PROLIANCE SURGEONS®

Elective Patient Care and Surgery in the Era of Pandemics:

A Blueprint for Responding and Recovering from SARS-CoV-2 and COVID-19, While Preparing for the Future

SUPPLEMENT #2 – *Restarting elective surgery at Contagious Infectious Disease (CID) Threat Level 2: Operational criteria for patient selection, protocols and procedures, and outcomes data collection, for demonstration of safety and efficacy of a progressive increase in surgical volumes.*

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Synopsis

- Criteria outlined for resuming certain subsets of elective surgery and procedures during current/expected COVID-19 CID Threat Level 2 conditions:
    - Surgical triage indications using Proliance Pandemic Elective Surgery Triage Algorithm specific for Communicable Infectious Disease Threat Level 2
    - Consider initial scheduling priority given to patients in severe pain, severe ADL dysfunction, and previously-postponed surgery where possible
- Patient-Provider Collaboration document, encouraging strict patient and family social distancing and safety precautions from time of surgery scheduling until at least 2 weeks postoperatively, to help prevent perioperative SARS-CoV-2 infection COVID-19
- Continued best-practice use of strict patient/provider screening, universal precautions, and PPE protocols by all CC and ASC personnel (including patients) during entire patient clinical and surgical experience.
- Weekly outcomes and COVID-19 infection/contact data accumulated and recorded on every patient for first 3 weeks post-operatively. Collated at CSO for sharing with WA DOH as needed.
- Patient and provider SARS-CoV-2 testing if/when rapid, high-sensitivity, widely-accessible testing becomes available.

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Introduction

As Proliance Surgeons, Inc. works towards eventually increasing elective surgical care in Western Washington, the need arises to proactively define operational plans to safely bring patients, providers, and surgical teams back to the care space.

When given approval by appropriate regulatory agencies to proceed with elective surgical care once more, we will accomplish these goals through:

- Enterprise-wide definition and standardization of criteria for resuming certain subsets of elective surgery and procedures;
- Maintenance of established, effective safety procedures and protocols;
- Robust engagement of patients to maintain proper perioperative social distancing and safety measures;
- Enterprise-wide follow-up data collection, collation, monitoring, and reporting

The purpose of this "supplemental" document is to provide a high-level operational outline and roadmap for increasing surgical care during the current COVID-19 CID Threat Level 2 period.

Criteria for Resuming Certain Subsets of Elective Surgery and Procedures

Indications/Triage for Surgery

We have previously described the Proliance "Pandemic Elective Surgery Triage Algorithm,"[1] based on three factors: patient diagnosis acuity, patient general health and co-morbidity (as related to potential for contraction of pandemic disease in the perioperative period), and evolving threat levels of communicable infectious disease (CID) in the region and locale.

In so doing, this elective surgery triage protocol allows for standardized classification of patient diagnosis and treatment acuity, while accounting for overall health and comorbidities as pertinent to unique surgical risk during a pandemic. From that document:

Patient Diagnosis Acuity

- **Elective Tier 1:** Low/"Fully Elective" – Conditions which, if left surgically untreated for more than 90 days, are NOT expected to cause significant pain, significant dysfunction in patient's daily life or work, and/or are NOT progressing, nor at significant risk to progress.
    - Example: Stable bunion with deformity and minimal to mild pain, no significant dysfunction, patient deferring suggested surgery while they consider personal "best time in life schedule" to proceed.

- **Elective Tier 2:** Medium/"Semi-Urgent" - Conditions which, if left surgically untreated for more than 90 days, ARE expected to cause significant pain, significant dysfunction in patient's daily life or work, and/or ARE progressing, or at significant risk to progress.
    - Example: Patient with severe knee DJD, significant pain and dysfunction in ADLs and vocation, awaiting recommended and consented total knee replacement.

- **Elective Tier 3:** High/"Semi-Urgent, Time Sensitive" - Conditions which, if left surgically untreated in a timely (3 weeks or less) and accepted standard-of-care fashion, ARE expected to cause significant pain, significant dysfunction in patient's daily life or work, and/or ARE progressing, or at significant risk to progress, but do not necessarily fall into the separate classification of "Urgent" care for other reasons.
    - Example: closed tibial shaft or similar fracture, which *could* be treated non-operatively, but for which current, accepted optimal standard-of-care protocols would dictate surgical treatment.

Patient General Health and Co-morbidities (as relates to pandemic disease contraction potential and severity)

These factors become important in the context of exposing higher-risk patients to leaving the safety of their homes during periods of social distancing or isolation, and undertaking a surgical experience. Such patients (as recognized by the ACS and others), should likely not have elective surgery if at all reasonable during periods of high-level CID threat.

