in accordance with the No Surprises Act

## III. Specific Factors Affecting Risk for Patient Assessment

Factors that increase the potential for inadequate assessment:

- A. Incomplete initial assessment
- B. Patient's failure to return for scheduled follow-up assessment
- C. Communication barriers (eg, language or cultural barriers, communication disorders, altered mental status, or level of consciousness)
- D. Psychological, social, or gender barriers

# PATIENT ASSESSMENT (continued)

- E. Patient's, legal guardian's, or responsible party's failure to disclose information regarding patient history
- F. Degree of patient's and/or family's cooperation and/or compliance
- G. Physical barriers (eg, obesity, trismus, trauma)
- H. Situational barriers (eg, life-threatening emergency, pending litigation)
- Regulatory and/or third-party decisions concerning access to care, indicated therapy, drugs, devices, and/or materials

## IV. Indicated Therapeutic Parameters for Patient Assessment

Patient assessment may be categorized into many different forms of encounter. Please refer to both the ICD-10 and the CPT coding manuals, as necessary. These encounters may be either initial or subsequent and may include but are not limited to the following:

The level of patient assessment may be determined by time or the level of medical decision making. If the level is determined on medical decision making, factors may include the number and complexity of the problem(s) addressed during the encounter; the amount and complexity of data to be reviewed and analyzed during the encounter; and the risk of complications and/or morbidity or mortality of patient management. Any level of the patient evaluation by may include any or all of the components of a comprehensive history and physical examination.

The CPT published by the American Medical Association should be referred to for guidance when determining the level of evaluation and management services based on time or medical decision making.

Patient assessment should be documented in the medical record. The medical history obtained from the patient, legal guardian, or responsible party; and the physical examination findings form the basis of this document. Documentation of a patient's condition and planned surgery or procedure includes the following elements, as indicated by the patient's presentation or form of encounter. A comprehensive history and physical examination may not be appropriate for all patients, and the components of the history and physical examination should be individualized for each patient.

- A. Office or other outpatient services
  - 1. New patient
  - 2. Established patient
- B. Hospital observation services
- C. Hospital inpatient services (eg, admission)
- D. Consultations
  - 1. Office or other outpatient consultations
  - 2. Initial inpatient consultations
  - 3. Confirmatory consultation (eg., second opinion)
- E. Preoperative assessment for outpatient surgery
- F. Emergency department services
- G. Other: nursing home, rehabilitation facility
- H. Past medical history
  - 1. Chief complaint
  - 2. History of present illness
  - 3. Past medical history, with elaboration of positive and significant negative findings
    - a. Medical, dental, and psychological conditions and/or illnesses
    - b. Hospitalizations
    - c. Anesthesia experience (adverse reactions or complications, such as personal or family history of malignant hyperthermia)
    - d. Past surgical history (operations: major and minor)
    - e. Past dental history
    - f. Medications and dosages (past and present, including herbal medicines, cannabis, and nonprescription/ OTC drugs)
    - g. Allergies and reactions (including latex allergy)
    - h. Vaccination status (COVID, Human Papilloma Virus, etc.)
  - 4. Review of systems (general and pertinent)
    - a. General

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# PATIENT ASSESSMENT (continued)

- b. Head, ears, eyes, nose, and throat (including oral cavity)
- c. Cardiovascular (including exercise tolerance quantified by metabolic equivalent of tasks (METs) activity (See Appendix 3)
- d. Respiratory
- e. Gastrointestinal
- f. Genitourinary (including the date of the last menstrual period, pregnancy status)
- g. Musculoskeletal
- h. Integumentary
- i. Neurologic
- j. Psychiatric
- k. Endocrine
- 1. Hematologic/lymphatic
- m. Allergic/immunologic
- 5. Family history
- 6. Social history
  - a. Biologic sex, gender identification
  - b. Occupation
  - c. Substance use (eg, tobacco [pack-years], alcohol [daily amount], cannabis, illicit or recreational drugs [specific drugs and frequency of use]), e-cigarette usage (vaping)
  - d. Other issues, as indicated by the patient's presentation (eg, religious or philosophical objections to care or treatment)
  - e. History of violence and abuse; present or past post-traumatic stress disorder issues
  - f. Coinhabitants (eg, partner, children)

## I. Physical examination

The surgeon is responsible for documenting an appropriate history and physical examination, although the patient may be referred to another qualified professional for an examination. For most ASA class I and II patients undergoing outpatient surgery, the history and physical examination may be focused. For the surgical inpatient (depending on individual institutional requirements) and/or patients of advanced ASA status, a more comprehensive history and physical examination may be necessary. A patient's refusal to consent to a medical history and physical examination must be documented in the medical record and cosigned by the patient so that there is no misinterpretation of the treatment options offered.

