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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

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Synopsis: The number and frequency of global infectious pandemics is increasing. While the current SARS-CoV-2 virus and COVID-19 disease pandemic has been the most widespread and crippling in recent history, it will certainly not be the last in many of our lifetimes.

COVID-19 has exposed serious inadequacies in the ability of world society, the medical community, and the medical supply industry to robustly and flexibly respond and adapt to a rapidly-spreading respiratory disease, especially when a large (and even currently, unknown) proportion of disease carriers remain asymptomatic.

Traditional social distancing, testing and quarantining, and waiting for both herd immunity and vaccination capabilities to develop are effective over a 3 to 18-month period. However, in their current iterations, they are far too slow, challenging to implement, socially-disruptive, and fraught with the peril of resurgent disease when lifted to be used solely as long-term management strategy.

A more proactive, adaptable, and universal strategy is required to prevent recurrent, massive human suffering, death, and social and economic disruption. Rapid, accurate, home-based testing, coupled with advanced technological contact tracing via cell phone data have been proposed, but still face developmental, validation, and privacy-rights hurdles.

Our healthcare system's ability to address and adapt quickly and flexibly to novel infectious disease has also been sorely tested. To keep patients and providers safe and healthy, and preserve a weakened personal protective equipment (PPE) supply chain, a radical, unprecedented, and widespread shutdown of all elective patient care in Washington State and elsewhere was undertaken. This placed many patients in situations of severe, unrelieved pain, untreated disease states, undiagnosed conditions that might prove severe or even fatal, or diagnosed conditions that might prove harder to treat when left to an unknown future date. In addition, the financial ramifications of such a shutdown on the US healthcare sector, which accounts for 18% of US GDP (2016), are staggering.

In such a crisis, there is an understandable desire to look immediately for rapid testing, effective medical treatment, development of herd immunity, and an eventual vaccine as the ultimate (and historically effective) solution to allow a return to more normal patient care. We would propose that while these measures are indeed essential and should be aggressively pursued, they do not address the basic challenge that we are seemingly entering a "new normal:" the "era of pandemics." Unless a proactive, effective, and permanent change in our healthcare delivery

system is undertaken, global society and the healthcare community will recurrently need to undertake the same draconian and crippling measures.

We propose that there exist (relatively) simple, scientifically-validated measures that can be undertaken to alter our care delivery process, which can both address easing of restrictions for elective care in the current crisis, but also proactively allow for prevention of disease spread during the next crisis. These include:

- Defining tiered levels respiratory infectious disease threat (RIDT);
- Correlated levels of universal precautions, and PPE use;
- Social distancing practices in healthcare facilities based on RIDT levels;
- Ongoing promotion of widespread personal and facility sanitization practices;
- Eventual use of patient and provider disease testing as a qualifying factor in treatment algorithms
    - ONLY when an effective test is available that can accurately prove the recipient either capable or incapable of transmitting disease.

These straightforward measures, if properly implemented, will allow for safe, progressive increases in elective patient care in both current and future crises.

Furthermore, using a "tiered-threat-level" system allows for adaptability of care process based upon existing pandemic/epidemic characteristics, and thus can operate at a less stringent level in times of epidemiological calm.

By not relying heavily on imperfect and evolving testing regimens, or time-consuming development of treatments and vaccines, these measures also allow for much more rapid initial response to future infectious disease hazards.

Goals

- Provide guidelines for helping Washington State's healthcare system safely begin to ease restrictions, and safely increase elective patient care and surgery while the ongoing COVID-19 crisis evolves to conclusion.

- Provide guidelines for how Washington State's healthcare system can rapidly respond and adapt to a potential resurgence of SARS-CoV-2 (or a mutation variant) if disease incidence surges upon widespread easing of social restrictions.

- Provide guidelines for simple, permanent changes in Washington State's healthcare system that not only increase patient and provider safety in the current crisis, but also allow for rapid, proactive, adaptable, effective, and sustainable management of future pandemics, epidemics, and similar public health crises.

- Create a simple and reproducible model that can easily be understood, and possibly adapted by other US states, healthcare systems, and nations.

Pertinent History

As the current COVID-19 pandemic began to affect the United States, Washington State quickly became an epicenter. The first case in the US was announced in Everett, WA, by the CDC on January 21, 2020: (https://www.doh.wa.gov/Emergencies/Coronavirus).

Progression of disease cases and deaths eventually led to a State of Emergency proclamation by Governor Inslee on February 29, 2020 and the subsequent "Stay Home – Stay Healthy" proclamation, updated March 23, 2020: (https://www.governor.wa.gov/news-media/inslee-announces-stay-home-stay-healthy%C2%A0order).

The Governor then moved to halt elective surgeries and procedures on March 19, 2020: (https://www.governor.wa.gov/news-media/inslee-orders-halt-elective-surgeries-and-dental-services-reserve-critical-equipment).

The language of the latter proclamation is critical to this discussion:

WHEREAS, *the COVID-19 disease, caused by a virus that spreads easily from person to person which may result in serious illness or death and has been classified by the World Health Organization as a worldwide pandemic, has broadly spread throughout Washington State, and significantly increasing the threat of serious associated health risks statewide; and*

WHEREAS, *the health care personal protective equipment supply chain in Washington State has been severely disrupted by the significant increased use of such equipment worldwide, such that there are now critical shortages of this equipment for health care workers. To curtail the spread of the COVID-19 pandemic in Washington State and to protect our health care workers as they provide health care services, it is necessary to immediately prohibit all hospitals, ambulatory surgery centers, and dental, orthodontic and endodontic offices in Washington State from providing health care services, procedures and surgeries that require personal protective equipment, which if delayed, are not anticipated to cause harm to the patient within the next three months, except as provided herein;*

FURTHERMORE*: based on the above situation and under the provisions of RCW 43.06.220(1)(h), to help preserve and maintain life, health, property or the public peace, I hereby prohibit all hospitals, ambulatory surgical facilities, dental, orthodontic and endodontic offices in Washington State from providing health care services, procedures, and surgeries that, if delayed, are not anticipated to cause harm to the patient within the next three months, with exceptions and as provided below. This does not include outpatient visits delivered in hospital based clinics.*

Examples of procedures to delay include, but are not limited to: most joint replacements, most cataract and lens surgeries, non-urgent cardiac procedures, cosmetic procedures, some endoscopy, and some interventional radiology services.

