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5 **Considerations for Cardiac Catheterization Laboratory Procedures**
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8 **During the COVID-19 Pandemic**
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11 *Perspectives from the Society for Cardiovascular Angiography and Interventions Emerging*

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13 *Leader Mentorship (SCAI ELM) Members and Graduates*
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Introduction:

The novel coronavirus, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) that causes coronavirus disease 2019 (COVID-19), is highly contagious and has resulted in a global pandemic.(1) Given the high mortality rate, up to 15% in the elderly and compromised patients, coupled with the lack of any currently available curative treatment, focus must be directed toward containing community exposure and spread.(2)

Initial reports from the experience in Wuhan, China suggest patients with established CVD may be at particularly high risk to progress to death. Remarkably, among the cohort of 191 reported by Zhou et al. in which 54 died, 13 of 15 patients with coronary artery disease had a fatal course (OR 21.4; 95%CI 4.6 to 98.8), and those with hypertension or diabetes were three times more likely to succumb.(3)

COVID-19 infection likely triggers many of the pathways that promote acute coronary syndrome (endothelial activation, oxidation of low-density lipoproteins, platelet activation, expression of tissue factor), as previously established in the setting of influenza. Whether there are additional pathogenic aspects specific to COVID-19 (interaction with ACE/ARB medications, NSAIDs, lymphocytic myocarditis, etc.) will require further investigation.(4-6) Since patients with cardiovascular disease are particularly susceptible, this document is intended to provide strategies for triage and management of care in the Cardiac Catheterization Laboratory (CCL).

Scope

Accordingly, this document has been created to guide the response to:

- Confirmed COVID-19 positive or
- Person under investigation (PUI) as defined by the presence of

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- 3 a) Fever.
- 4
- 5 b) Respiratory symptoms (cough, shortness of breath, sore throat).
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- 8 c) Either foreign travel within 14 days to a country with a Level 2 - 4 travel alert health
- 9
- 10 notice (CDC website) or exposure to a confirmed case or cluster of suspected
- 11
- 12 COVID-19 illness.
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16 **Guiding Principles for Confirmed or Suspected COVID-19 Patients**

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- 18 1. All STEMI patients including transfers should initially undergo clinical and COVID-19
- 19 screening evaluation in the Emergency Department.
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- 21
- 22 2. Currently, all STEMI patients should be brought to the CCL for primary PCI. Although
- 23 several reports are advising fibrinolytic therapy in these patients if the prevalence of COVID-
- 24 19 is high or system resources are in danger of becoming overwhelmed, the prevalence
- 25 globally currently favors continuing a primary PCI approach. As the prevalence of COVID-
- 26 19 increases causing systematic and infrastructural bottlenecks for care, especially given
- 27 regional variations, the primary therapeutic options may have to change (Appendix 1).
- 28
- 29
- 30 3. Alternative therapeutic options such as systemic fibrinolytic therapy may be considered for
- 31 low risk STEMI (e.g. inferior STEMI without right ventricular involvement or lateral
- 32 myocardial infarction without hemodynamic compromise) depending on local availability of
- 33 expertise and the prevalence and effects of the COVID-19 disease burden at the institution; a
- 34 potential downside is that these patients then often require prolonged ICU level of care and
- 35 may end up utilizing vital finite resources.
- 36
- 37 4. When possible, bedside procedures are preferable (e.g., intra-aortic balloon pump,
- 38 pericardiocentesis, ECMO, temporary venous pacemakers); CCLs should create COVID-19
- 39 carts with all potential supplies for these procedures.
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3 5. For treatment in the CCL, maximal protection to prevent staff exposure should be employed
4 including effective personal protective equipment (PPE).
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8 6. Percutaneous coronary intervention (PCI) should only be performed to the culprit vessel
9 unless a non-culprit lesion is deemed unstable or multiple culprit lesions are present.
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- 12 7. Performing endotracheal intubation in the CCL should be avoided to the extent as possible.
13
14 In patients with respiratory distress, early intubation (prior to transfer to the CCL) should be
15 considered in order to minimize aerosolization. Similarly, high-flow nasal cannula, non-
16 invasive ventilation, and use of an ambu bag should be avoided to minimize potential
17 aerosolization and dissemination of virus. If intubation is required in the CCL, all personnel
18 not essential to the act of intubation should exit the room to avoid the associated higher risk
19 of virus exposure during the process. If cardiopulmonary resuscitation (CPR) is required in
20 the CCL, consider using automated CPR devices for chest compression to minimize
21 personnel exposure.
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- 24 8. Within the CCL, a single procedure room should be designated for the care of COVID-19
25 patients, air flow modified to negative pressure if possible (though this is controversial), and
26 strategies for safe containment and elimination of the virus should be developed. In some
27 cases, this may involve utilization of HEPA filters in the room.
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43 **Epidemiology of COVID-19**