To help classify patients clearly, we employed the American Society of Anesthesiology Physical Status classification system, originally developed for defining patient fitness level for anesthesia via levels of systemic disease and comorbidities: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3348554/.

Use of this system, in conjunction with surgeon clinical judgement, allows the following acuity sub-classifications:

- "Type A" Patients – American Society of Anesthesia Physical Status class 1 and 2
- "Type B" Patients – ASA Physical Status class 3 and above
- Overall health, comorbidities, and other relevant risk factors should other be considered by clinician in deciding between Types "A" and "B"

*Threat Levels of **C**ommunicable **I**nfectious **D**isease **(CID)** in Region or Locale*

In our original source document[2], "Elective Patient Care and Surgery in the Era of Pandemics: *A Blueprint for Responding and Recovering from SARS-CoV-2 and COVID-19, While Preparing for the Future*, we proposed a new system of "Respiratory Infectious Disease Threat" (RIDT) Levels, which would help dictate appropriate indications and locations (inpatient vs. outpatient) for

elective surgical care, based upon level of perceived threat. This system also allowed for rapid changes in screening, universal precautions, PPE use, and surgical indications and triage in the case of a resurgence of COVID-19, or future pandemic.

However, over evolution of the current COVID-19 pandemic, we realized our initial system needed revision, to be more understandably applicable to changing pandemic dynamics, and to be equally useful in future, non-respiratory-disease pandemics.

Therefore, the name has been changed to "Communicable Infectious Disease (CID) Threat Level System," and with the following revised characteristics:

*Threat Levels of **C**ommunicable **I**nfectious **D**isease **(CID)** in Region or Locale*

- **CID Threat Level 1**:
  - No current or soon-expected local or regional CID pandemic threats identified, OR
  - CID pandemic threat has already occurred, peaked, and resolved, AND
  - If concerning potential threat exists, healthcare system has adequate capacity
- **CID Threat Level 2**:
  - Active local or regional CID pandemic, but not on significant upward infection curve/rate, OR
  - CID pandemic infection curve/rate has peaked, and is on downward trajectory, and is reasonably assumed to stay on downward trajectory, but not fully resolved, OR
  - Active local or regional CID pandemic, AND applicable healthcare systems are near, but not at full capacity.
- **CID Threat Level 3**:
  - Active local or regional CID pandemic, on upward infection curve/rate trajectory, or peaking, or staying at peak levels, before beginning significant downward resolution trajectory, OR
  - Active local or regional CID pandemic, and applicable healthcare systems are stressed for capacity

Determination of CID Threat Level

Determination of a particular CID Threat Level during the arc of a pandemic is suggested to be left situationally to the appropriate healthcare organization (e.g., Proliance Surgeons), system, advisory council or society, regulatory body or agency, or governmental authority, depending on circumstance. As noted below, we feel at the current time that Washington State is at CID Threat Level 2.

Pandemic Elective Surgery Triage Algorithm

Using the above-described criteria, we previously proposed[1] a comprehensive elective surgery triage algorithm for use before, during, and after pandemics, based on patient diagnosis acuity, patient general health and comorbidities, and evolving threat levels of communicable infectious disease (CID) in the region and locale. We also account for fluctuating healthcare system capacity needs (See Table 1, next page):

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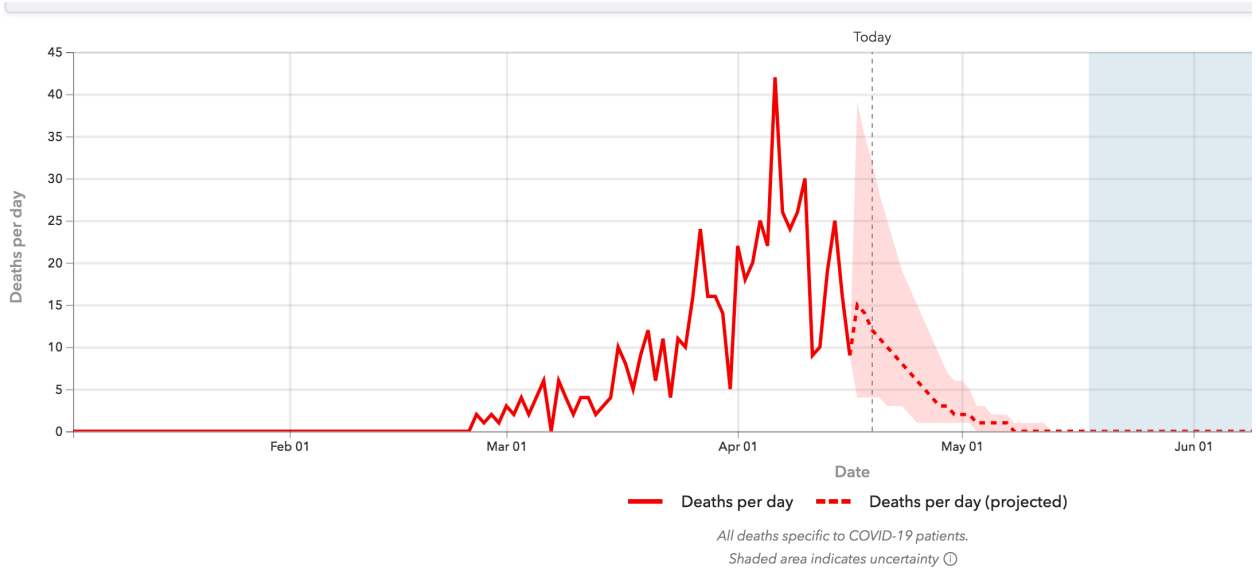
Table 1 – Pandemic Elective Surgical Triage Algorithm, based on patient diagnosis acuity scale, general health and co-morbidities, and evolving CID threat levels.
HOPD denotes "Hospital Outpatient Department." ASF denotes "Ambulatory Surgical Facility," the aggregate term used for ambulatory surgery centers, dental, gastroenterological, and other outpatient surgery/procedural facilities by Washington State regulatory agencies:

Patient acuity & health	CID Threat Level 1	CID Threat Level 2*	CID Threat Level 3*
Elective Tier 1, type A (ASA class 1-2)	Surgery/procedure at hospital, HOPD, ASF	Strongly consider postponement until return to level 1	Postpone until return to level 2 (as noted) or 1
Elective Tier 1, type B (ASA Class 3+)	Surgery/procedure at hospital; possible HOPD or ASF based on anesthesia consultation and institutional guidelines/protocols	Postpone until return to level 1	Postpone until return to level 1
Elective Tier 2, type A (ASA class 1-2)	Surgery/procedure at hospital, HOPD, or ASF	Surgery at hospital, HOPD, or ASF	Strongly consider postponement, in accordance with evolving recommendations and consultation with healthcare team
Elective Tier 2, type B (ASA Class 3+)	Surgery/procedure at hospital; possible HOPD or ASF based on anesthesia consultation and institutional guidelines/protocols	Strongly consider postponement until return to level 1	Postpone until return to level 2 (as noted) or 1
Elective Tier 3, type A (ASA class 1-2)	Surgery/procedure at hospital, HOPD, or ASF	Surgery at hospital, HOPD, or ASF	Consider postponement on case-by-case basis, in accordance with evolving recommendations and consultation with healthcare team
Elective Tier 3, type B (ASA Class 3+)	Surgery/procedure at hospital; possible HOPD or ASF based on anesthesia consultation and institutional guidelines/protocols	Consider postponement until return to level 1	Postpone until return to level 2 (as noted) or 1

*Levels 2 and 3 require heightened and appropriate levels of universal precautions, PPE use protocols, and ongoing consideration for PPE, equipment, capacity, and personnel needs in case of progression to, or maintenance of prolonged Level 3 threat.

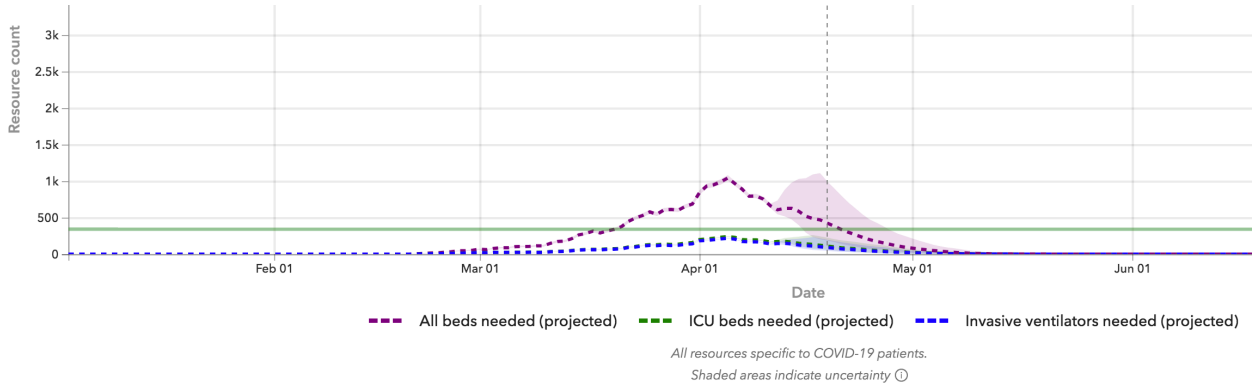
Current CID Threat Level (or Expected at Time of Restarting Elective Surgery)