- 1. General examination (Alert and Oriented [A&O] x 3)
- 2. Vital signs (heart rate, blood pressure [minimum for patient who will undergo anesthesia], temperature, respiratory rate)
- 3. Head, ears, eyes, nose and throat (including oral cavity)
- 4. Neck, including lymph nodes, trachea, and thyroid
- 5. Chest and lungs (inspection, palpation, percussion, auscultation)
- 6. Heart and great vessels (auscultation)
- 7. Breast (deferred, in most cases)
- 8. Abdomen
- 9. Pelvic/rectal (deferred, in most cases)
- 10. Musculoskeletal
- 11. Neurologic
- 12. Skin
- 13. Extremities
- J. Adjunctive studies

The decision to obtain any adjunctive studies must be based on the results of the preoperative patient assessment data, ASA physical status, and surgical risk classification. Laboratory or radiologic testing without specific clinical indications is not medically necessary, clinically beneficial, or cost-effective. In determining studies to be performed for imaging purposes, principles of ALARA (as low as reasonably achievable) should be followed. For women of

# PATIENT ASSESSMENT (continued)

childbearing age, the decision to perform urine or blood pregnancy testing prior to surgery and anesthesia should be based on an equivocal history of sexual activity and possibility of pregnancy and an uncertainty regarding the date of the last menstrual period. Routine urine or blood pregnancy testing of the pediatric patient is not clinically warranted without a specific indication. Adjunctive studies, when indicated, may include but are not limited to:

## Laboratory evaluation:

- 1. Complete blood count (CBC), white blood cell count, hemoglobin, hematocrit
- 2. Chemistry-7 (sodium, potassium, chloride, serum bicarbonate, blood urea nitrogen, creatinine, and glucose)
- 3. Prothrombin time (PT), partial thromboplastin time (PTT), and international normalized ratio (INR)
- 4. Platelet count
- 5. Bleeding time
- 6. Type and screen, type and cross-sensitivity
- 7. Arterial blood gas
- 8. Fasting blood glucose, random blood glucose, glucose tolerance test, hemoglobin A<sub>1c</sub>
- 9. Pregnancy testing (serum or urine)
- 10. Pulmonary function tests
- 11. Liver function tests
- 12. Urinalysis
- 13. Blood cultures, C-reactive protein levels

#### Radiologic examination:

- 1. Chest radiograph (CXR)
- 2. Panoramic radiograph
- 3. Periapical and/or occlusal radiographs
- 4. Maxillary and/or mandibular radiographs
- 5. Computed tomography (CT)
- 6. Computed tomographic angiography (CTA)
- 7. Cone beam computed tomography (CBCT)
- 8. Positron emission tomography (PET)
- 9. Positron emission tomography/computed tomography (PET-CT)
- 10. Positron emission tomography/magnetic resonance imaging (PET-MRI)
- 11. Single photon emission computed tomography (SPECT) scan
- 12. Magnetic resonance imaging (MRI)
- 13. Magnetic resonance angiography (MRA) (gadolinium, non-iodine based)
- 14. Ultrasound imaging
- 15. Radionuclide studies (bone scan)

#### Other tests:

- 1. Electrocardiogram (12-lead ECG)
- 2. Echocardiogram

## K. Assessment

The Oral and Maxillofacial Surgeon should compile all of the information related to the results of the patient assessment, ASA status, surgical risk classification, and planned surgical procedure to determine an appropriate differential diagnosis and alternative treatment options, including an option of no treatment. The decisions made at this point in the patient assessment may include a review of the literature and/or consultations with other professionals, such as physicians, dentists, and specialists.

#### L. Treatment plan

The Oral and Maxillofacial Surgeon may make treatment recommendations based on his/her assessment of the patient's needs and ability to undergo surgery. In general, there are several options for management, and these should be presented to the patient and discussed in terms of risks and benefits of treatment and nontreatment, material risks of the procedures, possible complications, risk of recurrence, and the possible need for additional

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procedures. The treatment plan may involve the need to submit a letter to a third-party company for predetermination of benefits for each patient before surgery. As such, it is important to properly code the diagnosis and treatment procedure using the latest ICD-10/CPT terminology.

#### V. Outcome Assessment Indices for Patient Assessment

Outcome indices are used by the Oral and Maxillofacial Surgeon and Oral and Maxillofacial Surgery specialty to assess aggregate outcomes of care. Outcomes are assessed through clinical functional evaluation of patients and laboratory and radiographic measures.

