Guidance for resuming elective surgeries and procedures

With near constant changes in knowledge of COVID-19, Constellation is providing considerations and recommendations as of April 30, 2020 for resuming elective procedures. Business resumption planning should first and foremost comply with any local, state, or federal statute, rules, and orders. In addition, your practice or facility should carefully consider patient needs; as well as, the health and safety of team members, and communities.

The federal government has issued *Opening Up America Again* guidelines. The recommendations provide a three-phased approach allowing states and localities flexibility in resuming non-emergent, surgical and procedural health care services. The federal recommendations provide a platform of considerations that should be met prior to advancing to additional Phases of the federal reopening guidelines.

Are you ready to resume non-emergent services?

Federal Considerations:

1. The federal criteria to reopen can be found at White House Guidelines to Open up America and specifically address:
   a) Symptoms; downward trajectory of both influenza-like and COVID-like syndrome cases within a 14-day period,
   b) Cases; downward trajectory of documented COVID-19 cases or downward trajectory of positive tests within a 14-day period,
   c) Hospitals; provide non-crisis standard of care for all patients (i.e., have enough PPE, staff, beds, ICU capacity and vents in case of a surge), and have robust testing in place for at risk health care Workers, including emerging antibody testing.

   These guidelines are foundational and indicate that the health care community is able to provide the usual care and treatment to all patients they serve. Health care organizations should continually assess the changing landscape of the community they serve and modify resumption of services according to their ability to provide non-crisis of care for all patients.

2. Once the foundational guidelines are satisfied, Phase 1 of the *Opening Up America Again* guidelines allow states and localities to grant; and facilities and surgeons to begin, resumption of outpatient, elective surgeries and procedures.

3. For states and localities without evidence of a disease rebound, advancement to Phase 2 allows in-patient surgeries and procedures to resume.

4. The ACS ASA AORN AHA Joint Statement for reopening elective surgery after COVID-19 also provides guidance to planning and resumption of surgical services.

State Considerations:

Local and state rules, regulations, and guidance for resumption of non-emergent services vary. In conjunction with federal guidance, you must be aware of and comply with those rules related to resuming elective services, defining emergent and non-emergent services, social distancing, and others.

Administrative Documentation

Throughout this and any emergency, we recommend keeping an emergency management administrative log or journal of the dates for decisions, proclamations impacting operations, critical operating conditions, and any changes in those conditions. Recording information while the experience and memories are fresh can strongly impact the ability to recall key details when questions may be asked years later.

Example: if you're not able to procure enough PPE (surgical masks or gloves) document your daily resolution attempts and use of CDC, state or local alternative strategies or directives. CDC Strategies to Optimize the Supply of PPE and Equipment

Consent Q & A

Q: Some professional associations and others have a suggested COVID-19 consent form. What is your recommendation for a separate and additional consent form?

Constellation will provide guidance on key elements that can make up a good informed consent process. We do not offer sample consent forms for any type of care or treatment, including COVID-19, because the informed consent process should focus on a conversation between provider and patient specific to that patient's circumstances. A consent form is meant to memorialize shared decision-making, not just check a box with a signature. The consent forms that we have seen offered are not specific to the situation within the specific organization. Each state, region within a state, even down to the facility level has a different experience with the disease, local rates of spread, and impact on resources. A form doesn't replace the dynamic conversation of patient specific risks including inherent procedural risks, the impact of comorbid conditions, and risks associated with the procedure being done during an outbreak such as a pandemic, or with waiting. A separate consent form or acknowledgement statement can be utilized but remember to have an informed consent discussion that continues beyond the decision to go forward with a planned procedure.

Q: Do I need to specifically mention in the informed consent document or documentation of the informed consent discussion with the patient, that the patient has consented to surgery during this COVID-19 pandemic?

Informed consent is a dynamic process and more than a form. The form and your documentation of the informed consent process demonstrates the shared mutual understanding between the health care practitioner and the patient. The Joint Statement from ACS, ASA, AORN and AHA (above), indicates the surgery and anesthesia consents should be those usually employed to meet facility policy and state requirements. Constellation recommends informed consent forms include a statement indicating patient understanding of the information provided, acknowledgment questions were invited and answered to their satisfaction, and it is their voluntary decision to proceed at this time with the procedure/treatment.

Q: Should patients be specifically informed of COVID-19 risk during an informed consent discussion?