In the absence of direct guidance from Washington State DOH, and after extensive analysis of COVID-19 modeling, expert opinions, and consultation with healthcare and governmental authorities, it is our position that Western Washington is crossing from CID Threat Level 3 into CID Threat Level 2 based upon the definitions in our classification system, in terms of daily mortality rates:



Source: University of Washington Institute for Health Metrics and Evaluation, April 19, 2020:https://covid19.healthdata.org/united-states-of-america/washington

And in terms of hospital bed, ICU bed, and ventilator capacity needs:



Source: University of Washington Institute for Health Metrics and Evaluation, April 19, 2020:https://covid19.healthdata.org/united-states-of-america/washington

Thus, any increase in elective surgery should be tailored to the "Level 2" portion of our Pandemic Elective Surgery Triage Algorithm. This sub-section is shown in Table 2 below:

Table 2 – Contagious Infectious Disease (CID) **Threat Level 2 portion** of Pandemic Elective Surgical Triage Algorithm, based on patient diagnosis acuity scale, general health and co-morbidities, and evolving CID threat levels. *HOPD denotes "Hospital Outpatient Department." ASF denotes "Ambulatory Surgical Facility," the aggregate term used for ambulatory surgery centers, dental, gastroenterological, and other outpatient surgery/procedural facilities by Washington State regulatory agencies.*

Patient acuity & health	CID Threat Level 2*
Elective Tier 1, type A (ASA class 1-2)	Strongly consider postponement until return to level 1
Elective Tier 1, type B (ASA Class 3+)	Postpone until return to level 1
Elective Tier 2, type A (ASA class 1-2)	Surgery at hospital, HOPD, or ASF
Elective Tier 2, type B (ASA Class 3+)	Strongly consider postponement until return to level 1
Elective Tier 3, type A (ASA class 1-2)	Surgery at hospital, HOPD, or ASF
Elective Tier 3, type B (ASA Class 3+)	Strongly consider postponement until return to level 1

*Levels 2 and 3 require heightened and appropriate levels of universal precautions, PPE use protocols, and consideration for PPE, equipment, capacity, and personnel needs in case of progression to, or maintenance of prolonged Level 3 threat.

Thus, in CID Threat Level 2 conditions, we suggest that "healthy," Type A patients in Elective Acuity Tiers 2 and 3 undergo surgery at the appropriate locations for their care. Surgeon clinical judgement in consultation with their patient should always remain the critical element of any decision to proceed with surgery.

"Healthy," Elective Acuity Tier 1, type A patients have by definition "conditions which, if left untreated for more than 90 days, are NOT expected to cause significant pain, significant dysfunction in patient's daily life or work, and/or are NOT progressing, nor at significant risk to progress." Thus, any decision to proceed with surgery must be carefully balanced by the surgeon and patient with the risk of COVID-19 infection inherent in any person-to-person contact, for patients, their families, providers, and teammates. Therefore, the option of surgical postponement should be "strongly considered."

"Unhealthy," type B patients in Elective Tier 1 should have their surgery postponed, and postponement should be "strongly considered" for Tiers 2 and 3. This is to continue minimizing the chance of potentially devastating COVID-19 contraction in these at-risk patients, by minimizing their non-essential person-to-person contact until reaching CID Threat Level 1. Again, Surgeon clinical judgement in consultation with their patient should always remain the critical element of any decision to proceed with surgery.

These triage guidelines are meant to support, not supplant surgeons' professional clinical judgement as to the safety and health of their patients and teams. We will add the cautionary note that if a resurgence of COVID-19 infections occurs specifically in patients undergoing elective surgeries in the time of Level 2 threat, regulatory agencies may interpret that a community has moved back into level 3 status, with the accompanying reestablishment of corresponding limitations on elective surgical care.

Furthermore, operational control of scheduling will remain unchanged from current status: at the individual ASC level, between surgeons and their ASC MEC/leadership teams. The Proliance QA Committee will still be available for counsel and advice, and to mitigate dispute if necessary.

Preferential Scheduling Order Upon Increasing Case Volumes

Recent prolonged cessation of elective surgery has created a large backlog of patients awaiting deferred elective surgical care. We recommend considering initial scheduling priority being given to patients in severe pain, severe ADL dysfunction, and/or previously-postponed surgery where possible.

Patient-Provider Collaboration, promoting strict patient and family social distancing and safety precautions, from time of surgery scheduling until at least 2 weeks postoperatively, to help prevent perioperative SARS-CoV-2 infection/COVID-19

As we increase elective surgical care, it remains critical to minimize threat of COVID-19 in our patients and providers. To that end, proper social distancing and safety measures such as frequent and thorough hand sanitization, mask use, etc., remain a key tool.