- A. General favorable outcomes associated with patient assessment
  - 1. Determination of accurate diagnoses
  - 2. Documentation of care or treatment recommendations based on an evidence-based rationale, when feasible
  - 3. Identification and documentation of risk factors associated with the patient assessment and recommended care or treatment versus nontreatment
  - 4. Successful achievement of assessment goals
  - 5. Accurate coding strategies
- B. General unfavorable outcomes associated with patient assessment
  - 1. Failure of the Oral and Maxillofacial Surgeon to perform a complete history and physical examination, except in urgent/emergent situations when this is not possible
  - 2. Failure of patient to disclose adequate information contributing to incomplete obtainment of a medical history
  - 3. Failure of patient to disclose information contributing to an incomplete physical examination
  - 4. Patient-related factors contributing to incomplete or inaccurate diagnoses
  - 5. Patient-related factors contributing to incomplete or inaccurate treatment recommendations and/or treatment
  - 6. Complications resulting from inadequate assessment (eg, unrecognized risk factors, such as immunocompromise and those taking antiresorptive drugs.)
  - 7. Failure of patient to obtain the necessary informed consent information that a prudent patient would want to know before any surgical procedure, including consideration for non-English speaking and hearing/visually impaired patients.
  - 8. Failure to understand cultural differences and apply the principles of cultural competency
  - 9. Failure of the patient to disclose a new or evolving condition
  - 10. Failure of patient to return for scheduled follow-up assessment and management
  - 11. Failure to obtain appropriate consultation, when indicated
  - 12. Failure to recognize the need for adjunctive studies based on patient history, physical examination, or ASA status
  - 13. Failure to adhere to AHA guidelines regarding SBE (Appendix 4) and ADA guidelines for TJR (Appendix 5) prophylaxis regimes in at-risk patients undergoing at-risk procedures
  - 14. Inappropriate medication prescribing (eg, allergy, drug interactions, overprescribing)
  - 15. Failure to recognize prescription medication abuse (eg, narcotics)
  - 16. Iatrogenic patient injury due to inadequate patient assessment
  - 17. Failure of patient to disclose use of medications or other legal/illegal agents

# SPECIFIC CLINICAL SCENARIOS

On occasion, the Oral and Maxillofacial Surgeon must perform an assessment of patients of advanced ASA status. The following clinical scenarios represent several of the more commonly seen disease processes organized by system and provide recommendations for assessment and management. These are only recommendations, and definitive patient assessment and management must be correlated clinically for each patient. In all cases of ASA class II or greater patients, consideration should be given to consultation with a physician for medical clarification of the patient's physiologic condition, and obtainment of a written medical risk assessment with perioperative recommendations to assist the Oral and Maxillofacial Surgeon in determining the appropriateness for outpatient OMS procedures that may include sedation or general anesthesia. For ASA II and greater patients, determination of the patient's MET level (metabolic equivalent) will give important information

# SPECIFIC CLINICAL SCENARIOS (continued)

about their cardiac and respiratory reserve (Appendix 3). The following parameters are recommendations ONLY and should be individualized for each specific surgical patient at the discretion of the Oral and Maxillofacial Surgeon.

### I. Cardiovascular System

- A. Rheumatic heart disease, valvular heart disease, heart murmurs, congenital heart disease
  - 1. Consider cardiology consultation, if indicated
  - 2. Consider ultrasonography or echocardiography for documentation of cardiac valvular function
  - 3. Follow AHA SBE prophylaxis regimens for the at-risk patients undergoing at-risk procedures (Appendix 4)
- B. Ischemic heart disease, hypertension, angina pectoris, myocardial infarction (MI)
  - 1. Determine current level of control (eg, exercise-tolerance, METs, stable vs unstable angina)
  - 2. Consider consultation with physician
  - 3. Consider Cardiac Risk Stratification for Noncardiac Surgical Procedures (Appendix 6)
  - 4. Use stress reduction techniques
  - 5. Consider deferring elective treatment for 1 month, and ideally 3 months, following MI
  - 6. Consider discontinuation of antiplatelet therapy only with cardiology consultation. For bare metal stents, the period of antiplatelet therapy is typically 6 months, while drug-eluting stents require 1 year of antiplatelet therapy after placement
  - 7. Consider limitation of epinephrine dosage contained in local anesthetic solution
  - 8. Be prepared for basic life support/advanced cardiac life support in emergency situations, as well as Pediatric Advanced Life Support for pediatric patients (see section on pediatric anesthesia outpatient sedation)
- C. Congestive heart failure
  - 1. Determine level of control by history and physical examination (eg, shortness of breath, dyspnea on exertion, paroxysmal nocturnal dyspnea, orthopnea, jugular venous distention, ankle edema)
  - 2. Consider consultation with physician
  - 3. Consider ECG, CXR, brain natriuretic peptide level
  - Consider oxygen supplementation
- D. Congenital heart disease

#### **II. Respiratory System**

- A. Chronic obstructive pulmonary disease, emphysema
  - 1. Consider consultation with physician
  - 2. Use supplementary steroids when indicated (Note: patients receiving therapeutic doses of corticosteroids who undergo a surgical procedure do not routinely require stress steroids if they continue their usual daily dose. Patients receiving physiologic replacement steroid doses due to primary hypothalamus-pituitary-adrenal axis disease do require perioperative supplementation)
  - 3. Use supplemental oxygen cautiously, since that may inhibit respiratory drive
  - 4. Consider pulmonary function testing to determine the extent of the disease and degree of respiratory reserve

# B. Asthma

- 1. Consider consultation with physician
- 2. Determine severity based on history (eg, childhood asthma that has resolved; frequency of inhaler use, respiratory-related hospitalizations) and careful physical examination including respiratory rate and lung auscultation
- 3. Consider prophylactic use of inhaler
- 4. Use stress reduction techniques
- 5. Consider pulmonary function testing