… Hospitals and ambulatory surgical facilities may perform any surgery that if delayed or canceled would result in the patient's condition worsening (for example, removal of a serious cancerous tumor or dental care related to the relief of pain and management of infection.)

Ambulatory surgical facilities are encouraged to work with their local hospitals to assist with surge capacity needs.

Several foundational goals and concepts spring from Governor Inslee's mandate:

- Epidemiological control of SARS-CoV-2 spread needs to be at the root of any response and recovery plan. Therefore, any response and recovery plan must consider the effect of the infectious arc of a pandemic on safe healthcare provision, and attempt to create a platform that responds to that arc. Even better if possible, that platform should be able to adaptably address potential future infectious disease occurrences.

- Maintenance of a robust and broad PPE supply chain is critical at all times for proper response to any epidemic or pandemic. It therefore needs to be accounted for in any response or recovery plan; *indeed, it might well be the "rate limiting step" in many cases.*

- The current working definition for elective patient care and surgery (in Washington State and elsewhere) denotes conditions that can safely wait for approximately three months or longer before management, without significant risk of harm to a patient.

- Cooperation among healthcare providers, healthcare systems, and regulatory agencies is critical to the long-term success of response, recovery, and preparation for the future.

Based upon this mandate, and the evident need to drastically limit all unnecessary person-to-person contact, Proliance Surgeons, Inc., other independent physicians and surgeons, hospital systems, and healthcare delivery systems across Washington State rapidly shut down all elective care (patient clinical visits and surgeries). Urgent and emergent care for non-COVID-19 patients continued via careful screening processes, balancing ethical urgency of their care with required PPE and equipment needs for COVID-19 patient care.

To accomplish this, we and others referenced triage guidelines from our professional societies, regulatory agencies, and governing bodies:

- American College of Surgeons: https://www.facs.org/covid-19/clinical-guidance/elective-case
- Centers for Medicare and Medicaid Services (CMS): https://www.cms.gov/files/document/cms-non-emergent-elective-medical-recommendations.pdf

- FACS Orthopedic Guidelines: https://www.facs.org/covid-19/clinical-guidance/elective-case/orthopaedics
- AAOS (Orthopedics): https://www.aaos.org/about/covid-19-information-for-our-members/
- NASS (Spine): https://www.spine.org/Portals/0/assets/downloads/Publications/NASSInsider/NASSGuidanceDocument040320.pdf

In many cases, difficult decisions needed to be made on an almost "wartime footing," which ran counter to normal contemporary standards of care. When decisions were made to postpone patients' care, they were informed that their care would be resumed "as soon as the crisis abates, and we are safely able to increase our elective care once again."

The crux question therefore becomes, "When will we be at that point, and how do we proceed once we get there?"

Roadmaps for general social recovery from COVID-19 and other pandemics have been proposed, including the much-referenced Gottlieb Report from the American Enterprise Institute: https://www.aei.org/research-products/report/national-coronavirus-response-a-road-map-to-reopening/.

While this and other proposals account for the easing of restrictions and a gradual return to social normalcy, they do not address the fact that **medical care can (and should) safely progress at a more rapid pace of easing.** This is driven by the need to efficiently ease the suffering of patients whose care has been postponed in early stages of a pandemic, and the fact that medical care delivery facilities and personnel are inherently more able to control the safety and infection-transmission potential of those environments.

Additionally, broad, society-focused reports rely fundamentally on the need to have widespread, accurate, and rapid testing of a large swathe of our population, with subsequent massive trace and quarantine measures in order to move into the "Phase II: Reopen, State by State" mode of a pandemic response. This makes sense for our population at large; prevention of disease resurgence is critical to sustainably reopening an entire society.

However, in the more controlled medical space, we should be planning not only for this pandemic, but subsequent pandemics as well, for which we will once again likely not have adequate testing, tracing, etc. **Thus, instead of relying heavily on currently imperfect testing, we can and should be developing robust, proven protocols and procedures that allow patient care to carefully and safely advance, while providing flexibility to rapidly adapt to future threats.**

Pertinent Foundational Science

A) Testing

Rapid, accurate, widespread testing for the presence of SARS-CoV-2 in both symptomatic and asymptomatic patients and citizens has been among the most daunting challenges of COVID-19 management in the US to date. Lack of such testing means we can't fully diagnose the extent of disease, adequately perform the most basic of epidemiological techniques such as contact tracing and quarantining, or even know if a negative test is "truly" negative.

Compounding this challenge is the fact that up to 80% of patients testing positive for SARS-CoV-2 can still be asymptomatic: https://www.cebm.net/covid-19/covid-19-what-proportion-are-asymptomatic/. Thus, if we are testing and tracing only symptomatic individuals, we are potentially missing a *massive* virus load in the general population, with chance for ongoing disease spread.

Current testing technology remains problematic in terms of access, speed, and false negative and positive results. Many excellent resources detail these important aspects and limitations: https://mbio.asm.org/content/11/2/e00722-20.

While both demand for, and access to more rapid "point of service" PCR testing is increasing, it is vital that we remember the limitations of this procedure as it currently exists. Indeed, on April 8, 2020, the World Health Organization came out against "point of service" testing for clinical decision making until further validation can be demonstrated: https://www.who.int/news-room/commentaries/detail/advice-on-the-use-of-point-of-care-immunodiagnostic-tests-for-covid-19.

