



PLASTIC SURGERY THE MEETING | SAN FRANCISCO | OCTOBER 16-19

COVID-19 MEMBER RESOURCES

COVID19 Member Resources

Considerations for the Resumption of Elective Surgery and Visits

ASPS Statement

As regions of the country begin to consider lifting some restrictions, members have requested an update to prior statements regarding elective procedures and breast reconstruction. A working group was convened which included plastic surgeons in practices across the country who live in urban and non-urban areas, are in different career stages, and work in academic, employed and private practice settings.

Sample COVID-19 Informed Consent Form

Local/Regional Factors: Hospital, local, and regional regulatory bodies will determine the actual practice in each hospital or facility. Thus, ASPS recognizes that the timing and implementation of a resumption of elective procedures and clinical visits is dependent on local/regional factors. We recommend that our members consult with their local hospital, county, state, and regional organizations and institutions to better determine the appropriate course for their situation, while considering the issues discussed below.

Ongoing Assessment: In addition, the dynamic nature of the COVID-19 crisis will likely necessitate an ongoing assessment of new trends, new data, new testing, and new treatments. Thus the considerations below will be reviewed regularly and updated as necessary.

Considerations: The following are issues to consider when determining the timing of reopening and the manner of implementation of reopening of operating rooms and offices.

The following considerations and recommendations are based on available information, CDC

guidelines and other regulations. Future CDC updates and guidelines and state/regional/county/local regulations should supersede the recommendations listed below.

Surge situation and statistics

Realizing that reported numbers are dependent on the availability of testing in the community, understand:

- **Statistics** in your community
 - Prevalence of COVID-19 in your community.
 - Incidence of COVID-19 in your community.
 - Local numbers of new COVID-19 cases should be consistently decreasing.
 - Local numbers of new COVID-19 deaths and ICU patients should be consistently decreasing.
- **Testing Availability:** What is the testing situation in your areas?
 - Is testing easily accessible in your area?
 - What kind of tests are available?
 - RNA/PCR and isothermal nucleic acid amplification tests (*see "Testing" section under Safety heading below*)
 - Serology tests for SARS-CoV-2 antibodies (IgM / IgG) (*see "Testing" section under Safety heading below*)
 - What are the sensitivity and specificity of the tests being used in your area?
- **Regulations:** Know your National, State, Local regulations - do they allow elective surgeries?
- **Local Hospital/Medical System:** Are they in a crisis (surge) situation?
 - Even if you plan outpatient procedures in off-site locations, this may be important in the event of an emergency or complication. In addition, critical resources may need to be diverted to local hospitals if a crisis situation exists.
 - Are Ventilators and ICU beds available?
 - Are acute care (hospital) beds available?

Space

- **Social Distancing measures:** Consider patient flow plans that allow for social distancing protocols in your perioperative area and in the office.
 - Waiting room spacing/staggered scheduling.

- Consider the total number of people in the office at any one time.
- Consider having patients and family wait in their cars or off site.
- Consider the availability of wipes and other hygiene/cleaning products.
- Discontinue self-service hospitality stations (coffee, water, etc.) that may act as means of virus transmission.
- **Cleaning:** Reassess cleaning protocols in your office and facility
 - Have a plan for terminal cleaning of perioperative/OR areas and enhanced maintenance cleaning of clinics, especially in high-touch areas. Show patients that this is being performed.
 - Have multiple hand sanitizing dispensers available throughout the office.
- **Transfers:** Know your availability of transfer options for your Office-Based OR/Ambulatory Surgery Center.
 - This may vary day by day and, thus, may necessitate regular reassessment.

Supplies

- **Is there adequate overall PPE in your community?** - i.e., elective surgery will not pull PPE from critical care areas.
- **What is the availability of appropriate PPE for your office and/or facility?**
 - The current CDC guidelines recommend N95s and eye protection, gowns, and gloves should be used in aerosolization generating procedures. Procedures "above the clavicle" are particularly noteworthy for increased risk.
 - Universal masking is currently recommended by the CDC in hospitals as well as general masking in public when social distancing is not feasible/possible.
 - Continue to check **CDC guidelines** as these recommendations may change.
- **Are there adequate anesthesia supplies for facilities with operating rooms?**
 - Glidescopes
 - Sedatives
 - Oxygen
 - Inhaled anesthetics
 - Protecting your anesthesia machine
 - Consider viral HEPA filter - protect inflow/outflow to protect the patient as well as the anesthesia machine.
 - See **other recommendations**

- **Are there adequate cleaning supplies?**
 - See **list of disinfectants for use against COVID-19 from the EPA**
- **Evaluate the reliability, consistency, and adequacy of your office and OR supply chain**
 - In many areas, PPE such as surgical masks, N95's, gowns, gloves and cleaning supplies are sporadic, on back order, or not available.
 - Appropriate PPE must be available to open safely!