#### III. Endocrine System

- A. Diabetes mellitus
  - 1. Determine level of diabetic control (based upon history, fasting blood glucose analysis, glucose tolerance test, hemoglobin A<sub>1c</sub>; Appendix 7)

Note: The decision to obtain immediate glucose level depends on many variables, including patient factors and surgical factors, such as clinical signs and symptoms of hypoglycemia or hyperglycemia, whether the patient is taking insulin or oral hypoglycemic agents only, presurgical NPO status, plan

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# SPECIFIC CLINICAL SCENARIOS (continued)

for local versus intravenous sedation, general anesthesia, length of planned surgery, and patient's self-reporting of level of glucose control

- 2. Avoid hypoglycemia
- 3. Consider hypoglycemic agent scheduling adjustment
- 4. Consider insulin reduction, as necessary (see Appendix 8)
- 5. Consider discontinuation or reduction of oral hypoglycemic agents before surgery, although second-generation sulfonylureas may be continued. Consideration for discontinuation of metformin prior to surgery, or for those having IV contrast, to prevent the risk of lactic acidosis should be based on an assessment of renal function. Delayed gastric emptying may occur with glucagon-like peptide-1 (GLP-1) receptor agonists with an increased risk of aspiration. These medications may require prolonged preanesthetic cessation
- 6. Consider rescheduling surgery if blood glucose level is significantly elevated, but this decision should be based on an overall assessment of the patient and their planned procedure
- 7. Consider prophylactic antibiotics
- 8. Consider H<sub>2</sub> blockers and prokinetic agents to reduce aspiration risks
- 9. Consider an extended period of NPO status due to gastroparesis with careful prophylaxis with agents that inhibit acid reflux, as necessary
- 10. Use stress reduction techniques
- 11. Consider cardiac evaluation and potential for "silent" heart disease
- B. Adrenal insufficiency due to exogenous steroid use
  - 1. Use stress reduction techniques
  - 2. Consider steroid supplementation, although evidence does not support this for the majority of patients on chronic steroid usage

# IV. Hematologic Disorders

- A. Coagulopathy, bleeding disorders (eg, von Willebrand disease, hemophilia), therapeutic anticoagulation
  - 1. Determine pertinent laboratory values (eg, CBC with platelets, PT, PTT, INR)
  - 2. If necessary, temporary discontinuation of anticoagulation or antiplatelet therapy (with prescribing physician consultation) to achieve a reasonable INR for surgical hemostasis based on specific procedures performed
  - 3. If necessary, discontinuation of anticoagulants (eg, rivaroxaban [Xarelto], dabigatran [Pradaxa], and apixaban [Eliquis]) up to 48 hours prior to surgery, based consultation with prescribing physician (see Appendix 9)
  - 4. Consider the use of a reversal agent if required based upon the specific anticoagulant/antiplatelet drug used (Appendix 9)
  - 5. Consider adjustment of medication(s) for the patient on multiple anticoagulants or antiplatelet medications (eg, clopidogrel [Plavix] and aspirin) if necessary and with consultation with prescribing physician
  - 6. Determine factor level or platelet count if indicated, and supplement as necessary (with hematologist consultation)
  - 7. For extended length cases or for patients at increased risk, deep vein thrombosis prophylaxis maybe considered using compression stockings or subcutaneous medications (eg, heparin, enoxaparin)
  - 8. Consider workup for hypercoagulable states: Factor V Leiden, protein C and S deficiency, prothrombin G20210 mutation, and antithrombin III deficiency
  - 9. The provider should have a detailed history of systemic comorbidities (eg, diabetes, liver failure, and/or kidney failure) when evaluating the INR prior to surgical intervention since studies have suggested that the INR range should be lower than in patients without comorbid disease

#### B. Anemia

- 1. Consider a CBC with platelet count
- 2. Consider auto-donation of blood or blood products if a large percentage of blood volume loss during surgery is anticipated

#### V. Gastrointestinal Disorders

- A. Hepatitis
  - 1. Avoid medications with hepatic metabolism, such as acetaminophen (Tylenol)
  - 2. Consider liver function tests, PT/PTT, INR, platelet count, bleeding time

# SPECIFIC CLINICAL SCENARIOS (continued)

- 3. Consider hepatitis B surface antigen screening
- 4. Monitor the use of NSAIDs and OTC medications
- 5. Consider hepatitis C panel

#### VI. Renal Disease

- A. Renal failure
  - 1. Consider avoidance of drugs with renal metabolism
  - 2. Consider hemodialysis or peritoneal dialysis regimen and schedule surgery accordingly
  - 3. Consider the impact of medications removed by hemodialysis
  - 4. Monitor the use of NSAIDs and OTC medications

### VII. Neurologic Disorders

Some neurologic disorders, such as intellectual disability, attention-deficit/hyperactivity disorder, autism, and their associated medical treatments may affect the ability of an Oral and Maxillofacial Surgeon to perform an adequate patient assessment and subsequent management. Consideration should be given to comprehensive dental and oral surgical management in an operating facility under sedation or general anesthesia