Some of our patients may not fully understand or share our level of commitment to these concepts. Thus, they may inadvertently place themselves, their families, and our Proliance members at unnecessary risk of COVID-19, by contracting SARS-CoV-2 infection either before coming to our ASCs, or during their postoperative recovery. We want to avoid this by any reasonable means.

Additionally, postoperative COVID-19 disease can result in significant surgical complications, including wound seeding from secondary pneumonia infection, DVT/VTE disease from prolonged bedrest, etc. This could lead to significant morbidity, and poorer surgical outcomes.

Finally, rates of postoperative COVID-19 disease will be monitored by Proliance, and likely by Washington State regulatory agencies. If a spike in COVID-19 infections occurs with the progressive increase in elective care, these agencies may elect to require restriction of care once more, or at least at ASCs that cannot demonstrate data supporting lack of such a spike. Therefore, it behooves our patients, their families, our providers, and our organization to take appropriate measures to minimize our patients' chances of SARS-CoV-2 infection before and after surgery.

To that end, the Proliance QA Committee and Board of Directors have designed and approved a "Provider-Patient Collaboration" document, reminding providers and patients of the benefits of strict patient and family social distancing and safety precautions from time of surgery scheduling until at least 2 weeks postoperatively, to help prevent perioperative SARS-CoV-2 infection, and COVID-19 disease.

This document, the text of which is shown below (and will be available as separate PDF for widespread distribution and use) will be given to ALL patients (elective, urgent, and emergent) as informational support at the time of their surgery scheduling.

If surgeons or providers additionally wish to initial their portion of the Collaboration, and after thoughtful discussion ask their patients to sign the patient portion, they are free to do so. However, they are not allowed to require patients to sign in cases of urgent or emergent care.

In elective cases, if a surgeon feels strongly that a patient should sign their portion, and the patient refuses, then the surgeon must either still provide appropriate, expert care, or arrange for similar care for the patient in a timely fashion elsewhere.

Please see document on page below:

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Provider-Patient COVID-19 Health and Social Responsibility Collaboration

In the setting of the current COVID-19 pandemic, it is critical to our patients' health and successful surgical outcomes to avoid COVID-19 infection after surgery.

In times of restrictive social isolation "Stay Home, Stay Safe" programs, the very act of leaving home and coming to a hospital or ambulatory surgery center (ASC) carries some inherent risk of SARS-CoV-2 exposure, and then COVID-19 disease. Therefore, it is incumbent on surgeons, their teams, and their facilities to provide as safe and sanitary a patient surgical experience as possible to achieve currently. Patient, caregiver, and family/"dwelling partner" actions and behavior are even more critical to prevention of COVID-19 during the postoperative recovery phase of care, as it lasts much longer than just the day of surgery.

An infection of COVID-19 in a patient recovering from surgery not only threatens their life and health, but can lead to postoperative complications, and have permanent damaging effect on the outcome of their surgery. Therefore, a COVID-19 infection is critical to prevent.

The, simplest, most scientifically-proven prevention methods to date include:

- Social distancing of *at least* 6 feet between people at all times if possible.
- Minimizing interaction with other people except as necessary (e.g., medical follow-up and physical therapy visits).
- Avoid any close contact with people who are sick with COVID-19 symptoms (cough, fever, body aches, general fatigue).
- Frequent hand washing or sanitizing for at least 20 seconds each time, especially **before and after** eating or touching the face or nose, putting on and taking off face masks or coverings, and necessary touching of others (e.g., patient medical care, changing surgical dressings, etc.).
- Regular and frequent cleansing of high-use surfaces (e.g. counters, doorknobs, drawer, cupboard, and refrigerator handles) with soap, bleach, or germicidal/viricidal cleansers.
- Wearing a face mask or cloth covering nose and mouth when outside your home at all times; people can jog or ride their bike alongside someone while breathing heavily, before they know it.

In order to provide you, your family, and those close to you the safest surgical experience possible, your Proliance surgeon or provider is asking you to voluntarily enter into this "Health and Social Responsibility Collaboration:"

Surgeon and Proliance Understanding:

To the best of our ability, your surgeon, surgical team, and all of Proliance will collaborate to provide all of our patients with the safest and most sanitary surgical experience possible, to avoid the potential of COVID-19 and other diseases.

Patient Understanding:

To the best of my ability, I will collaborate to abide by the COVID-19 prevention measures listed above from now until at least the first 2 weeks after my surgery. I will collaborate to ask my caregivers, "dwelling partners," and those who come in near contact with me to do the same.

Continued best-practice use of screening, universal precautions and PPE by all CC and ASC personnel (including patients) during entire patient clinical and surgical experience.