Staff (adequacy and safety)

- **Is your staffing adequate to cover your anticipated needs?**
- **Do you have the supplies to address the safety of your staff?** (see *"Supplies" above*)
- **Consider screening of employees as well as patients.**
 - Consider temperature checks and symptom questionnaires on site - follow CDC, state, or local guidelines.
 - Consider contacting patients prior to their visit to your site to assess for symptoms and opportunities to minimize risk.
 - Consider an attestation document prior to procedure.
- **Evaluate a plan to minimize face-to-face exposure** time for outpatient clinical settings. For example:
 - Consider telehealth/virtual encounters, in preparation or as a substitute for in-person encounters.
 - Encourage patients to use online patient portals, electronic communication, mail, or fax to complete registration and other paperwork prior to arriving if available.
 - Consider having patients wait in the car until their appointment time.
 - Minimize the number of family members allowed with the patient.
 - Avoid unnecessary staff in the office and in the operating/procedure room:
 - Use telehealth roles for staff as appropriate.
 - Minimize non-essential staff, observers, students, industry representatives.
- **Ensure staff is educated** regarding
 - Appropriate donning/doffing (where appropriate)
 - Proper Hand hygiene
 - Cleaning protocols: cleaning products that include:
 - 70-90% isopropyl alcohol, or
 - 60-70% ethanol

- **UV light** works well theoretically, but not used in many virology labs because dust impedes the effect. **Disinfectants**
- Social distancing and other safety measures for your clinical areas (see above).
- Recognizing signs and symptoms of COVID-19.
- COVID-19 disease process and risks.
- Ways to minimize their exposure outside of the work setting.
- **Are anesthesia services and personnel available?** (if applicable)
- **Have a plan for dealing with potential exposures in the office/OR.** If a patient turns out to be COVID+ after they have been to your office/OR or if one of your staff members is positive.
 - **Prevention and Control Recommendations for Patients**

Safety in the office/clinic

- **For patients or staff that are known COVID-19 positive**, or to rule out COVID-19 positive, **per current CDC guidelines** (future CDC guidelines or state/regional/county/local regulations or laws supersede the recommendations below)
 - If they have symptoms, they should reschedule/be off until they are at least three (3) days since resolution of fever without fever-reducing medications AND three (3) days since improvement of any respiratory symptoms (cough, shortness of breath, etc) AND either
 1. Test negative from at least two consecutive NP swab specimens collected >24 hours apart. or
 2. At least 7 days have passed since symptoms first appeared
 - If they are asymptomatic and tested COVID-19, they should reschedule/be off until they are at least 10 days since their first positive COVID-19 test assuming they do not subsequently develop symptoms.
 - When staff returns to work, they should:
 - Wear a facemask for source control at all times until all symptoms are completely resolved or until 14 days after illness onset, whichever is longer.
 - Be restricted from contact with severely immunocompromised patients (cancer, transplant, etc) until 14 days after illness onset.
- **PPE** (based on current information at the time of this document and may change; follow current **guidelines of the CDC**, state, county, and local regulations/guidelines)
 - To address asymptomatic and pre-symptomatic transmission, implement source control for everyone entering a health care facility regardless of symptoms.
 - Surgical masks are to be used in all clinical areas by staff.

- Patients may wear either cloth masks or surgical masks.
- For non-clinical areas, patients and staff may wear cloth masks.
- Eye protection worn upon entry to the patient room or care area.
- N95 masks or other FDA/NiOSH approved equivalent and eye protection, gowns and gloves, should be used for procedures that may lead to aerosolization of viral particles. N95 with exhaust valves may not provide source control and also should not be used in the OR.
 - **Examples of Aerosolization Generating Procedures per the CDC** include:
 - Open suctioning of airways
 - Sputum induction
 - CPR
 - Intubation/Extubation
 - Non-invasive ventilation (eg BiPAP, CPAP)
 - Bronchoscopy
 - Manual ventilation
 - Potentially nebulizer administration
 - High Flow O2 delivery
 - Surgery/procedures involving instrumentation in the head and neck region
- For Clinic Procedures: Injectables, peels, microneedling, hydrfacial-type services
 - Universal masking (N95 or other FDA/NiOSH approved) and eye protection/face shield (patient masked as feasible)
 - Gowns and gloves are dependent on the degree of anticipated contact
- If considering Reprocessing / Reusing / Extended use of PPE, follow **guidelines per NIH, CDC**, and other regulatory bodies.