## VIII. Musculoskeletal System

- A. TJR
  - 1. Follow ADA recommendations regarding prophylaxis with antibiotics (Appendix 5)

## IX. Miscellaneous

- A. Obesity
  - 1. Consider body mass index calculation
  - 2. Consider altered airway anatomy
  - 3. Consider decreased respiratory reserve
  - 4. Consider medication dosage adjustment
  - 5. Consider an extended period of NPO status
- B. Pregnancy
  - 1. Defer urgent surgery to the second trimester if possible or ideally postpartum
  - 2. Consider drug safety pregnancy profiles (Appendix 10)
- C. MRONJ (Also see Diagnosis and Management of Pathological Conditions chapter)
  - 1. Consider consultation with prescribing physician
  - Consider discontinuation of bisphosphonate medications as well as other antiresorptive agents for a brief period before and/or after surgery if systemic conditions permit and in consultation with the prescribing physician
  - 3. Consider the risks associated with Rank-L inhibitors such as denosumab (Xgeva)
  - 4. Consider the risks associated with vascular endothelial growth factor inhibitors such as bevacizumab (Avastin)
  - 5. Consider debridement, sequestrectomy, or resection of existing necrotic bone as well as extraction of teeth in already necrotic bone
  - 6. Consider preoperative and perioperative antibiotics and antimicrobial rinses
  - 7. Consider preoperative pentoxifylline (Trental) and tocopherol (vitamin E)
- D. Malignant hyperthermia
  - 1. Recognize risk factors, signs, and symptoms
  - 2. Be prepared to manage/transfer patient for treatment
- E. Radiation Therapy
  - 1. Ascertain dosage in the area of planned treatment, use of jaw shields, and presence of xerostomia
  - 2. Consider prophylactic hyperbaric oxygen therapy
  - 3. Consider preoperative pentoxifylline (Trental) and tocopherol (vitamin E)
  - 4. Consider preoperative and perioperative antibiotics and antimicrobial rinses
  - 5. Care with general practitioner colleagues about the necessity of oral cavity prep aration and rehabilitation prior to any RT. Consider timing of extractions of any teeth in the field of radiation with poor or guarded prognosis
- F. Communicate and coordinate
- G. Elderly (>65 years old) patients

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# SPECIFIC CLINICAL SCENARIOS (continued)

- 1. Consider progressive functional decline of all major organ systems
- 2. Consider altered cardiac function and reduced METs
- Consider increased perioperative morbidity and mortality with preexisting history of cardiovascular disease or MI
- 4. Consider decreased pulmonary reserve and function
- 5. Consider advanced age as predictor of postoperative pulmonary complications
- 6. Consider increased sensitivity to the respiratory-depressant effects of opioids and benzodiazepines
- 7. Consider impaired hepatic and renal function
- 8. Consider altered drug metabolism
- 9. Consider increased sensitivity to the central depressant effects of anesthetic agents and medications
- Consider increased perioperative morbidity and mortality with inability to achieve acceptable levels of pain control
- 11. Consider increased incidence of adverse drug reactions and interactions due to polypharmacy
- 12. Consider increased susceptibility to postoperative delirium and the effect of anesthetic agents on long-term cognition and memory
- 13. Consider increased risk for nutritional deficiencies
- 14. Consider cognitive impairment, including effect of opioids if applicable
- 15. Consider declines in motor function and occupational tasks
- H. Pediatric considerations (<12 years old)
  - Obtain thorough medical history from knowledgeable parent/guardian or directly from pediatrician if concerned with quality of information.
  - Consider decreased pulmonary reserve and additive effect of any other pulmonary conditions, especially when planning sedative/anesthetic care.
  - 3. Consider the differences in dosages and pharmacokinetics of medications, including local and general anesthetic agents in comparison to adults.
  - 4. Consider and plan for postoperative pain control with appreciation of the increased risk of airway compromise with opioids in this patient population.

## **APPENDICES**

# APPENDIX 1

#### AMERICAN SOCIETY OF ANESTHESIOLOGISTS PHYSICAL STATUS CLASSIFICATION SYSTEM

ASA class I	A normal healthy patient
ASA class II	A patient with mild systemic disease
ASA class III	A patient with severe systemic disease
ASA class IV	A patient with severe systemic disease that is a constant threat to life
ASA class V	A moribund patient who is not expected to survive without an operation
ASA class VI	A declared brain-dead patient whose organs are being removed for donor purposes

Note: If a surgical procedure is performed emergently, an "E" is added to the previously defined ASA classification.

American Society of Anesthesiologists. https://www.asahq.org/resources/clinical-information/asa-physical-status-classification-system. Accessed January 5, 2022. Reprinted with permission.

#### APPENDIX 2

## AMERICAN SOCIETY OF ANESTHESIOLOGISTS FASTING GUIDELINES

Ingested Material	Minimum Fasting Peri	od
Clear liquids	2 hours	
Breast milk	4 hours	
Infant formula	6 hours	
Nonhuman milk	6 hours	
Light meal	6 hours	
Fatty meal	8 hours	

American Society of Anesthesiologists: Practice guidelines for preoperative fasting and the use of pharmacologic agents to reduce the risk of pulmonary aspiration: application to healthy patients undergoing elective procedures. *Anesthesiology* 114:495, 2011. Reprinted with permission.