With relaxation of US FDA regulations on developing and marketing this type of test, 70 companies have filed to sell their product, all without having to prove efficacy prior to sale. As recently as April 12, the Association for Public Health Laboratories called for additional FDA oversight to prevent the effects of false negative or positive test outcomes: https://apnews.com/6f918ac77eefa34beaa381003a7663f9

Further concerns to point out:

1) *False negative rates of testing up to 50% have been reported.* Even in the best of traditional laboratory settings, institutions like Mayo Clinic have recently reported a 10% false negative rate: https://www.sciencedaily.com/releases/2020/04/200409144805.htm. **Thus, we cannot be sure even if we test all patients and providers that we are truly "safe" to allow those with negative tests to interact with others without maintaining universal precautions.**

2) *False positives can and do occur.* PCR testing measures mRNA levels in the nares or oropharynx of an individual. Lab specimens can be contaminated; some tests can cross-react with other non-COVID coronaviruses, and we do not yet know if, or how long

individuals can carry "just" the mRNA strands without the critical "spike protein" which allows infection, and therefore would not infect others despite a positive test.
The implications are significant: Imagine a critical provider tests positive, but has no symptoms, and they quarantine for 2 weeks but remain asymptomatic. Then perhaps they even test positive *again* at the end of quarantine because non-infectious mRNA remains in their nares. Are we helping patients and the medical community more via that prolonged quarantine, or if we instead allowed all *asymptomatic* providers to care for *asymptomatic* patients under strict universal precautions?

3) Serological tests for antibodies have not yet been shown to equate with guarantee of prolonged host immunity. Until we know if someone with a positive antibody titer can be re-infected or not with SARS-CoV-2, we cannot safely assume that they can care for patients (or be cared for themselves) without still maintaining universal precautions.

We should absolutely pursue widely-available, rapid, accurate, predictive testing, and generate the essential disease science that goes with it. When more perfected and reliable, it will serve as an incredibly useful and critical tool in patient and staff health and safety. But currently that is not the case, and similarly will likely not be the case at the time of onset for the next epidemic or pandemic.

Therefore, at the current time, we submit that testing should *not* be a "gateway" determinant in which asymptomatic individuals provide or receive care. Current testing capability has too high a chance of luring us into a false sense of security, and potentially limiting asymptomatic, test-positive health care providers from delivering care. We instead make the argument for using strict and robust universal precautions and appropriate PPE as the cornerstone for recovery and future prevention, while integrating testing as a key component if and when the results can be accurate enough to be actionable.

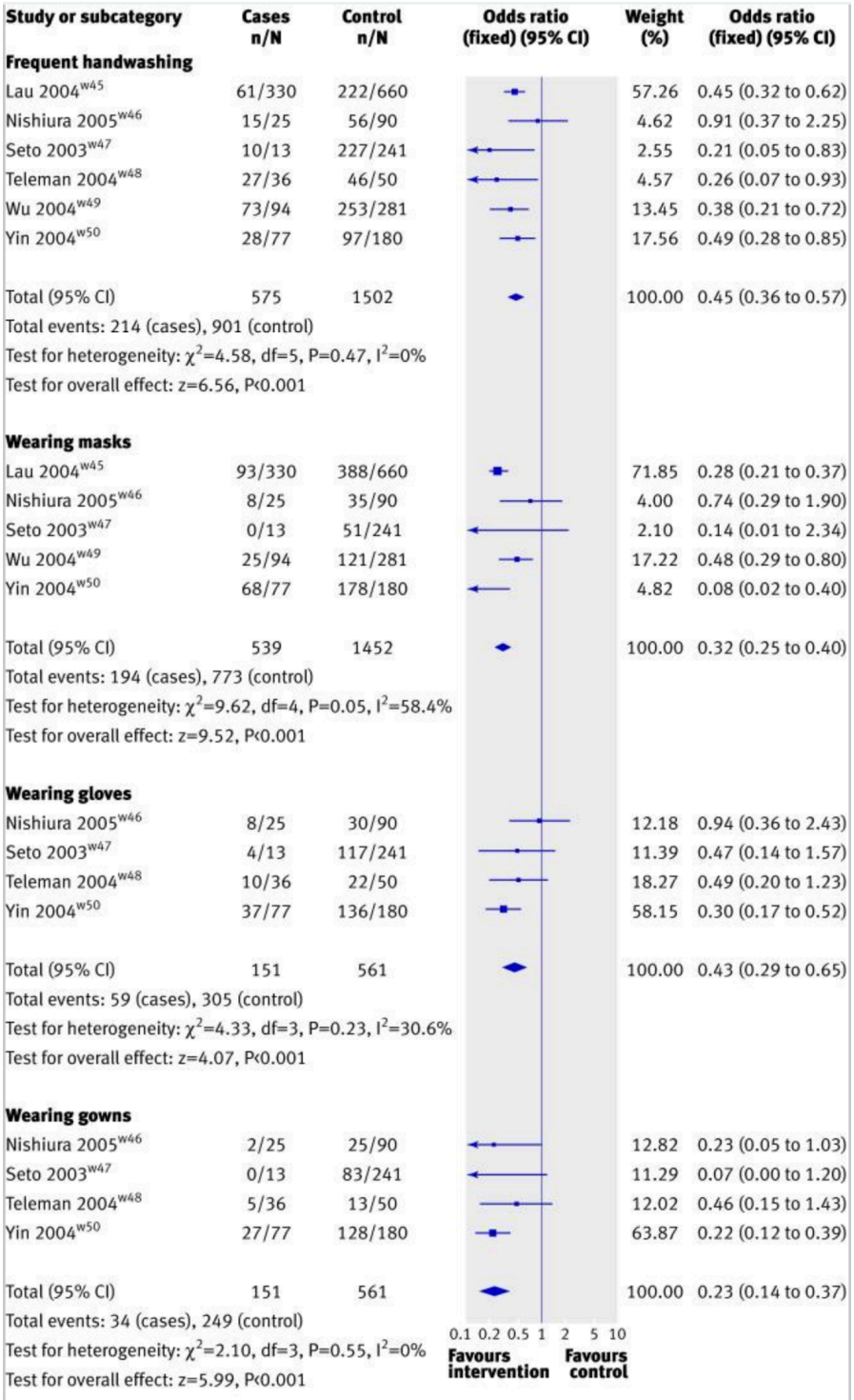
B) Effect of Robust Universal Precautions and Basic PPE on Previous Respiratory Viral Epidemics

Widespread and robust use of PPE and sanitary techniques has been shown to be exceptionally effective in reducing the spread of respiratory viruses similar to SARS-CoV-2. The following article demonstrating this came out in 2008 after the SARS-CoV-1 and Swine flu epidemics: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2190272/

Table 1, taken from that article, demonstrates the efficacy shown in a variety of studies for various forms of universal precautions (handwashing, masks, gloves, and gowns). The further to the left of the midline the blue dots move, the more effective the intervention is than not using it at all.