Pre-op

- **Asymptomatic.** Patients undergoing operations, procedures, and engaging in face-to-face clinical visits should be asymptomatic. Consider onsite screening of staff and patients - temperature and symptom questionnaire.
- **Presymptomatic patients.** Given some reports of increased morbidity and mortality of patients who undergo an operation during the presymptomatic/incubation period of COVID, efforts should be made to minimize the chance of operating on these patients.
- **Testing considerations** (See "*Testing information*" at the end of this document).

Note that this information is based on information available at the time of this document. As testing improves and evolves, recommendations for testing may change.

- **COVID-19: RNA/PCR and isothermal nucleic acid amplification tests**

- ASPS recommends that members use their clinical judgment and employ measures to avoid operating on a patient who is asymptomatic in the incubation period to minimize postoperative risks and intraoperative exposure for both the patient and the surgical team.

In an effort to mitigate risk:

- Preoperative PCR testing for acute infection of elective surgical patients is recommended. Pre-op PCR testing should be performed as close to the surgery date as feasible, but in time to get results. This statement is mitigated with the understanding that unavailability of and access to testing may be a barrier. ASPS is working with the national supply chain and test distributors to explore options to help members gain access to appropriate testing. Patients may also be referred to local outpatient testing options including primary care doctors, clinics, and local/regional testing sites.
- Encourage preoperative patients to self-quarantine for 5-7 days prior to the operation to try to minimize the chance of being in the incubation/presymptomatic phase during the operation.
- Consider calling patients for symptom screening 2 weeks prior to the anticipated procedure.
- Currently, the gold standard is the Nasal/nasopharyngeal PCR test but this may change as other modalities of tests are approved and made available.

- If a patient has a Positive PCR COVID-19 test, an elective operation should be postponed. (See *"In the Office/Clinic" section*).
- The assessment and increased risks specific to COVID19 must be discussed with patients prior to any operation or procedure.
- After testing all patients preoperatively, the likelihood of operating on a presymptomatic COVID-19 patient is = (local prevalence rate) x (false negative test rate).
- Consider engaging with relevant anesthesia providers, nurses and OR staff regarding testing rationale, to ensure that there is team agreement and confidence.

- **Serology tests for SARS-CoV-2 antibodies (IgM / IgG)**

- Given the current limited understanding of COVID-19 antibodies and the quality of available tests, the utility of serology (IgG/IgM) testing for preoperative testing of patients to assess immunity is questionable.

- Testing staff - at this time the utility of testing of staff with the currently available serology tests is unknown (See "Discussion about Serology Tests" below).
- The role of serological testing will evolve over the coming months and guidelines regarding use of these tests will be adjusted accordingly.
- **Informed Consent:** Consider either additional COVID-19 language in existing consents (or a separate consent) to address potential for exposure to COVID-19, limitations of testing and other mitigating measures, as well as the risk of undetected infection at the time of procedure leading to potential increased morbidity and mortality.
 - **ASPS sample Informed Consent for COVID-19**

In the OR

- **Ensure adequate PPE:** Consider precautions specific to LASER above the clavicle. CDC continues to update these guidelines and thus those should supercede those listed below
 - Surgeon: PPE (see PPE section above)
 - OR Staff: PPE (same PPE for both scrub tech and surgeon)
 - Anesthesia: PPE, including N95, face shield and gown
- **Minimize exposure in room during intubation/extubation**
 - Know aerosolization time based on air-exchange rate in the operating room.
 - Consider having the surgical team leave/ minimize people the room during intubation and aerosolization time above.
- **Anesthesia mitigation measures:** Consider anesthesia tents and glidescopes.
- **Minimize unnecessary equipment and supplies** in the room.
 - Consider limiting supplies in the room specifically to those required for each case.

Post-op

- Consider telehealth when appropriate and available for pre-op/post-op discussions, and post-op wound checks.
- Consider 7-day post-op social isolation period to reduce incidence of a new exposure and infection as feasible, excluding needed post-op visits.

Scheduling considerations

In the event that the scheduling of operations needs to be phased in, the following factors can be

considered, with the recognition that prioritization will be made at a hospital and surgeon level dependent on local/regional factors.

- **Risk to the patient**

- The urgency of the case would take most precedence: Emergent > Urgent – will a delay in surgery have a detrimental effect on the patient? > Elective
 - **Comorbidities:** Take caution with patient co-morbidities and risk for COVID-19 morbidity/mortality (until adequate testing is available):
 - Age > 65, DM, HTN, Cardiac, COPD / asthma, Obesity
 - ASA status
 - **Likelihood of complications:** Risk of the procedure
 - **Likelihood of needed postoperative long term care**, such as a nursing home or inpatient rehab.
 - **Prolonged time in the OR:** Multiple procedures or long complicated cases.