#### APPENDIX 3

#### ESTIMATED ENERGY REQUIREMENTS FOR VARIOUS ACTIVITIES

	Can You		Can You
1 MET	Take care of yourself?	4 METs	Climb a flight of stairs or walk up a hill?
$\downarrow$	Eat, dress, or use the toilet?	$\downarrow$	Walk on level ground at 4 mph?
<u> </u>	Walk indoors around the house?	<b>1</b>	Run a short distance?
↓ ↓ ↓ 4 METs	Walk a block or 2 on level ground at 2-3 mph? Do light work around the house like dusting or washing dishes?	\	Do heavy work around the house like scrubbing floors or lifting or moving heavy furniture? Participate in moderate recreational activities like golf, bowling, dancing, doubles tennis, or throwing a baseball or football?
		>10 METs	Participate in strenuous sports like swimming, singles tennis, football, basketball, or skiing?

Fleisher LA, Beckman JA, Brown KA, et al: ACC/AHA 2007 guidelines on perioperative cardiovascular evaluation and care for noncardiac surgery. *J Am Coll Cardiol* 50:e159, 2007.

#### APPENDIX 4

#### AMERICAN HEART ASSOCIATION PREVENTION OF INFECTIVE ENDOCARDITIS

Cardiac Conditions Associated With the Highest Risk of Adverse Outcome From Endocarditis for Which Prophylaxis With Dental Procedures Is Recommended

Prosthetic cardiac valve Previous IE

Congenital heart disease (CHD)\*

Unrepaired cyanotic CHD, including palliative shunts and conduits

Completely repaired congenital heart defect with prosthetic material or device, whether placed by surgery or by catheter intervention, during the first 6 months after the procedure<sup>†</sup>

Repaired CHD with residual defects at the site or adjacent to the site of a prosthetic patch or prosthetic device (which inhibits endothelialization) Cardiac transplantation recipients who develop cardiac valvulopathy

# Dental Procedures for Which Endocarditis Prophylaxis Is Recommended for Patients

All dental procedures that involve manipulation of gingival tissue or the periapical region of teeth or perforation of the oral mucosa\*

#### Regimens for a Dental Procedure at a Single Dose 30-60 Minutes Before Procedure

R	Regimen: Single Dose 30 to 60 Min Before Procedure				
Situation	Agent	Adults	Children		
Oral	Amoxicillin	2 g	50 mg/kg		
Unable to take oral medication	Ampicillin OR	2 g IM or IV	50 mg/kg IM or IV		
	Cefazolin or ceftriaxone	1g IM or IV	50 mg/kg IM or IV		
Allergic to penicillins or ampicillin-oral	Cephalexin* <sup>†</sup> OR	2 g	50 mg/kg		
	Azithromycin or clarithromycin OR	500 mg	15 mg/kg		
	Doxycycline	100 mg	<45 kg; 4.4 mg/kg; >45 kg; 100 mg		
Allergic to penicillin or ampicillin and unable to take oral medication	Cefazolin or ceftriaxone <sup>†</sup>	1g IM or IV	50 mg/kg IM or IV		

Clindamycin is no longer recommended for antibiotic prophylaxis for a dental procedure.

Abbreviations: IM, intramuscular; IV, intravenous.

<sup>\*</sup> Except for the conditions listed above, antibiotic prophylaxis is no longer recommended for any other form of CHD.

<sup>†</sup> Prophylaxis is recommended because endothelialization of prosthetic material occurs within 6 months after the procedure.

<sup>\*</sup> The following procedures and events do not need prophylaxis: routine anesthetic injections through noninfected tissue, taking dental radiographs, placement of removable prosthodontic or orthodontic appliances, adjustment of orthodontic appliances, placement of orthodontic brackets, shedding of deciduous teeth, and bleeding from trauma to the lips or oral mucosa.

<sup>\*</sup> Or other first- or second-generation oral cephalosporin in equivalent adult or pediatric dosage.

<sup>†</sup> Cephalosporins should not be used in an individual with a history of anaphylaxis, angioedema, or urticaria with penicillins or ampicillin. In: Walter R. Wilson, Michael Gewitz, Peter B. Lockhart, Ann F. Bolger, Daniel C. DeSimone, Dhruv S. Kazi, David J. Couper, et al. Prevention of Viridans Group Streptococcal Infective Endocarditis: A Scientific Statement From the American Heart Association. Circulation 143 (20): e963-978, 2021.

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#### APPENDIX 5

#### AMERICAN DENTAL ASSOCIATION ANTIBIOTIC PROPHYLAXIS FOR DENTAL PATIENTS WITH TOTAL JOINT REPLACEMENTS

#### Management of Patients With Prosthetic Joints Undergoing Dental Procedures

#### Clinical recommendation:

In general, for patients with prosthetic joint implants, prophylactic antibiotics are not recommended prior to dental procedures to prevent prosthetic joint infection.