Note: The "odds ratio" on the far right means: if a person not using an intervention has a 100% (1.00) chance of contracting infection, then a person using that intervention has that fraction of a 100% chance. Thus, a 0.40 odds ratio means the person using the intervention has a 60% less chance of contracting infection than the unprotected person:

Table 1 – "Evidence from case control studies on effect of frequent handwashing or wearing of masks, gloves, or gowns on prevention of severe respiratory syndrome (SARS)."
From Jefferson, T., et al.: Physical interventions to interrupt or reduce the spread of respiratory viruses: systematic review. BMJ. 2008 Jan 12; 336(7635): 77-80.



Study or subcategory	Cases n/N	Control n/N	Odds ratio (fixed) (95% CI)	Weight (%)	Odds ratio (fixed) (95% CI)
Frequent handwashing					
Lau 2004[w45]	61/330	222/660		57.26	0.45 (0.32 to 0.62)
Nishiura 2005[w46]	15/25	56/90		4.62	0.91 (0.37 to 2.25)
Seto 2003[w47]	10/13	227/241		2.55	0.21 (0.05 to 0.83)
Teleman 2004[w48]	27/36	46/50		4.57	0.26 (0.07 to 0.93)
Wu 2004[w49]	73/94	253/281		13.45	0.38 (0.21 to 0.72)
Yin 2004[w50]	28/77	97/180		17.56	0.49 (0.28 to 0.85)
Total (95% CI)	575	1502		100.00	0.45 (0.36 to 0.57)
Total events: 214 (cases), 901 (control)					
Test for heterogeneity: χ^2=4.58, df=5, P=0.47, I^2=0%					
Test for overall effect: z=6.56, P<0.001					
Wearing masks					
Lau 2004[w45]	93/330	388/660		71.85	0.28 (0.21 to 0.37)
Nishiura 2005[w46]	8/25	35/90		4.00	0.74 (0.29 to 1.90)
Seto 2003[w47]	0/13	51/241		2.10	0.14 (0.01 to 2.34)
Wu 2004[w49]	25/94	121/281		17.22	0.48 (0.29 to 0.80)
Yin 2004[w50]	68/77	178/180		4.82	0.08 (0.02 to 0.40)
Total (95% CI)	539	1452		100.00	0.32 (0.25 to 0.40)
Total events: 194 (cases), 773 (control)					
Test for heterogeneity: χ^2=9.62, df=4, P=0.05, I^2=58.4%					
Test for overall effect: z=9.52, P<0.001					
Wearing gloves					
Nishiura 2005[w46]	8/25	30/90		12.18	0.94 (0.36 to 2.43)
Seto 2003[w47]	4/13	117/241		11.39	0.47 (0.14 to 1.57)
Teleman 2004[w48]	10/36	22/50		18.27	0.49 (0.20 to 1.23)
Yin 2004[w50]	37/77	136/180		58.15	0.30 (0.17 to 0.52)
Total (95% CI)	151	561		100.00	0.43 (0.29 to 0.65)
Total events: 59 (cases), 305 (control)					
Test for heterogeneity: χ^2=4.33, df=3, P=0.23, I^2=30.6%					
Test for overall effect: z=4.07, P<0.001					
Wearing gowns					
Nishiura 2005[w46]	2/25	25/90		12.82	0.23 (0.05 to 1.03)
Seto 2003[w47]	0/13	83/241		11.29	0.07 (0.00 to 1.20)
Teleman 2004[w48]	5/36	13/50		12.02	0.46 (0.15 to 1.43)
Yin 2004[w50]	27/77	128/180		63.87	0.22 (0.12 to 0.39)
Total (95% CI)	151	561		100.00	0.23 (0.14 to 0.37)
Total events: 34 (cases), 249 (control)					
Test for heterogeneity: χ^2=2.10, df=3, P=0.55, I^2=0%					
Test for overall effect: z=5.99, P<0.001					

Taken in aggregate, if someone uses maximal "reasonably readily available" universal precautions, including a mask, gloves, a gown, and washes their hands before and after, they have a 0.09 odds ratio of contracting disease (91% reduced chance)!

Table 2 – *From Jefferson, T., et al.: Physical interventions to interrupt or reduce the spread of respiratory viruses: systematic review. BMJ. 2008 Jan 12; 336(7635): 77-80.*

Pooled estimates of effect of public health interventions to interrupt transmission of SARS from case-control studies

Intervention	No of studies (references)	Odds ratio (95% CI)	Intervention effectiveness* (%)	Number needed to treat (95% CI)†
Frequent handwashing (>10 times daily)	6 (w48, w45-w47, w49, w50)	0.45 (0.36 to 0.57)	55	4.00 (3.65 to 5.52)
Wearing mask	5 (w45-w47, w49, w50)	0.32 (0.25 to 0.40)	68	6.00 (4.54 to 8.03)
Wearing N95 mask	2 (w45, w47)	0.09 (0.03 to 0.30)	91	3.00 (2.37 to 4.06)
Wearing gloves	4 (w46, w47 w45, w50)	0.43 (0.29 to 0.65)	57	7.00 (4.15 to 15.41)
Wearing gown	4 (w45, w46, w47, w50)	0.23 (0.14 to 0.37)	77	5.00 (3.37 to 7.12)
Handwashing, mask, gloves, and gown combined	2 (w46, w47)	0.09 (0.02 to 0.35)	91	3.00 (2.66 to 4.97)

*Odds ratio−1.

†Number needed to treat to prevent one case.