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45 The Case Fatality Rate (CFR) for COVID-19 is unknown. If one divides the total
46 number of deaths by the total number of confirmed cases, the resultant CFR would be 4.1%
47 (9,867 /242,714 based on data from March 19, 2020).(7) This is likely an overestimate, given
48 that widespread testing has not been available and the denominator is likely much larger. In
49 contrast, on the Diamond Princess Ship, which was a contained environment, 7 of 705 people
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3 who tested positive for SARS CoV-2 died, resulting in a CFR of ~ 1%, likely a more realistic
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5 estimate. Even if only 1% of all infected individuals died, the high transmissibility of COVID-19
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7 (Reproduction number, R, 2.2; 95% CI, 1.4–3.9) will translate into high mortality.(8) The
8
9 percentage of individuals who will become infected in the general population is estimated by the
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11 equation $1-1/R$, or 55% (95% CI 30%-75%), ~20% of whom will require hospitalization based
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13 upon observations from currently impacted countries. These data suggest that unmitigated, ~180
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15 million people living in the US could become infected, and ~27-36 million might require
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17 hospitalization. That there are approximately 1 million hospital beds in the United States
18
19 highlights the need to ‘flatten’ the transmission curve as much as possible through measures such
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21 as social distancing, reduction in transmission probability and ultimately effective treatment
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23 (Figure 1).(9, 10)
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29 **Infection Control**

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31 Attention should be paid to meticulous infection control with appropriate PPE. In
32
33 addition, frequent wipe downs of commonly touched objects in the control rooms (i.e.
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35 keyboards, mouse, door handles) should be performed. Recommendations on how to safely clean
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37 cell phones using 70% isopropyl alcohol wipes have been issued by different vendors. In
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39 addition, all supplies that cannot be effectively cleaned at the end of each case should be
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41 removed if possible, so as to avoid the potential for cross-contamination.
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48 **Social Distancing**

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50 In the CCL, the number of clinicians capable of performing these specialized procedures and
51
52 providing specialty care are limited, thus distancing should be pursued using several concrete
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54 steps. Routine meetings and conferences should be converted to an online or telephone format.
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3 Morning CCL “huddles” should be suspended or converted to web-based or telephone-based
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5 format. Staffing rotations should also be considered, as described below.
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8 **1. Screening of Patients Prior to Cardiac Catheterization:** The Centers for Medicare and
9
10 Medicaid Services announced that all elective surgeries, non-essential medical, surgical, and
11
12 dental procedures be delayed during the pandemic. Deferral minimizes risk of exposure to
13
14 COVID-19 for patients and staff, and maximizes availability of inpatient beds in anticipation
15
16 of a surge in hospitalization required for COVID-19 infected patients. Broadly speaking,
17
18 there are three levels of infection control (Figure 2).(11)
19
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21 **2. Health Care Provider Personal Protective Equipment (PPE)**
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24 a) The CDC has not provided specific advice regarding PPE to address the unique needs of
25
26 CCL or associated clinical personnel. Perspective has been shared, however, from the
27
28 experience with Severe Acute Respiratory Syndrome (SARS) in 2005. All CCL
29
30 personnel who were in contact with SARS patients wore N95/99/100 respirators,
31
32 protective eyewear, full face shields, disposable caps, gowns, surgical gloves, and shoe
33
34 covers. These precautions served to protect clinicians from airborne, droplet and contact
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36 infectious sources.(11) Lead aprons should be worn under PPE to prevent contamination.
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38 Empirically, these precautions should be extended to the treatment of patients with
39
40 COVID -19, as this condition bears many similarities to SARS. If a procedure is
41
42 undertaken that confers a high risk of generating aerosol product, an advanced barrier,
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44 hooded HEPA (high-efficiency particulate air) powered air-purifying respirator
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46 (PAPR/CAPR) should be worn. In the CCL, these procedures may include: endotracheal
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48 intubation, cardiopulmonary resuscitation or tracheal suctioning. It is unclear if glasses
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3 such as lead glasses provide adequate protection; additional splash protection and face
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5 shielding are preferred. Full face masks are recommended.
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8 b) Refer to the CDC guideline for proper donning and doffing of PPE and other online
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10 resources being used by healthcare centers to educate their staff:

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12 (1) <https://www.cdc.gov/hai/pdfs/ppe/PPE-Sequence.pdf>

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14 (2) https://www.youtube.com/watch?v=RqIJ-SPIG0E&feature=emb_logo