For patients with a history of complications associated with their joint replacement surgery who are undergoing dental procedures that include gingival manipulation or mucosal incision, prophylactic antibiotics should only be considered after consultation with the patient and orthopedic surgeon.\* To assess a patient's medical status, a complete health history is always recommended when making final decisions regarding the need for antibiotic prophylaxis.

#### Clinical reasoning for the recommendation:

- There is evidence that dental procedures are not associated with prosthetic joint implant infections.
- There is evidence that antibiotics provided before oral care do not prevent prosthetic joint implant infections.
- There are potential harms of antibiotics including risk for anaphylaxis, antibiotic resistance, and opportunistic infections like Clostridium difficile.
- The benefits of antibiotic prophylaxis may not exceed the harms for most patients.
- The individual patient's circumstances and preferences should be considered when deciding whether to prescribe prophylactic antibiotics prior to dental procedures.

#### APPENDIX 6

#### CARDIAC RISK\* STRATIFICATION FOR NONCARDIAC SURGICAL PROCEDURES

Risk Stratification	Procedure Examples		
High (reported cardiac risk often more than 5%)	Aortic and other major vascular surgery		
- · · ·	Peripheral vascular surgery		
Intermediate (reported cardiac risk generally 1 to 5%)	Intraperitoneal and intrathoracic surgery		
	Carotid endarterectomy		
	Head and neck surgery		
	Orthopedic surgery		
	Prostate surgery		
Low <sup>†</sup> (reported cardiac risk generally less than 1%)	Endoscopic procedures		
	Superficial procedure		
	Cataract surgery		
	Breast surgery		
	Ambulatory surgery		

<sup>\*</sup> Combined incidence of cardiac death and nonfatal myocardial infarction.

# APPENDIX 7 THE RELATIONSHIP AMONG HBA1C, BLOOD GLUCOSE, AND EAG\*

Hb <sub>a1c</sub> %	Blood Glucose (mg/dl)	eAG(mmol/l)	
6	126	7.0	
6.5	140	7.8	
7	154	8.6	
7.5	169	9.4	
8	183	10.1	
8.5	197	10.9	
9	212	11.8	
9.5	226	12.6	
10	240	13.4	

<sup>\*</sup> Adapted from: https://professional.diabetes.org/diapro/glucose\_calc.

<sup>\*</sup> In cases where antibiotics are deemed necessary, it is most appropriate that the orthopedic surgeon recommend the appropriate antibiotic regimen and when reasonable write the prescription. Copyright © 2015 American Dental Association. All rights reserved. This page may be used, copied, and distributed for non-commercial purposes without obtaining prior approval from the ADA. Any other use, copying, or distribution whether in printed or electronic format, is strictly prohibited without the prior written consent of the ADA. ADA Center for Evidence-Based DentistryTM. Sollecito TP, Abt E, Lockhart PB, et al: The use of prophylactic antibiotics prior to dental procedures in patients with prosthetic joints: Evidence-based clinical practice guidelines for dental practitioners. A report of the American Dental Association Council on Scientific Affairs. J Am Dent Assoc 146:11, 2015

<sup>†</sup> These procedures do not generally require further preoperative cardiac monitoring. Fleisher LA, Beckman JA, Brown KA, et al. ACC/AHA 2007 guide-lines on perioperative cardiovascular evaluation and care for noncardiac surgery. *J Am Coll Cardiol*. 50:e159, 2007

# APPENDIX 8

## PERIOPERATIVE INSULIN MANAGEMENT

Insulin Regimen	Day Before Surgery	Day of Surgery	Comments
Insulin pump	No change	No change	Use "sick day" or "sleep" basal rates
Long-acting peakless insulins	No change	75-100% of morning dose	Reduce nighttime dose if history of nocturnal or morning hypoglycemia
On the day of surgery, the morning dose of basal insulin may be administered			3 1787
			on arrival to the ambulatory surgery facility
Intermediate-acting insulins	No change in daytime dose 75% of dose if taken in the evening	50-75% of morning dose	See comments for long- acting insulins
Fixed combination insulins	No change	50-75% of morning dose of intermediate-acting component	Lispro-protamine only available in combination, therefore use insulin instead on the day of surgery. See the comments for long-acting insulins
Short- and rapid-acting insulins	No change	Hold the dose	The state of the s
Non-insulin injectables	No change	Hold the dose	

Joshi GP, Chung F, Vann MA, et al. Society for Ambulatory Anesthesia consensus statement on perioperative blood glucose management in diabetic patients undergoing ambulatory surgery. *Anesth Analg* 111:1378, 2010. Reprinted with permission.