The bottom line? ***Assuming an adequate PPE supply chain*, these are simple interventions that can be immediately and sustainably undertaken to protect patients and providers, without the need to limit care for universal testing early on in *any* respiratory pandemic, now or in the future; while still waiting for rapid and accurate testing, effective treatments, and vaccines to be developed over time.**

How to Determine if "It's Time?"

Obviously, there is no perfect metric for determining the exact point at which we should increase the levels of elective patient care. Variables such as resurgence of disease with easing of social restrictions, PPE levels, unexpected supply chain disruption, hospital and ASC capacity, viral

mutations, and health status of critical staff all play roles. However, for Washington State, we can perhaps use the foundational messages in Governor Inslee's mandate as a rough guide:

Epidemiological control of SARS-CoV-2 spread needs to be at the root of any response and recovery plan. Therefore, any response and recovery plan must consider the infectious arc of a pandemic on safe healthcare provision, and attempt to create a platform to uniformly address potential future infectious disease occurrences.

Modeling from the University of Washington Institute for Health Metrics and Evaluation (IHME) demonstrates that due to adapting and maintaining strict social distancing precautions, Washington State appears to be past our peak in daily deaths from COVID-19, and entering the downward side of that curve We also may see a reduction of deaths to zero per day by mid-May: https://covid19.healthdata.org/united-states-of-america/washington.

As with any model, there are many critical assumptions as well as degrees of error that must be acknowledged. Perhaps the most critical assumption is that strict social distancing protocols for our public-at-large must be maintained. But given a steady decline in the daily mortality rate, can we now define science-based protocols and procedures to start bringing patients back to elective care in a safe and progressive fashion? We believe the answer is "yes."

It appears definitely not yet time to lift widespread social distancing and "stay at home" recommendations for the general public. Given the potential lack of scientific training, experiential background, and comprehension of risk in our citizenry, reasonable concern exists that too rapid, too close resumption of personal interaction could lead to a massive resurgence of disease propagation: https://www.seattletimes.com/seattle-news/health/what-comes-next-the-coronavirus-end-game-will-require-massive-testing-and-maybe-high-tech-tracking/

Medical health facilities however provide the optimum location to begin safe easing of social restrictions: they are controlled spaces, staffed by providers with understanding and experience in managing disease and infections. Especially in the surgical arena, providing exceptional infection control precautions is simply a daily way of life for providers. If there is any space in society-at-large for which the first steps should be taken, it would be in these locations.

The key required component to allow this progression to elective care and surgery in healthcare facilities at the current time is a firm commitment to universal precautions by all patients and providers across the board, with access to proper PPE. While discussed in detail later, for the current threat level, this includes:

1) Universal temperature screening and questioning for infectious symptoms for everyone entering a healthcare facility;
2) Universal hand sanitization by everyone entering a healthcare facility;
3) Universal mask wearing at all times required for everyone in direct patient care areas in a healthcare facility, and recommended for providers and staff in "low risk" areas (e.g. administration);

   a. If PPE supplies cannot support them with universal surgical masks, patients should be mandated to wear instead some type of cloth mask covering nose and mouth while in the facility;
4) Gloves to be worn by all providers touching patients or passing materials back and forth with patients if possible, and both before and after contact hand sanitization;
5) Frequent cleaning of hard surfaces, doorknobs and drawer pulls, equipment, etc., with germicidal/viricidal cleanser.
6) Addition of gowns, eye protection, and N-95 masks for high-risk procedures such as intubation, extubation, colonoscopies, or procedures which induce significant risk of coughing or sneezing by patients.

As shown in the above-mentioned articles, implementation of these simple measures decreases the chance of disease transmission by over 90%.

Maintenance of a robust and broad PPE supply chain is critical at all times for proper response to any pandemic or epidemic, and needs to be accounted for in any response or recovery plan. Indeed, it might well be the "rate limiting step" for any response and recovery plan.

If we assume that the key to steadily increasing elective patient care across the healthcare landscape is proper use of universal infection precautions and associated PPE, then adequate access to that PPE is obviously critical.

Fortunately, the types of PPE/equipment that have been in shortest supply in this pandemic (N-95 masks, ventilators, etc.) are not the most critical at this moment for use in the elective patient care space. Simple surgical-style masks, hand sanitizer, and gloves will accomplish most or all of the goals set. For the surgical/procedural realm, gowns, eye protection, and (situationally) N-95 masks will be necessary as well.

In the recent past, and in many places currently, our national supply chain for these items was (and is) severely compromised. However, due to a variety of factors, availability of these items in the Pacific Northwest is slowly but steadily increasing. We are also learning by necessity how to safely reprocess and reuse these critical items. Obviously, maximally enhancing this availability and improvement is at the essence of any long-range management plan.

To properly address PPE levels for increasing levels of elective patient care, hospitals and HOPDs should be able to demonstrate they have an adequate supply of appropriate PPE for the above-mentioned usage patterns, AND still be able to withstand an unexpected resurgence of COVID-19 in their region. ASCs should be able to demonstrate they have an operational level of necessary PPE. **If these criteria are met, then it seems increasingly reasonable that the expanding capabilities of the national and international supply chain will allow them to back-fill ongoing needs as time passes. If that is indeed the case, then steady increase in elective patient care appears logistically reasonable from a PPE standpoint at this time.**

The working definition for elective patient care and surgery appears to involve conditions that can safely wait for three months or longer before management without significant risk of harm to the patient.

This definition, while broad, parallels those of many medical and regulatory bodies, and represents a good starting point for appropriately rationing and prioritizing care, provider capacity, hospital capacity, equipment, and PPE at the start of a severe public health crisis.

However, as time goes on in any shutdown, patients' levels of pain, illness, and dysfunction can evolve, and what was once considered "elective" may move into "semi-elective," "urgent," or even "emergent" categories. As this occurs, ability to treat may become more difficult, and outcomes less predictable or acceptable. Furthermore, if a shutdown continues beyond two to three months, do those patients held in postponement early on now inherently move to a more urgent status?