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17 c) The steps for donning and doffing PPE are critically important, and one must remain
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19 attentive to the fact that the front surface of facemasks, gowns and other PPE are
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21 contaminated once used and should be disposed of accordingly. These steps are outlined
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23 in Table 1 and Appendix 2. Personnel should then wash hands appropriately, shower (if
24
25 needed), and change scrubs.
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28 i. **Environmental/Engineering:** To the extent possible, environment and engineering
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30 control measures should be deployed to reduce the viral burden in the air through
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32 reduction in droplets spreading and optimization of ventilation and direction of
33
34 airflow. If feasible, institutions should consider dedicating specific procedure
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36 room(s) for presumed and confirmed cases of COVID-19. *Reducing droplet spread:*
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38 This involves measures such as the wearing of surgical masks by presumed or
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40 confirmed COVID-19 positive patients. There is a high risk of droplet dissemination
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42 during airway management for patients who are already intubated or require
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44 emergent intubation in the CCL. Appropriate measures for mechanical ventilators
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46 and other resuscitation equipment are necessary. All non-essential catheterization
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48 laboratory equipment should be removed from the procedure room, or covered, prior
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50 to bringing the patient into the room.. Furthermore, reducing the number of
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3 personnel who enter or exit the procedure room during each case will be important to
4 minimize exposure and transmission of infection. Meticulous deep cleansing and
5
6 disinfection of the CCL after catheterization procedures for COVID-19 patients are
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8 important components of infection control. UV light-based disinfection may also be
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10 a reasonable strategy to employ.(12) Thorough cleaning procedures may require
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12 extra time; therefore, if feasible, such cases should be performed as the final
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14 procedure of the day.(13) Those procedures which may be performed at the bedside
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16 in suspected or COVID-19 positive patients should be done so after consultation
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18 with the care team, in order to minimize the need to remove the patient from an
19
20 isolation room, and avoid risk of additional exposure through transportation to the
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22 CCL. Since contaminated surfaces can be a source of disease transmission, staff
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24 members responsible for cleaning should wear full PPE.
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31 ii. *Modification of ventilation system:* The standard positive pressure ventilation
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33 system of the CCL consists of an air-handling unit (AHU) that distributes
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35 conditioned air to different functional units, including the procedure room and
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37 control room. In principle, a positive pressure room with adequate air changes could
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39 quickly eliminate the virus from the environment and it has been shown that the risk
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41 of cross-contamination from airborne infection is low if staff are adequately
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43 protected with appropriate PPE. (14, 15) That noted, the use of negative pressure
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45 ventilation offers optimal protection to personnel working in adjacent areas. It may
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47 be feasible to convert a lab to a negative pressure room temporarily, but this
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49 typically cannot be achieved instantaneously, and so may not be as helpful for
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STEMIs and other procedures performed on an emergency basis. If temporary

conversion to a negative pressure room is performed, cross-contamination of other rooms may occur.

3. **Administrative control measures:** Vendors, visitors, observers, research coordinators, and any non-essential personnel should be restricted from the CCL to the extent possible during the pandemic.
4. **Personnel Management and Contingency Planning:** Older adults (age >65), people with chronic cardiac or pulmonary disease, diabetes mellitus or hypertension have a higher risk of serious illness following COVID-19 infection.(5) It may thus be desirable to minimize operators and CCL staff with these conditions from being directly exposed to presumed or confirmed COVID-19 cases. All CCL teams should also discuss and implement backup policies and schedules, in case that an operator or CCL staff member becomes ill or is quarantined and cannot participate in clinical coverage for a period of time.
5. **Alternative Staffing Models:** Given the limited staffing resources (both physician and support staff) to attend to cardiac emergencies such as STEMI, consideration should be given to alternative staffing models that aim to limit exposure of an individual to as few other individuals in the workplace as possible. From the perspective of the catheterization laboratory, one such approach would be through creation of a “clustered team model.”

Clustering Model

- a) *A team consists of 1 attending physician, 1 cardiovascular fellow, and 2-3 nurses/cardiovascular technologists. These teams stay together until someone requires quarantine at which point the whole team is out of the pool until the quarantine is lifted.*
- b) *Monday -Thursday : 2 teams working during the day. Separate team on-call during the night.*
- c) *Friday – Sunday: Function as the weekend with 1 team on-call for this entire period.*

Hospital/Home Model

- a) *One IC attending primary for daytime cases M-Thurs, One IC attending backup for daytime cases (from home); other attendings available as needed; rotate primary and secondary IC in successive weeks.*
- b) *Weeknight and weekend on-call coverage stays unchanged from pre-COVID.*
- c) *Nursing and tech staffing follows same protocol as attendings*

Ideally, separate clustered teams would have no contact with one another during the period of the COVID pandemic. One alternative to a clustered model would be for interventional cardiologists and staff to take turns working from home, in isolation and presumably at lower risk of contracting COVID-19. This minimizes the chances that multiple members of the CCL staff are infected and unable to work at any given time. Regardless of model employed, it will be impossible for attending physicians to completely halt exposure to patients and healthcare providers outside of the catheterization laboratory so these models do not necessarily limit the possibility of an attending physician spreading the disease to other areas. However, the model does increase the chances of the catheterization laboratory staying functional even as disease prevalence rises.