Below are listed current Proliance Surgeons screening, universal precautions, and PPE protocols for ASC surgery (in use for urgent and emergent surgery while in CID Level 3). We will continue this level of protocol use during CID Threat Level 2:

I. **Patient Screening**
   - **a.** Patients with a positive COVID-19 test, suspected exposure, or any current symptoms (cough, cold, fever, diarrhea, etc.) will not be scheduled for surgery.
   - **b.** Patients who have been approved for surgery will be thoroughly screened for COVID-19 status.
   - **c.** Screening will take place prior to arrival, upon arrival to the center and during their pre-operative intake.
   - **d.** Patients with a previous positive COVID-19 test or with a previous suspected COVID-19 infection will need to be screened vs negative PCR test vs positive IgG antibodies and approved by the medical director of the center.

II. **Staff Screening**
   - **a.** Employees will not report to work if they have a positive COVID-19 test or have any clinical symptoms of COVID-19 as outlined by the Surgical Case Selection Guidelines.
   - **b.** Any Employee who has been potentially exposed should immediately contact their Administrator:
     - **i.** "Exposed" is currently defined by the CDC as having close contact within 6 feet of an individual with a known or suspected COVID-19 patient/teammate. The timeframe for having contact includes 48 hours before the COVID-19 positive person became symptomatic. Evolving CDC and OSHA guidelines will be communicated regularly to Administrators from the Proliance CSO.
   - **c.** All care providers will be screened for symptoms upon entry to the facility.
   - **d.** The center will follow all corporate guidelines on managing employees that meet requirements for quarantine, test positive for COVID-19, or are in a "high risk" category.

III. **Social Distancing**
   - **a.** Whenever possible, Social Distancing will be practiced by all individuals within the Facility, including, but not limited to, patients, staff, providers, vendors and delivery personnel. If the waiting area has insufficient space for patients to be socially distanced, then patients should be asked to wait outside or in their vehicles until they are called for their appointment.
   - **b.** Patient companions will not be allowed to wait in the Facility.
   - **c.** Employees will use a dedicated workstation, when possible physically separated by 6 feet from others.

IV. Protocol Based on Exposure Level:

a. Low Risk: This area is the least restrictive in that it is people who do not have contact with the general public, *i.e*, patients. Typical areas include the business office, locker rooms and staff lounges. Entering these zones should include strict hand hygiene. Frequent surface disinfection will occur in high use areas, such as the breakroom and locker rooms and employees shall perform disinfection when using a new workstation. The current public health recommendations for the general public including social distancing, glove and mask use, and hand washing should be followed.

Masks (procedural, surgical, or N-95 as able to be provided by the facility) are recommended, but are not required. Please note that N-95 masks are only *required* in the High or Very High Risk Areas as detailed below.

Any persons actively coughing, sneezing or showing other symptoms should also be physically separated.

It is our ongoing goal to increase our supply chain and reprocessing capabilities as swiftly as possible, to allow every member of Proliance access to N95 (or N95 filtering equivalent) masks if they wish to wear one.

b. Medium Risk: This area is more restrictive in that the general public is allowed. These areas include check-in and waiting rooms and patient care areas like preoperative bays, nurse's stations and corridors. This would also include patient exam rooms, cast rooms, simple procedure rooms, and X-ray suites under typical use circumstances.

Patients and accompanying persons will be required to wear either facility-provided masks (if available), or bring their own mask or face covering for their appointment. Patients or parties without masks or face coverings will need to reschedule their appointment. Patient masks or face coverings may be removed as needed for applicable patient care (e.g., ENT and Ophthalmological examinations and procedures).

Masks (procedural, surgical, or N-95 as able to be provided by the facility) are required for all Proliance personnel at all times except while eating or drinking. Please note that N-95 masks are only *required* in the High or Very High Risk Areas as detailed below.

Gloves are strongly recommended, but may be substituted if necessary for frequent hand washing or sanitization, especially before and after patient contact.

Frequent surface disinfection will occur in high use areas, and employees shall perform disinfection when using a new workstation.

Any patient actively coughing, sneezing or showing other symptoms should be physically separated.

It is our ongoing goal to increase our supply chain and reprocessing capabilities as swiftly as possible, to allow every member of Proliance access to N95 (or N95 filtering equivalent) masks if they wish to wear one.

c. **High or Very High Risk:** This is the most restrictive category, and includes areas where patients are treated as possible COVID-19 patients and where droplet aerosolizing procedures (such as intubation, extubation, or other airway manipulations) or situations take place.
Appropriate eye protection, gown and gloves and a properly sealed N95 (or N95 filtering equivalent) mask are required. Fitted N-95 masks will be provided by the facility or Proliance CSO to all personnel working in these areas, initially using a "4-mask, paper bag rotation technique," until further sterilization/re-use protocols and capabilities are achieved.
For non-intubation/extubation situations, or when significant patient coughing is not expected, surgical mask use is allowed instead of N-95 masks. Protective eyewear and gloves are recommended at all times.
When an N95 equivalent mask is being used, an overlaying surgical mask must be used to prevent soiling or splashing if possible. Movement of staff is restricted. These areas are typically the operating room, procedure room and PACU Phase I (if and when intubations or extubations are taking place there).