We believe the answer is again "yes." **If we can move forward safely in a manner that protects patients and providers, and uses resources within available supply chain capabilities, it is indeed time to give those "on hold" patients (and new ones) access to the appropriate elective care.**

This is not only an issue of medical ethics in healing the sick and injured. It is also an important socio-economical one: the longer that standard, effective care is delayed, the greater the potential overall costs to the healthcare system of having to "play cleanup" for "deferred maintenance." The sooner we can safely care for patients, the better for them, and for us all.

Cooperation among healthcare providers and systems is critical to long term success of response and recovery.

We agree this is a fundamental principle of response, recovery, and long-term adaptation of our healthcare system to respond to future pandemics, including:

- Coordinated construction and agreement on industry-wide universal precaution protocols and PPE use based on standardized, gradated respiratory infectious disease threat (RIDT) levels;

- Coordination of supply chain use and robust inventory maintenance across the industry;

- Development of risk assessment and response protocols to evolving current and recurring future RIDT levels; Locally, regionally, and nationally, in conjunction with our various monitoring and regulatory agencies (Depts. of Health, CDC, CMS, etc.). Being able to rapidly and broadly raise and lower standardized threat levels will dictate corresponding evidence-based responses. This allows community, patient, and provider assurance, system stability, proper and optimal use of supply chains, and efficacy of practice that is currently lacking.

At Proliance Surgeons, we stand ready to enter into a long-term dialogue with all of our healthcare colleagues to create this new, more robust, more efficient, more flexible, and more efficacious system to the benefit of the all.

New Respiratory Infectious Disease Threat (RIDT) Levels, with Corresponding Universal Precaution and PPE Use Guidelines

- *RIDT Level 1 – **Low** Threat of Community Infectious Respiratory Disease*

    - **Definition:** No known active local, regional, or national RID epidemic, or potential global pandemic threats identified. (This would have been "pre-Wuhan," or during the very early stages of Hubei Province spread).

    - **Corresponding Universal Precautions and PPE Use Guidelines:**
    - Routine hand sanitization procedures followed.
    - No routine mask use in care spaces.
    - ALL patients with symptoms of respiratory infection (cough, sneezing, fever, etc.) should be given a procedural or surgical mask to wear during their care/visit if PPE supplies permit.
    - ALL providers with symptoms of respiratory infection (cough, sneezing, fever, etc.) should wear a procedural or surgical mask and consider gloves while caring for patients, and be encouraged to stay home if possible.
    - Surgical teams use standard surgical mask, eye protection, gown, and gloves universal precautions.
    - RID Testing – none, other than for standard care requirements.

- *RIDT Level 2 – **Medium** Threat of Community Infectious Respiratory Disease*

    - **Definition:** Identified or active local, regional, or national RID epidemic or global pandemic, before local/regional infection/mortality incidence curves begin significant rise. OR, when local/regional infection/mortality curves have peaked, and then have begun to meaningfully fall.

    - **Corresponding Universal Precautions and PPE Use Guidelines:**
    - Aggressive, more frequent hand sanitization procedures followed.
    - Universal screening for fever and symptoms undertaken for all patients and providers immediately upon entering a care facility.
    - All patients should be provided a procedural or surgical mask if available, or wear a personal cloth mask or mouth/nose covering otherwise.
    - Strict social distancing protocols observed; expanded time schedules, terminal room sterilization between cases, physical spacing of patients in waiting, preoperative, and PACU areas.
    - Minimum family members/caregivers accompany patient to visit.

- Family members of surgical patients wait away from facility until called back at end of case for patient discharge.
- All direct patient-care providers must wear a procedural or surgical mask at all times except food and drink breaks when in the care facility.
- All other personnel in non-care spaces (e.g. administrative areas) are recommended to wear masks at all times, but must maintain social distancing regardless.
- Surgical areas
  - Operating Rooms - masks at all times, gown, gloves, eye protection for non-intubation procedures. N-95 masks reasonable to consider, based on procedure type, and PPE availability.
  - Neuraxial and regional anesthesia if possible (to avoid intubation/extubation when appropriate).
  - Intubation and Extubation – N-95 masks with surgical over-mask, eye protection, gown, gloves.
- PACU
  - Masks and gloves for routine patient recovery in asymptomatic patients without airway manipulation or coughing.
  - For patients being extubated in PACU, or expected coughing, etc.: add N-95 masks, eye protection, gowns.
- RID Testing (*assumes rapid, widely available, highly accurate and scientifically-predictive test capability; not currently available for SARS-CoV-2*):
  - Providers – consider recurrent testing at appropriate intervals based on disease epidemiological profile. Positive test leads to removal from care provision, and appropriate quarantine and contact trace.
  - Patients – testing within 48 hours of surgical procedure. Positive test leads to postponement of surgery, appropriate quarantine and contact trace.

- *RIDT Level 3 – **High** Threat of Community Infectious Disease*

  - **Definition:** Active local, regional, national RID epidemic or global pandemic, when local/regional infection/mortality incidence curves are rising to, or at peak levels.

  - **Corresponding Universal Precautions and PPE Use Guidelines:**
  - Only urgent and emergent patient care undertaken; all elective care postponed. Urgent and emergent care continued per professional society and regulatory agency triage guidelines until RIDT Level reduced to Level 2 or Level 1.
  - Aggressive, frequent hand sanitization procedures followed.
  - Universal screening for fever and symptoms undertaken for all patients and providers entering a care facility.
  - All patients should be provided a surgical mask if available, or wear a cloth mask or mouth/nose covering otherwise.