6. Patient Selection

With the guiding principle of decreasing exposure as low as reasonably achievable to COVID-19 patients, we propose the following:

A subset of patients should be considered for *deferral* of urgent diagnostic or interventional procedures in the catheterization laboratory during the pandemic:

- a) STEMI patients with severe pneumonia should undergo conservative treatment which could include fibrinolytic therapy.
- b) NSTEMI with low-risk features stabilized with medical therapy (i.e. without refractory chest pain, or evidence of hemodynamic or electrical instability).
- c) Type II MI or myocardial injury with elevated troponin levels related to sepsis or acute respiratory distress syndrome.
- d) Troponin positive myocarditis without cardiogenic shock.
- e) Elective cardiac, structural and vascular diagnostic procedures or intervention with stable, non-life-threatening symptoms.

Limitations of this document:

It should be acknowledged that this document is being written at a time when a full understanding of the transmission, severity, and appropriate treatment strategy for COVID-19 is not well understood, and testing turnaround times are long and variable. The strategies suggested in this document are based on limited data and might change.

Conclusion

The COVID-19 pandemic will impact many patients we care for with cardiovascular disease. The preparedness of healthcare providers is critical in providing the best quality of care with soon to be limited resources, while keeping all personnel as safe as possible. The current key elements include 1) rescheduling of all non-urgent, elective CCL procedures, 2) careful patient selection for urgent and emergent CCL procedures with recognition of potential shifts in risk/benefit ratios in the setting of a highly contagious virus, 3) meticulous donning and doffing

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3 of PPE along with cleaning of CCL areas, 4) performance of bedside procedures when possible,
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5 and 5) staffing modifications to limit infectivity and preserve staff availability.
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For Review Only

Table 1: Sample steps for donning and doffing personal protective equipment for CCL staff.

Donning:

1. Tall disposable shoe covers
2. Covid-19 designated lead apron.
3. Leaded glasses or prescription glasses
4. First head cover (cover ears)
5. N95 Mask
6. Second head cover (cover ears)
7. Surgical mask
8. Eye protection: Goggles or face shield
9. Hand Hygiene: Surgical scrub
10. Non-sterile gown
11. Sterile gloves 1
12. Sterile gown
13. Sterile gloves 2

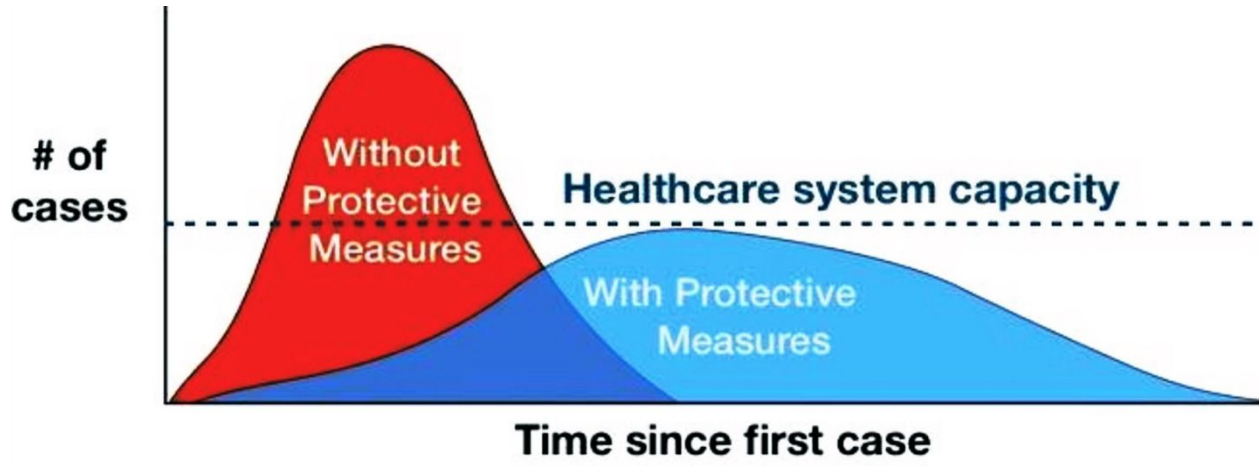
Doffing:

1. Hand Hygiene (HH1)
2. Remove surgical gown by breaking neck/back straps and dispose sterile gloves.
3. HH2 with alcohol foam in room
4. Remove eye protection
5. Remove surgical mask
6. Remove second head cover in room
7. Remove PPE gown and gloves
8. HH3 with alcohol foam in room
9. Remove shoe covers at doorway in room and step out of room
10. HH4 with alcohol-based disinfectant (i.e.: Sterillium)
11. Remove N95 mask
12. Remove first head cover
13. HH5 with surgical scrub
14. Remove Covid-19 lead
15. Change to clean scrubs

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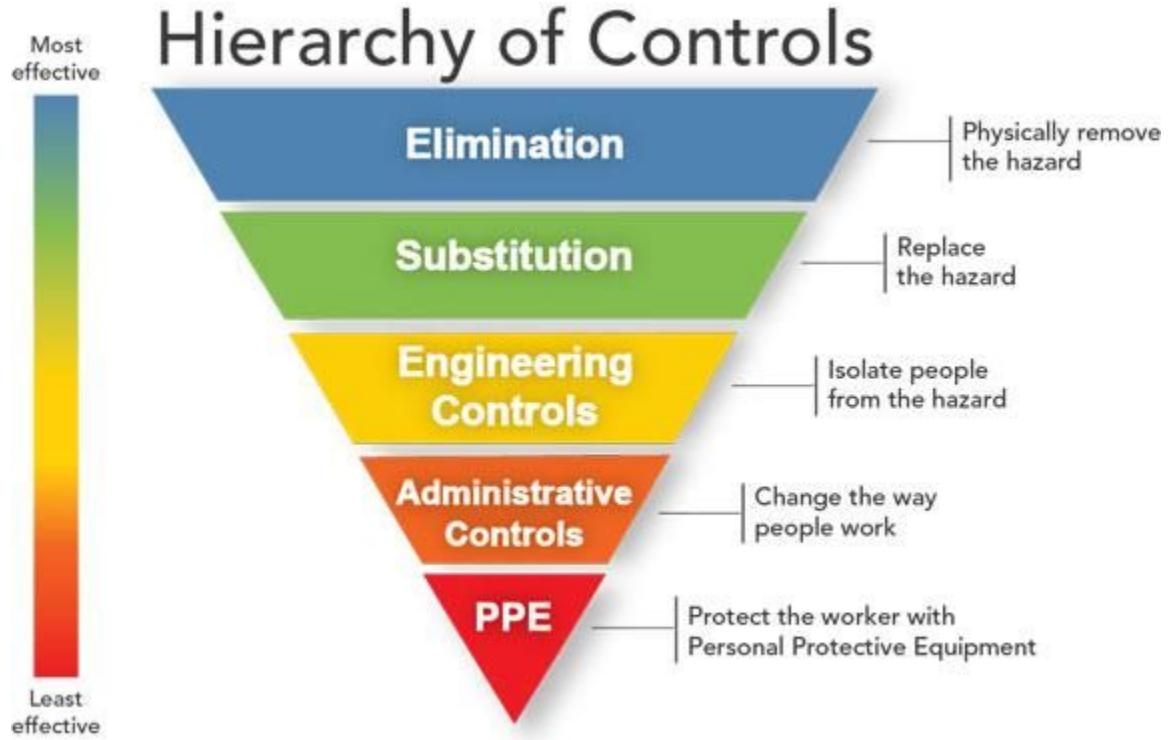
Figure 1: Importance of ‘flattening’ the transmission curve