V. Protocol for Aerosolized Generating Procedure (AGP):

Minimize staff exposure: Ensure only vital staff are present in the OR during aerosolizing procedures. In most cases, this is the anesthesiologist and RN circulator.

I. INTUBATION

a. Patient will be brought to the operating room with mask covering in place.
b. Prior to intubation, all personnel not wearing N-95 masks and other appropriate PPE will leave the OR, except the anesthesiologist and RN circulator. These team members will don the appropriate PPE per current anesthesia guidelines: at minimum a N95 mask or N95 filtering equivalent with an overlying surgical mask, appropriate eye protection, isolation gown (reusable or disposable), and gloves.
c. Stop Sign will be placed on the OR door to alert staff of an AGP in progress.
d. Once the patient is intubated, the team in the OR will add 14-18 minutes (depending on the OR) to the current time and the countdown will begin. If all team members are wearing N-95 masks and PPE as above, and observing proper use techniques, then the delay will not be required.
e. As soon as the room is cleared (14-18 minutes), the stop sign on the outside of the OR door will be turned over to show the Good to Go side, and the additional members of the OR team can re-enter.
f. The anesthesiologist and RN Circulator may doff their gown in the appropriate receptacle in the OR at this time if desired.

II. EXTUBATION

a. Prior to extubation, all not wearing N-95 masks and other appropriate PPE personnel will leave the OR, except the anesthesiologist, RN circulator, and/or the anesthesia tech. These team members will don the appropriate PPE: at minimum a N95 mask or filtering equivalent with an overlying surgical mask, appropriate eye protection, isolation gown (reusable or disposable), and gloves
b. Stop Sign will be placed on all OR doors to alert staff of an AGP in progress.
c. Once the patient is extubated, the team in the OR will add 14-18 minutes (depending on the OR) to the current time and the countdown will begin.
d. As soon as the room is cleared, the stop sign will be turned over to show the Good to Go side, and the additional members of the OR team can re-enter.
e. Once the room is cleared, the patient will be transported to PACU with a standard oxygen mask in place.

III. ROOM RE-ENTRANCE/CLEARANCE

a. After an aerosolizing procedure, the wait time for re-entry is 14-18 minutes, but in some centers the timing may be longer due to the air exchange rate.
b. The recommendation is to allow for at least 4 complete air exchanges.
c. Administrators should verify the rate of exchange with the HVAC vendor as this varies center to center.
d. Patients who have been extubated will wear a standard oxygen mask for transfer to minimize risk to PACU staff.
e. Children emerging from anesthesia following mask induction/maintenance for BMT can proceed directly to the PACU with an oxygen mask, with or without a surgical mask (under the oxygen mask) for transfer. These patients will be recovered in a separate space “cry room”.

VI. Protocol for Personal Protective Equipment (PPE)

I. N95 Mask

a. KN95 or other filter equivalent masks may be substituted for N95 masks.
b. Once fit tested, the care provider will be provided with the appropriate size/style mask and an open lid/bag container in which to sequester their personal mask.
c. Follow the guidelines for placement, removal and use to prevent contamination or soiling of the inner surface of the mask.
d. Reuse of masks must follow current FDA, DOH or QA committee guidelines
e. Do not reuse masks that are:

i. Soiled
ii. Broken
iii. Unable to obtain a seal
iv. Contaminated by use during direct care without careful reuse precautions (i.e. not covered by facemask or face shield while providing direct patient care)

f. Do not clean N95 masks.
g. Do not dispose of N95 masks unless damaged.
h. All N95 Masks or their filtering equivalent will be stored in a dry location on-site. Masks should not be taken home, or stored off-site.

II. Surgical Masks

a. Care providers will be provided with the appropriate size/style mask and a paper ("breathable") bag container in which to sequester their personal mask during food and water breaks during the day.
b. Follow the guidelines for placement, removal and use to prevent contamination or soiling of the inner surface of the mask. When not in use, the mask should be stored in the provider's personal paper bag container.
c. Reuse of masks must follow current FDA, DOH or QA committee guidelines; use of a new mask AND a new personal paper bag for storage each day is preferred.
d. Do not clean surgical masks.
e. Do not reuse masks that are:
   i. Soiled
   ii. Broken
   iii. Unable to obtain a reasonable facial covering/seal
   iv. Contaminated by use during direct care without careful reuse precautions (i.e. not covered by facemask or face shield while providing direct patient care)

III. Gowns

a. Only cloth gowns will be considered for reuse.
b. Cloth gowns will be professionally laundered via a contracted vendor.
c. Cloth gowns that require sterilization will be tracked similar to sterile instruments.