- Strict social distancing protocols observed; expanded time schedules, terminal room sterilization between cases, physical spacing of patients in preoperative and PACU areas.
- Family members wait away from facility until called back at end of case for patient discharge.
- All providers must wear a surgical mask at all times except food and drink breaks when in the care facility.
- All other personnel in non-care spaces (e.g. administrative areas) are recommended to wear masks at all times.
- Surgical areas
    - Operating Rooms - masks at all times, gown, gloves, eye protection for non-intubation procedures. N-95 masks reasonable to consider, based on procedure type, and PPE availability.
    - Neuraxial and regional anesthesia if possible (to avoid intubation/extubation when appropriate).
    - Intubation and Extubation – N-95 masks with surgical over-mask, eye protection, gown, gloves.
- PACU
    - Masks and gloves for routine patient recovery in asymptomatic patients without airway manipulation or coughing.
    - For patients being extubated in PACU, or expected coughing, etc.: add N-95 masks, gowns.
- RID Testing (*assumes rapid, widely available, highly accurate and scientifically-predictive test capability; not currently available for SARS-CoV-2*):
    - Providers – consider recurrent testing at appropriate intervals based on disease epidemiological profile. Positive test leads to removal from care provision, and appropriate quarantine and contact trace.
    - Patients – testing within 48 hours of surgical procedure. Positive test leads to postponement of surgery, appropriate quarantine and contact trace.

PROLIANCE SURGEONS®

Elective Surgical Patient Triage Based on Surgery Acuity, Patient Health, and Respiratory Disease Threat Level

We are electing to use the initial triage categories "1A to 3B" as defined by American College of Surgeons (ACS) Elective Surgery Acuity Scale, developed early in the COVID-19 pandemic arc: https://www.facs.org/covid-19/clinical-guidance/triage:

Elective Surgery Acuity Scale (ESAS)

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Tiers/Description	Definition	Locations	Examples	Action
Tier 1a	**Low acuity surgery/healthy patient** Outpatient surgery Not life threatening illness	HOPD ASC Hospital with low/no COVID- 9 census	Carpal tunnel release Penile prosthesis EGD Colonoscopy	Postpone surgery or perform at ASC
Tier 1b	**Low acuity surgery/unhealthy patient**	HOPD ASC Hospital with low/no COVID-19 census		Postpone surgery or perform at ASC
Tier 2a	**Intermediate acuity surgery/healthy patient** Not life threatening but potential for future morbidity and mortality. Requires in hospital stay	HOPD ASC Hospital with low/no COVID-19 census	Low risk cancer Non urgent spine Ureteral colic	Postpone surgery if possible or consider ASC
Tier 2b	**Intermediate acuity surgery/unhealthy patient**	HOPD ASC Hospital with low/no COVID-19 census		Postpone surgery if possible or consider ASC
Tier 3a	**High acuity surgery/healthy patient**	Hospital	Most cancers Highly symptomatic patients	Do not postpone
Tier 3b	**High acuity surgery/unhealthy patient**	Hospital		Do not postpone

HOPD – Hospital Outpatient Department
ASC – Ambulatory Surgery Center

(Note – the "Action" items in this Table were generated by the ACS as recommended protocols early in the COVID-19 pandemic).

Recommended Elective Surgery Triage Algorithm, Based on ESAS Acuity and New RIDT Levels:

- **Triage for RIDT Level 1** – All elective surgeries undertaken at appropriate locations
  - Tiers 1A-2B at HOPD or ASC;
    - Type B patients possibly at hospital Inpatient setting.
  - Tiers 3A and 3B – Hospital inpatient setting.

- **Triage for RIDT Level 2** – Some limitation of elective surgeries
  - Tiers 1A and 2A – HOPD or ASC.
  - Tiers 1B and 2B – Consider postponement based on individual patient risk factors.
  - Tier 3A – Hospital inpatient setting.
  - Tier 3B - Consider postponement based on individual patient risk factors and facility capacity/PPE needs.

- **Triage for RIDT Level 3** – Postponement of all elective surgeries unless not performing within 3 months or other agreed-upon time frame will place patient in harm, significant risk of permanent or non-reparable injury, or dramatically worsen long-term outcome.
  - Tiers 1A and 1B – Postpone.
  - Tier 2A – Consider postponing vs. proceeding based on above risk criteria, other guidelines from specialty societies, etc.
  - Tier 2B – Strongly consider postponing if possible until RIDT drops to Level 2.
  - Tier 3A – Hospital inpatient based on individual hospital triage process.
  - Tier 3B - Consider postponing if possible until RIDT drops to Level 2; if not possible, then Hospital inpatient based on individual hospital triage process.

(Summary table on next page).

Table 4 – Summary of recommended elective surgery triage algorithm, based on ACS Elective Surgery Acuity Scale (ESAS), and our newly-described Respiratory Infectious Disease Threat (RIDT) Levels:

ACS ESAS Tier	RIDT Level 1	RIDT Level 2	RIDT Level 3
1A (Low acuity surgery, Healthy patient)	Undertake surgery at HOPD or ASC	Undertake surgery at HOPD or ASC	Postpone surgery until RIDT level drops
1B (Low acuity surgery, Unhealthy patient)	Undertake surgery at HOPD, ASC, or (select patients) Inpatient hospital setting	Consider postponing surgery, based on individual case and patient factors	Postpone surgery until RIDT level drops
2A (Intermediate acuity surgery, Healthy patient)	Undertake surgery at HOPD or ASC	Undertake surgery at HOPD or ASC	Consider proceeding vs. postponing at HOPD or ASC based on accepted professional society and regulatory agency guidelines
2B (Intermediate acuity surgery, Unhealthy patient)	Undertake surgery at HOPD, ASC, or (select patients) Inpatient hospital setting	Consider postponing surgery, based on case and patient factors. Consider location (ASC vs. inpatient) based on infection risks and staff/PPE/equipment needs at all locations	Strongly consider postponing surgery until RIDT level drops. Consider location (ASC vs. inpatient) based on infection risks and staff/PPE/equipment needs at all locations
3A (High acuity surgery, Healthy patient)	Undertake surgery at Inpatient hospital setting	Hospital inpatient setting, considering current and expected hospital facility staffing, PPE, and equipment needs	Hospital inpatient setting, considering hospital facility staffing, PPE, and equipment needs, in conjunction with hospital review panel
3B (High acuity surgery, Unhealthy patient)	Undertake surgery at Inpatient hospital setting	Consider postponing surgery, based on case and patient factors; consider hospital facility staffing, PPE, and equipment needs, in conjunction with hospital review panel	Postpone surgery