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# APPENDIX 9

# ANTIPLATELET AND ANTICOAGULANT DRUGS

Anticoa (Direc Anticoa	t Oral	Mechanism of	Reversal Agent Generic/	Discontinue	Antiplatelet I (Novel Oral A Othe	ntiplatelets/	Mechanism	Reversal Agent	Discontinue
Generic	Proprietary	Action	Proprietary	(D/C) or Not (N)	Generic	Proprietary	of Action	Generic/ Proprietary	(D/C) or Not (N)
Warfarin Half-life: 20-60 hours	Coumadin	Antagonist of vitamin K, and affecting II,VII,IX,X	Vitamin K/ Phytonadione Kcentra  Prothrombin Complex Concentrate (4-factor	D/C based upon INR (If > 4 no surgery)	Acetyl salicylic acid Half-life: 15- 20 min	Aspirin, BioPak, Adira	Inhibits TXA <sub>2</sub> and platelet aggregation	None	D/C depends upon dosing: 325 vs 81 mg
Dabigatran Half-life: 12- 17 hours	Pradaxa	Inhibitor of free thrombin. Thrombin bound to fibrin; inhibits activity of IIa (INR not required)	PCC) Isdarucizuma b Praxbind	N based upon number of teeth to be removed (>2 discuss with physician)	Dipyridamole	Persantine	Blocks adenosine transport in platelets, erythrocytes and endothelial cells. Acts on platelet A2- receptors increasing cAMP and blocks platelet	None	Works with ASA and not usually used alone. Short half-life D/C based upon dual effects with other antiplatelet drugs
Rivaroxaban Half-life: 9- 13 hours	Xarelto	Selective factor Xa inhibitors (INR not required)	Andexanet Alfa Andexxa	N based upon the number of teeth; ie > 2-3	Clopidogrel bisulfate Half-life:7- 9 hours	Plavix, Iscover	aggregation Inhibit platelet aggregation by blocking ADP binding to platelet receptors (P <sub>2</sub> Y <sub>12</sub> ) and activation of GPIIb-IIIa	None	Do not D/C up to 1 year. After 1 year check with physician prior to D/C based upon complexity of procedure
Apixaban Half-life: 9- 14 hours	Eliquis	Selective factor Xa inhibitors (INR not required)	Andexanet Alfa Andexxa	N based upon the number of teeth; ie > 2-3	Ticlopidine hydrochlorid e	Ticlid, Ticlodone	complex Inhibits platelet binding to ADP- fibrinogen as well as platelet	None	D/C 10- 14 days prior to elective surgery
Heparin (LMWH) Enoxaparin Half- life:4.5 hr Dalteparin Half-life: 2.2 hr	Lovenox Fragmin	Inhibit activity of Xa and IIa	Protamine sulfate	Used for bridging to avoid undue thromboemb olic events	Cilostazol	Pletal	aggregation Prevents platelet aggregation and indices vasodilatory effects	None	Must D/C 10- 14 day prior to elective surgery
Z.Z 111			Protamines		Prasugrel Half-life: 7 hours	Effient	A thieno- pyridine that binds irreversibly toP <sub>2</sub> Y <sub>12</sub> platelet	None	N: do not D/ C for elective surgery
					Ticagrelor Half-life: 7- 9 hours	Brilique	receptors A thienopyridine that binds irreversibly to P <sub>2</sub> Y <sub>12</sub> platelet	Bentracimab Brilinta	N: do not D/ C for elective surgery
							receptors		

#### APPENDIX 10

#### PREGNANCY RISK CATEGORIES (FDA CATEGORIES)

#### FDA Pregnancy Category Definition (Language summarized from 21 CFR 201.57)

Category	Definition
A	Adequate and well-controlled (AWC) studies in pregnant women have failed to demonstrate a risk to the fetus in the first trimester of pregnancy (and there is no evidence of a risk in later trimesters).
В	Animal reproduction studies have failed to demonstrate a risk to the fetus and there are no AWC studies in humans AND the benefits from the use of the drug in pregnant women may be acceptable despite its potential risks OR animal studies have not been conducted and there are no AWC studies in humans.
С	Animal reproduction studies have shown an adverse effect on the fetus, there are no AWC studies in humans, AND the benefits from the use of the drug in pregnant woman may be acceptable despite its potential risks OR animal studies have not been conducted and there are no AWC in humans.
D	There is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience or studies in humans, BUT the potential benefits from the use of the drug in pregnant women may be acceptable despite its potential risks (eg, if the drug is needed in a life-threatening situation or serious disease for which safer drugs cannot be used or are ineffective).
X	Studies in animals or humans have demonstrated fetal abnormalities OR there is positive evidence of fetal risk based on adverse reaction reports from investigational or marketing experience, or both, AND the risk of the use of the drug in a pregnant woman clearly outweighs any possible benefit (eg, safer drugs or other forms of therapy are available).

Food and Drug Association (FDA) WebWebsiteWeb site. http://www.fda.gov/downloads/advisorycommittees/committeesmeetingmaterials/pediatricadvisorycommittee/ucm272377.pdf. Accessed January 11, 2022. Current FDA labeling has changed to remove these categories. Table is presented for reference purposes only.

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This list of selected references is intended only to acknowledge some of the sources of information drawn on in the preparation of this document. Citation of the reference material is not meant to imply endorsement of any statement contained in the reference material. The list is not an exhaustive compilation of information on the topic. Readers should consult other sources to obtain a complete bibliography.

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