IV. Eye Protection

a. Eye protection i.e., goggles or a disposable face shield must cover the front and sides of the face. Contact lenses are not considered adequate eye protection. Personal eyeglasses must cover the front and sides if to be used as eye protection.

b. Reusable eye protection (e.g., goggles) must be cleaned and disinfected according to manufacturer's reprocessing instructions prior to re-use. Disposable eye protection should be discarded after use

V. General Conservation Recommendations

a. Minimize the number of care givers that need to wear critical PPE.

<u>Weekly outcomes and COVID-19 infection/contact data accumulated, recorded, and collated on every surgical patient for first 3 weeks post-operatively</u>

As we restart elective surgical practice, we need to demonstrate to our patients, ourselves, and regulatory agencies that we are doing so in a safe and effective manner. To that end, we will need to ensure patients undergoing surgery in our ASCs or hospitals do not experience rates of COVID-19 infection higher than the average population (and hopefully lower).

The only way to effectively achieve this goal is through collection of accurate and comprehensive follow up data.

To that end, the Proliance CSO team has developed in concert with Phreesia, our patient engagement tool/platform, an enterprise solution to automatically contact patients and capture basic follow up data at postoperative days 7, 14, and 21.

Data captured will include overall subjective recovery status, COVID-19 symptoms, caregiver/"dwelling partner(s)" COVID-19 symptoms, and potential COVID-19 contacts. Data will be collated and monitored via a real-time dashboard at the CSO.

Specific operational detail regarding this process will be forthcoming soon.

<u>Patient and provider SARS-CoV-2 testing if/when rapid, high-sensitivity, widely-accessible testing becomes available</u>

As carefully and thoroughly outlined in our original source document[2], we absolutely support the general concept of increasing safety of patients and providers through universal SARS-CoV-2 testing.

However, we do not yet advocate routine patient or provider preoperative SARS-CoV-2 testing *at this time.* In brief, this is due to the following significant concerns:

- False negative rates for current testing technology vary from 10-80% in the literature. "A bad test may be worse than no test at all." Given current accuracy concerns, we feel greater safety exists through patients and providers continuing to conduct themselves

as if everyone in a facility could be an asymptomatic SARS-CoV-2 carrier (including themselves).

- Lack of availability for rapid testing means that many small centers and clinics, especially in remote areas, will not be able to get tests back within a meaningful period. If/when comprehensive testing eventually occurs, it should be undertaken within 48 hours of surgery, otherwise the risk of a patient becoming infected between the time of the test surgery becomes significantly problematic.

- Cost – testing currently runs in the range of $100-150 per test. Prior to COVID-19, Proliance Surgeons operated on 5,000 patients per month in 20 different ASCs. Even at half volumes, testing at that price point would result in a cost to the healthcare system of $375,000 per month. And given the level of current testing inaccuracy, we will *still* need to treat every patient and provider as an asymptomatic carrier post-testing. In that context, this level of expenditure strikes us as questionable use of healthcare dollars.

When and if more accurate, rapid disease predictive testing becomes widely available, becomes "community standard of care," or becomes mandated by circumstance or appropriate regulatory agencies or authorities, we will rapidly deploy it for appropriate screening use.

Summary

Proliance Surgeons feels confident in moving at this time to safely and progressively bringing elective surgical patients back to our ASCs and affiliated hospitals. Our foundational policy work to date has generated the proper algorithms, protocols, and tools to prove the safety and efficacy of our methods and outcomes. Finally, we can thereby also develop a standardized roadmap for pandemic response and recovery that should serve our patients, our providers, and the healthcare community well, during the current COVID-19 crisis and into the future.

References

1. Peterson, C.A., II, Falicov, A.F, and Proliance Quality Assurance Committee: Elective Patient Care and Surgery in the Era of Pandemics: *A Blueprint for Responding and Recovering from SARS-CoV-2 and COVID-19, While Preparing for the Future.* Supplement #1 – *Revisions to Elective Surgical Care Patient Acuity Definitions and Communicable Disease (CID) Threat Level System, with Subsequent Proposed Pandemic Elective Surgery Triage Algorithm.* Proliance Surgeons, Inc., PS policy and action plan recommendation, released to general public April 22, 2020.

2. Peterson, C.A., II, and Falicov, A.F.: Elective Patient Care and Surgery in the Era of Pandemics*: A Blueprint for Responding and Recovering from SARS-CoV-2 and COVID-19, While Preparing for the Future.* Proliance Surgeons, Inc., PS policy and action plan recommendation, released to general public April 13, 2020.