- **Resource needs**

- **Beds**
 - **Current hospital status:** within a hospital, current inpatients may be prioritized over non-hospitalized patients if the operation is needed for the patient to be discharged or to avoid readmission.
 - **If an elective case and patient is not currently in the hospital**, assess the likelihood/risk of needing an ICU bed/ventilator or a hospital bed post-operatively. In this scenario, if resources are an issue, elective outpatient operations might be prioritized over elective same-day admits that may need a hospital bed.
- **Blood:** Likelihood of needing a blood transfusion - assess local blood availability.
- **Anesthesia:** Does the patient need intubation, sedation, and/or local/regional anesthesia?

Service

- **Communicate with your patients the efforts employed for their safety re: COVID-19.** For example:
 - Cleaning
 - Social distancing measures
 - Testing where applicable
 - PPE where applicable
 - Telehealth options

- **Communicate with patients that, for their safety, surgery may be canceled** based on factors such as:
 - Development of symptoms,
 - Suspicion of exposure
 - Positive screening test.
 - Community need for resources.
- **Communicate that a second surge is expected**, and we will evaluate the safety of surgery, procedures, and office visits on an ongoing basis
- **Develop a financial policy regarding cancellations** and communicate this clearly preoperatively.
- **Communicate more frequently** with your patients, even just to "check-in."

Supplemental testing information

- **COVID-19: RNA/PCR and isothermal nucleic acid amplification tests**
 - RNA/PCR and isothermal nucleic acid amplification tests demonstrate the presence of viral particles, which are present in both symptomatic and asymptomatic individuals who are infected with the virus, and throughout the period of time when an individual sheds virus.
 - This test is usually done with a nasal/ nasopharyngeal swab
 - Many tests have reported sensitivities to be as low as 60-70% and thus may miss COVID-19 positive patients 30-40% of the time. In the absence of national data, ask your hospital/lab for internal validation data on in-house tests.
 - It is unclear if the high false negative rates are due to testing or due to swab techniques or specimen handling.
- **Serology tests for SARS-CoV-2 antibodies (IgM / IgG)**
 - This test is usually done with a finger prick.
 - There are qualitative and quantitative tests for IgM and IgG.
 - Qualitative tests only report out whether antibodies are detected or not. Currently there are only a few that are marketed under the FDA Emergency Use Authorization provision, but none are verified by the FDA
 - Quantitative tests can report the level/titers of the antibodies- currently none of these are approved in the US but have been employed in other countries
 - Quality of tests:
 - Most tests were allowed on the market by FDA under emergency protocols, without

- the usual level of evaluation. Thus, the quality and reliability of these tests are unknown.
- Some may have cross-reactivity with other non-COVID-19 coronaviruses, or have low detection rates.
- Utility of tests:
 - The antibody tests for IgG and IgM show that the person has antibodies but
 - It is still unknown whether these antibodies are protective or whether you can still get COVID-19 again.
 - It is still unknown if all previous COVID-19 positive patients will have antibodies and how long they persist.
 - Current tests do not establish immunity or exclude active infection.
 - **Thus, given the serology testing with our current limited understanding of COVID-19 antibodies, the utility of serology testing for preoperative testing of patients is questionable.**
 - If accurate, validated tests were readily available and if the presence of the detected antibodies were understood to confer a protective immunity, then serology testing (IgG/IgM) may have a role as:
 - An adjunct with PCR testing of patients. Serology testing does not rule out active infection and thus should not be used alone to rule out active COVID-19 infection in preoperative patients.
 - A means to test staff for past infection/immunity. However, depending on the evidence for how long the antibody is expected to remain (indefinitely/time-limited), consideration would be needed as to the timing and regularity of testing.
 - The tests may have utility to determine the prevalence of COVID-19 exposure in the population.
 - The tests may also have utility in determining who is eligible to donate their plasma in a COVID-19 Convalescent Plasma program where the plasma of a patient who has recovered from COVID-19 is transfused in a patient with an acute COVID-19 infection.
 - A quantitative test may also have the additional utility of identifying plasma that has a higher concentration of antibodies for convalescent plasma transfusion. Plasma with higher titers may require fewer units for efficacy and preferentially used.

For more information, please see our [ASPS COVID-19 Member Resource page](#) and check with your local, county, state, and regional resources for local guidance.

Approved by the ASPS Executive Committee on April 21, 2020.

Additional resources

- [White House Opening Up America Again](#)
- [CMS Reopening Guidelines Phase One](#)
- [AHA ACS ASA AORN Joint Statement](#)
- [ACS Local Resumption of Elective Surgery Guidance](#)



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