General infection risk or any known outbreak (like MRSA or COVID-19) should be part of the consent process. If the practitioner believes COVID-19 information is pertinent to the patient's risks and informed decision making, then certainly they should inform and discuss this with the patient. COVID-19 risk information and discussion can and should be written into the provider's documentation of the informed consent process.

Q: Are there things patients shouldn't be told?

Even in the absence of a global pandemic, promises of "perfect" outcomes or vague statements that patients will be, "as good as new," should be avoided.

Making statements like "we follow all ___ guidelines" will require that those guidelines are in fact followed to the letter, and the frequent changes to many COVID-19 guidelines are monitored, communicated, and fully implemented in practice. You will be expected; and judged, to perform and act to those standards whether in a pandemic or not. During this unprecedented time, we have all learned that there are things we just don't know. If there is an unknown, such as should I self-isolate from my pet upon my return home, it is okay to share what we don't know definitively, to follow the most current guidelines and record the concern

Patient Education Q & A

Q. How should patients be educated of COVID-19 risks?

It will be vital to provide credible COVID-19 information to patients and the general public. Information updates as more is learned about the virus and COVID-19 illness, so this may require monitoring and updating. Remember to include educational materials in the preferred language of your patient, when you can. A resource that provides fact sheets translated into various

languages is hosted by the Betsy Lehman Center called the COVID-10 Health Literacy Project https://covid19healthliteracyproject.com/

Resource suggestions include the CDC resources available from the CDC.

- Symptoms: https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html,
- How to Protect Yourself: https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/index.html, and
- Those Needing Extra Precautions https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/index.html

Q: How should we deliver patient education?

Patient pre-op education and preparation should utilize virtual means as much as is feasible. This can include telephonic or video telehealth methods. Discharge teaching can be provided at the bedside while the patient's caregiver is on the phone or available via video telehealth methods. Arrangements can also be coordinated at that time for the driver/caregiver to pull up outside and the patient be delivered to the car; mitigating risks of having the driver/caregiver coming into the facility.

Outpatient Procedures Specifically

This CDC provides guidance for ambulatory surgery specifically:
Outpatient and Ambulatory Care Settings

- Identifying cases to be scheduled
- Consider which patients you will exclude from scheduling at this phase
- Prepare your patient to safely come in for their surgery.

Constellation also recommends you take into consideration recommendations from applicable professional societies, such as those on the following page (not a complete list).

Professional Societies (not a complete list)

ACS ACS Local Resumption of Elective Surgery GuidanceCOVID-19 and Surgery	American Society for Gastrointestinal Endoscopy GI Society Recommendations
AORN COVID-19 Support	American Society of Anesthesiologists COVID-19 Information
American Academy of Ophthalmology Coronavirus and Eye Care	American Society of Breast Surgeons Recommendations for Prioritization, Treatment and Triage of Breast Cancer Patients During the COVID-19 Pandemic: Executive Summary
American Academy of Orthopaedic Surgeons COVID-19: Member Resource Center	American Society of Clinical Oncology ASCO Coronavirus Resources
American Academy of Otolaryngology–Head and Neck Surgery Coronavirus Disease 2019: Resources	American Society of Colon & Rectal Surgeons ASCRS 2020 Coronavirus Update
American Association for the Surgery of Trauma COVID-19 Resources	American Society of Plastic Surgery ASPS Guidance Regarding Elective and Non-Essential Patient Care
The American Association of Gynecologic Laparoscopists COVID-19: Webinar from Experts on the Front Lines of the Virus Crisis	American Society of Transplant Surgeons COVID-19 Resources for Transplant Professionals
American College of Obstetricians and Gynecologists COVID-19 FAQs for Obstetrician–Gynecologists, Gynecology	American Urological Association Coronavirus Disease 2019: AUA Information Center
American Association of Neurological Surgeons COVID-19 Information Hub	Society of Critical Care Medicine Emergency
American Association of Oral and Maxillofacial Surgeons COVID-19 Updates	Society of Gynecologic Oncology COVID-19 Resources for Health Care Practitioners
American Association of Orthopedic Surgeons COVID-19: Member Resource Center, including Recommendations for Elective Surgery	Society of Surgical Oncology COVID-19 Resources
American College of Gastroenterology Webinars and Resources on COVID-19	Society of Thoracic Surgeons COVID-19
American Medical Association Care for Critically Ill Patients With COVID-19	Society for Vascular Surgery COVID-19