Adapted from CDC / The Economist

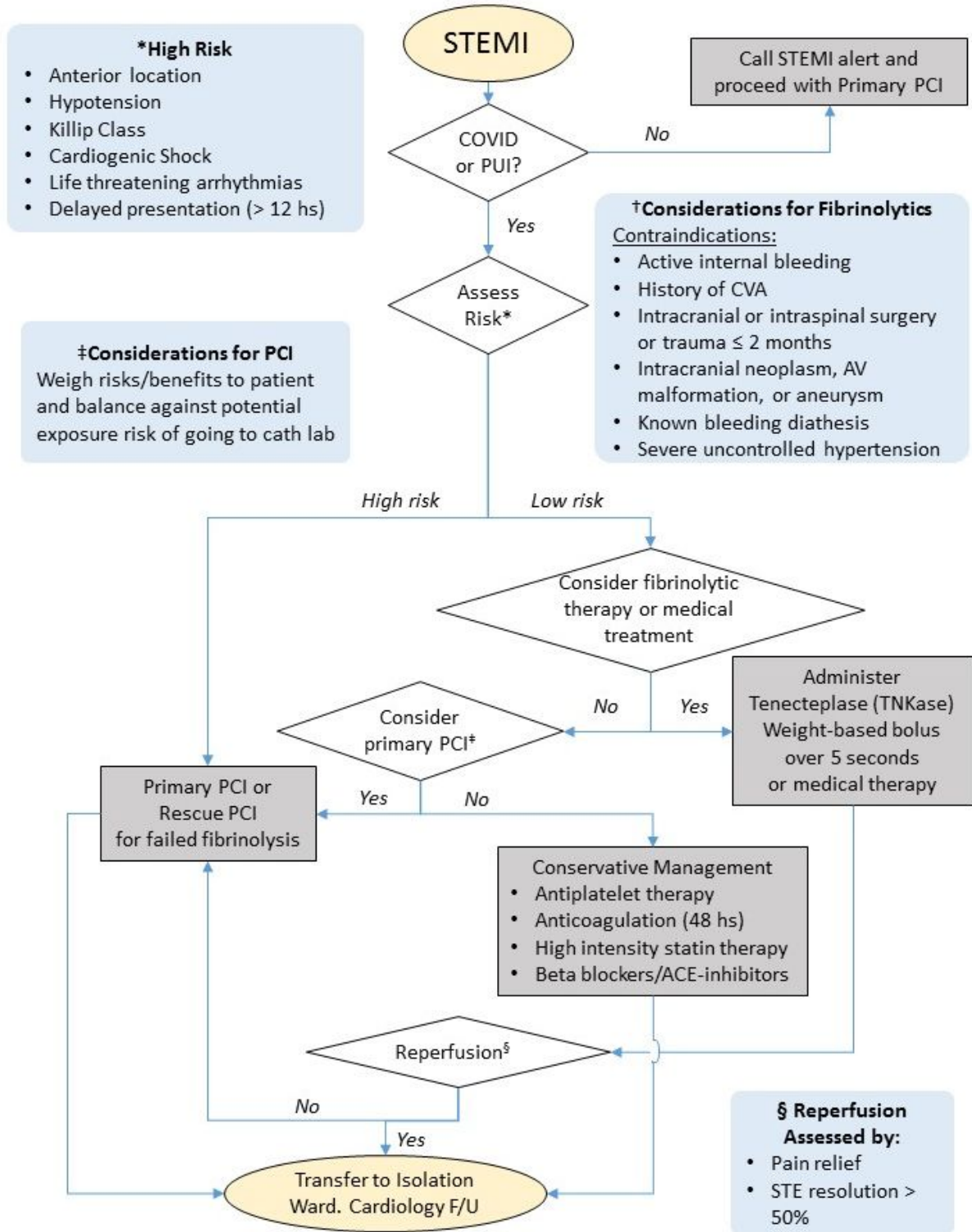
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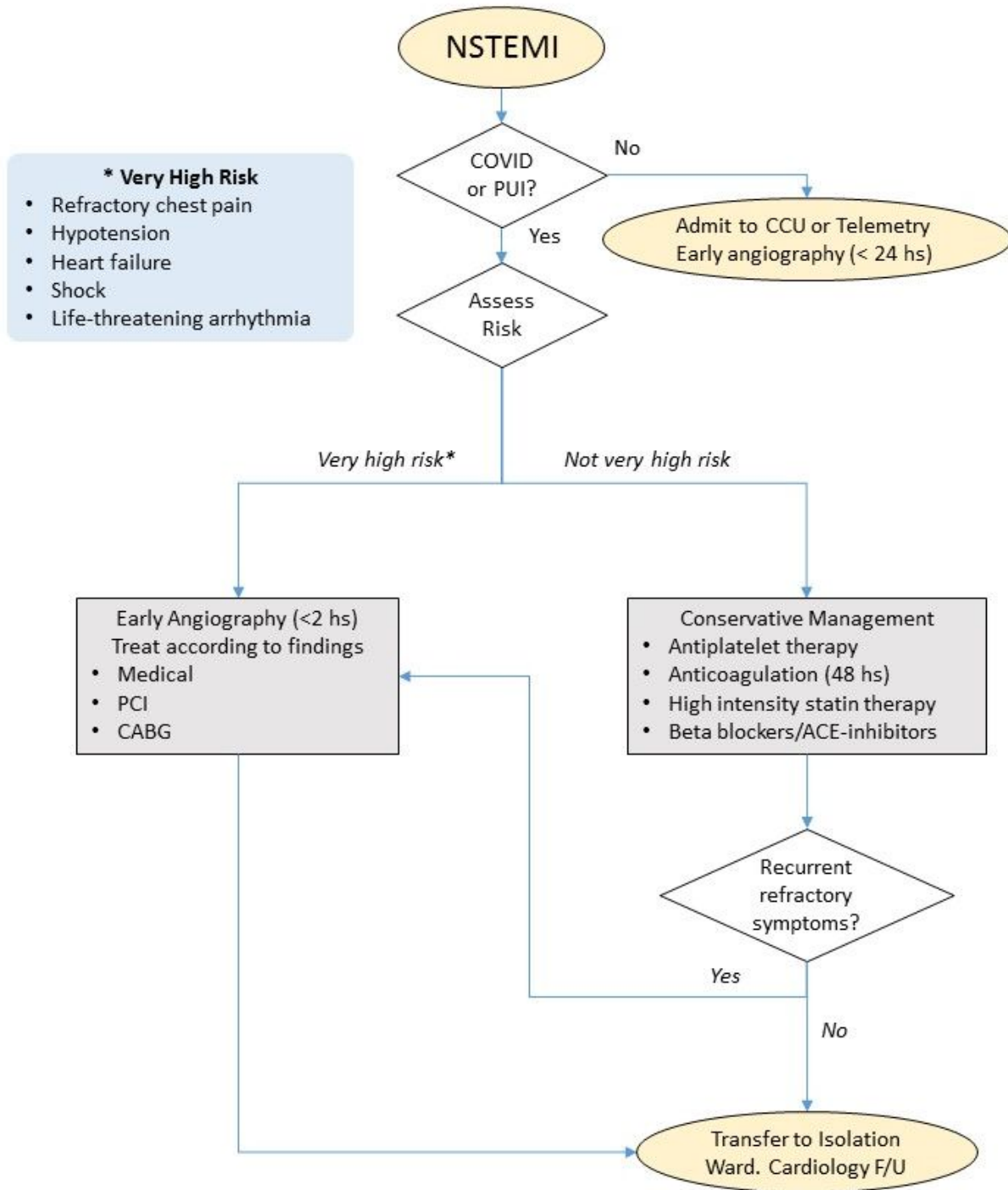
Figure 2: Levels of infection control