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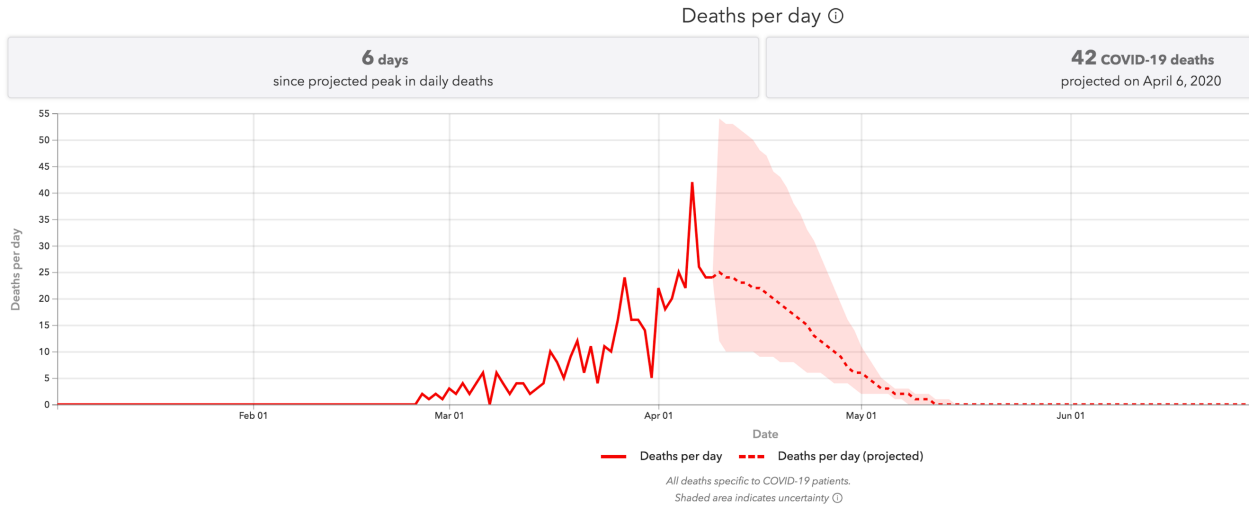
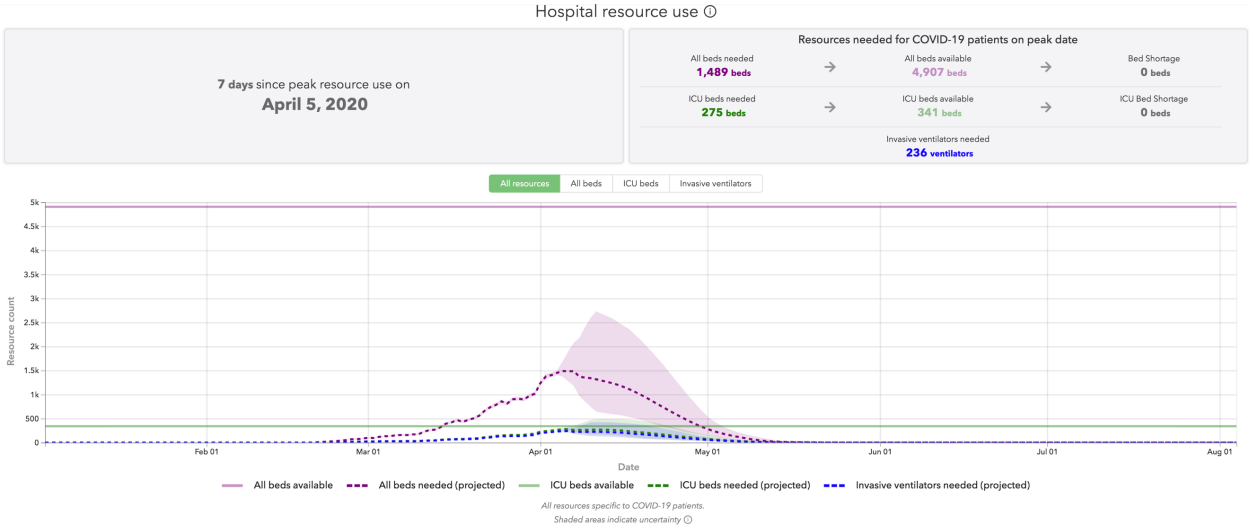
Is it Time to Ease Restrictions on Elective Surgical Care in Washington State?

Based on the above criteria, we believe we are moving from RIDT Level 3 (High) into Level 2 (Medium) in many (but not all) areas of Washington State. We have seen local and regional mortality rate curves reach their apparent peak, and head towards an expected decline. We also appear to be past our peak need for ICU beds and ventilators:
https://covid19.healthdata.org/united-states-of-america/washington





Thus, we maintain that with the proper universal precautions, PPE availability and use, and continued aggressive social distancing measures as outlined, coupled with increasing SARS-CoV-2 testing capability and accuracy over time, we can now move safely into increased surgical care of elective patients in the Tier 1A and 2A categories.

Patients in the "B" ("unhealthy patient") category of the ACS guidelines should be considered on a case-by-case basis by the hospital or ASC medical executive teams or review panels before proceeding to surgery.

Summary

As we move from the height of the COVID-19 pandemic in Washington State, we need now to consider how to safely, progressively, and compassionately increase elective patient care and surgery. As we undertake that process, it behooves us not just to react to COVID-19, but to proactively create a revised system of patient care that will serve us when future epidemics or pandemics strike.

While increasingly robust testing capabilities, treatment protocols, and eventual vaccine capability will likely "solve" the scourge of COVID-19, it appears likely that at some point in the not-too-distant future, we will be faced with another grave challenge in this new "era of pandemics."

At that point, once again relying heavily on robust testing or treatment may fail us, as it has for the stages of COVID-19 thus far. Implementation of a new strategy of adaptable universal precautions and PPE use, tailored to a tiered level of respiratory disease threat at any point in time, will allow us to plan for future events, rapidly deploy resources, respond to local conditions in an intentional and coordinated fashion, protecting our patients and providers. We will then be able to continue providing essential urgent and emergent care, while having an established, standardized blueprint for how and when we are safely able to increase elective patient care once more.