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Appendix 1: Proposed management algorithm for ACS patients, modified from University of Miami





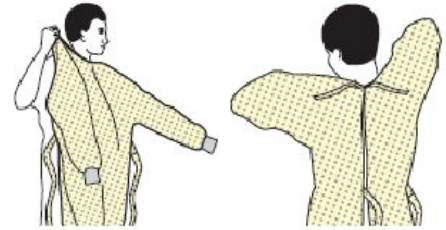
Appendix 2

SEQUENCE FOR PUTTING ON PERSONAL PROTECTIVE EQUIPMENT (PPE)

The type of PPE used will vary based on the level of precautions required, such as standard and contact, droplet or airborne infection isolation precautions. The procedure for putting on and removing PPE should be tailored to the specific type of PPE.

1. GOWN

- Fully cover torso from neck to knees, arms to end of wrists, and wrap around the back
- Fasten in back of neck and waist



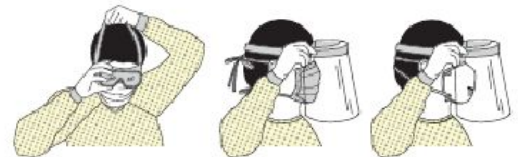
2. MASK OR RESPIRATOR

- Secure ties or elastic bands at middle of head and neck
- Fit flexible band to nose bridge
- Fit snug to face and below chin
- Fit-check respirator



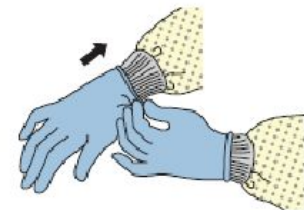
3. GOGGLES OR FACE SHIELD

- Place over face and eyes and adjust to fit



4. GLOVES

- Extend to cover wrist of isolation gown



USE SAFE WORK PRACTICES TO PROTECT YOURSELF AND LIMIT THE SPREAD OF CONTAMINATION

- Keep hands away from face
- Limit surfaces touched
- Change gloves when torn or heavily contaminated
- Perform hand hygiene

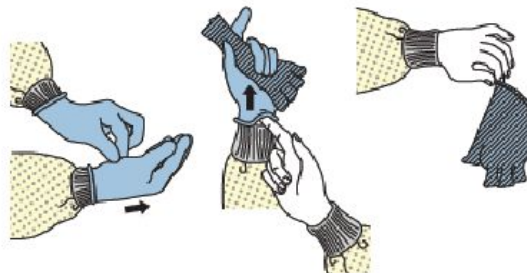


HOW TO SAFELY REMOVE PERSONAL PROTECTIVE EQUIPMENT (PPE) EXAMPLE 1

There are a variety of ways to safely remove PPE without contaminating your clothing, skin, or mucous membranes with potentially infectious materials. Here is one example. **Remove all PPE before exiting the patient room** except a respirator, if worn. Remove the respirator **after** leaving the patient room and closing the door. Remove PPE in the following sequence:

1. GLOVES

- Outside of gloves are contaminated!
- If your hands get contaminated during glove removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Using a gloved hand, grasp the palm area of the other gloved hand and peel off first glove
- Hold removed glove in gloved hand
- Slide fingers of ungloved hand under remaining glove at wrist and peel off second glove over first glove
- Discard gloves in a waste container



2. GOGGLES OR FACE SHIELD

- Outside of goggles or face shield are contaminated!
- If your hands get contaminated during goggle or face shield removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Remove goggles or face shield from the back by lifting head band or ear pieces
- If the item is reusable, place in designated receptacle for reprocessing. Otherwise, discard in a waste container



3. GOWN

- Gown front and sleeves are contaminated!
- If your hands get contaminated during gown removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Unfasten gown ties, taking care that sleeves don't contact your body when reaching for ties
- Pull gown away from neck and shoulders, touching inside of gown only
- Turn gown inside out
- Fold or roll into a bundle and discard in a waste container

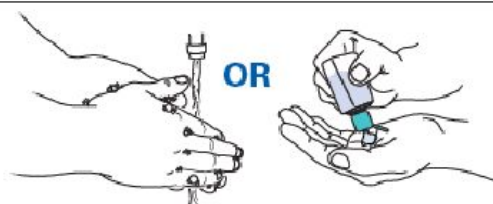


4. MASK OR RESPIRATOR

- Front of mask/respirator is contaminated — DO NOT TOUCH!
- If your hands get contaminated during mask/respirator removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Grasp bottom ties or elastics of the mask/respirator, then the ones at the top, and remove without touching the front
- Discard in a waste container



5. WASH HANDS OR USE AN ALCOHOL-BASED HAND SANITIZER IMMEDIATELY AFTER REMOVING ALL PPE



**PERFORM HAND HYGIENE BETWEEN STEPS IF HANDS
BECOME CONTAMINATED AND IMMEDIATELY AFTER
REMOVING ALL PPE**

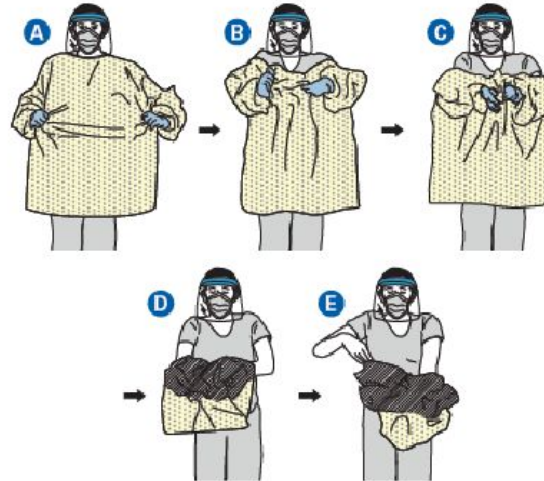


HOW TO SAFELY REMOVE PERSONAL PROTECTIVE EQUIPMENT (PPE) EXAMPLE 2

Here is another way to safely remove PPE without contaminating your clothing, skin, or mucous membranes with potentially infectious materials. **Remove all PPE before exiting the patient room except a respirator, if worn. Remove the respirator after leaving the patient room and closing the door. Remove PPE in the following sequence:**

1. GOWN AND GLOVES

- Gown front and sleeves and the outside of gloves are contaminated!
- If your hands get contaminated during gown or glove removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Grasp the gown in the front and pull away from your body so that the ties break, touching outside of gown only with gloved hands
- While removing the gown, fold or roll the gown inside-out into a bundle
- As you are removing the gown, peel off your gloves at the same time, only touching the inside of the gloves and gown with your bare hands. Place the gown and gloves into a waste container



2. GOGGLES OR FACE SHIELD

- Outside of goggles or face shield are contaminated!
- If your hands get contaminated during goggle or face shield removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Remove goggles or face shield from the back by lifting head band and without touching the front of the goggles or face shield
- If the item is reusable, place in designated receptacle for reprocessing. Otherwise, discard in a waste container

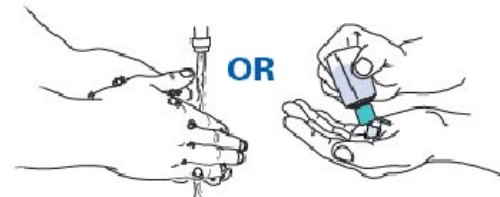


3. MASK OR RESPIRATOR

- Front of mask/respirator is contaminated — **DO NOT TOUCH!**
- If your hands get contaminated during mask/respirator removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Grasp bottom ties or elastics of the mask/respirator, then the ones at the top, and remove without touching the front
- Discard in a waste container



4. WASH HANDS OR USE AN ALCOHOL-BASED HAND SANITIZER IMMEDIATELY AFTER REMOVING ALL PPE



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REMOVING ALL PPE**



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