



COVID-19: Downstream Implications for Sterile Compounding

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*Note: Slide 23 was updated on 3/4/20
after the initial webinar*



Learning Objectives



At the end of this webinar, you will be able to:

- Discuss the CDC recommendations to the general public about COVID-19 and know where to get reliable information.
- Use existing SOPs to conserve garb and screen compounding personnel to ensure that workers who are sick do not enter the compounding area.
- Consider temporary changes to work practices to maintain a state of microbial control while dealing with garb shortages.

CDC Coronavirus Disease 2019



What You Should Know

[How it spreads](#)

[Symptoms](#)

[Prevention & treatment](#)

[Testing](#)

[Frequently Asked Questions](#)

[About COVID-19](#)

Situation Updates

[Situation summary](#)

[Cases in the U.S.](#)

[Global locations with COVID-19](#)

[Risk assessment](#)

[CDC in Action](#)

[Latest Updates](#)

Information For

[Communities, schools, and businesses](#)

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[For Specific Audiences](#)

Be Part of the Solution, Not Part of the Problem



Be Part of the Solution, Not Part of the Problem



- Avoid
 - close contact (within 6 feet) with people who are sick
 - touching eyes, nose, and mouth
 - coming to work when sick
- Wash hands with soap and water and lather for at least 20 seconds immediately upon returning home from public spaces, before eating, after using the bathroom, and anytime you suspect hands are contaminated.
- If soap and water are not immediately available, use alcohol-based hand sanitizer with at least 60% IPA. Carry it with you.
- Cover cough or sneeze with tissue and discard.

Face Mask Use

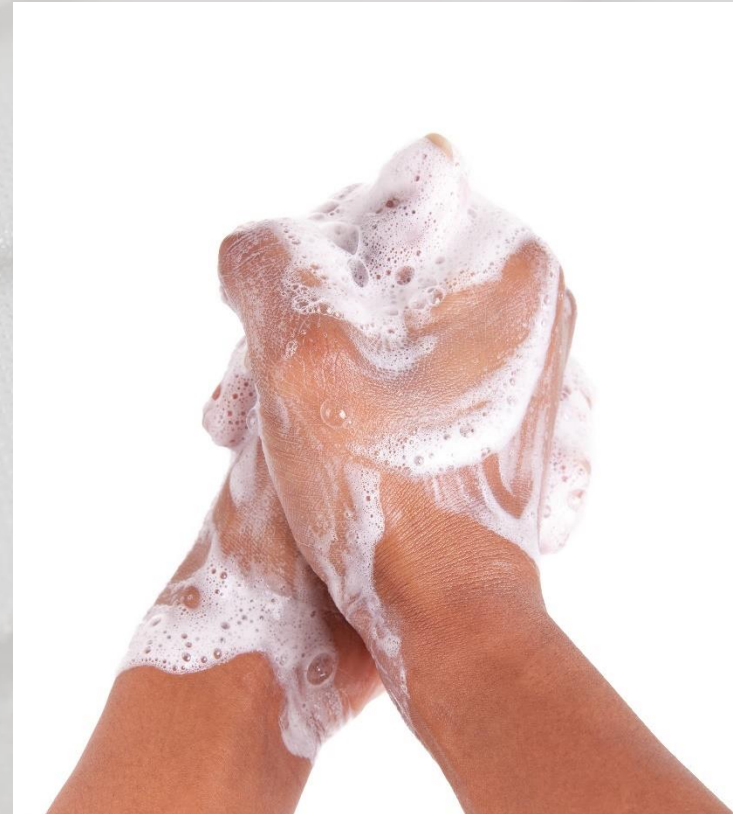


- Face masks are **NOT** recommended for the general public.
- CDC does not believe wearing a face mask protects from COVID-19.
- Face masks **SHOULD** be worn by people who show symptoms to prevent spreading the disease.
- Since face masks and respirators are critical for those caring for persons who are sick, widespread use by the public exacerbates the shortage for those who need them (like us!).

Face Mask Use (continued)



- If a face mask is worn, it must be worn properly if caring for a sick person (folds facing down, on tight, no gaps).
- Do not hoard face masks for personal use.
- Frequent handwashing is, overwhelmingly, the most important infection-prevention action now and always!!!





Why COVID-19 may affect our practice

- Much of the disposable apparel used in health care and cleanroom environments originates in China (the city of Wuhan in particular).
- There are many facilities throughout China that are functioning at less-than capacity due to workforce self-isolation.
- The Chinese government has diverted production from facilities manufacturing disposable, protective apparel for their own use.
- Facilities outside of China can be impacted in that many raw materials originate in China. Should the virus spread to neighboring countries, work forces could be impacted as well.

How will COVID-19 affect our practice?



- Price increases are already occurring.
- Masks and hand sanitizers are already in short supply in retail stores.





The primary concern in the compounding area is the maintenance of a microbial state of control

So what can we do?

Enforce Existing SOPs and Practices



- “Individuals that may have a higher risk of contaminating the CSP and the environment must report these conditions to the Designated Person (DP).”

Fever	Rashes	Recent tattoos	Oozing sores
Conjunctivitis (pink eye)		Active respiratory infection	

- Exclude these persons from the controlled environment.
- Report to Designated Person (DP).
- Keep a log of these instances, symptoms, and when they returned to work.



Enforce Existing SOPs and Practices (continued)



- Staff must strictly adhere to established, contamination-control principles, including proper behavior in controlled environments.
- Personnel “must maintain proper personal hygiene” (2019).
 - Shower/Bathe daily.
 - Wear freshly laundered clothing.
- “Remove items not easily cleanable and not necessary for compounding.”

Enforce Existing SOPs and Practices (continued)



- Stage preps and batches outside of the compounding area and transfer into room in a bin that segregates items.
- Perform meticulous material handling using EPA registered one-step sporicidal disinfectant cleaner.
- Minimize the number of trips crossing the line of demarcation (or perimeter line of SCAs)

All these should be part of current good practice!

Enforce Existing SOPs and Practices (continued)

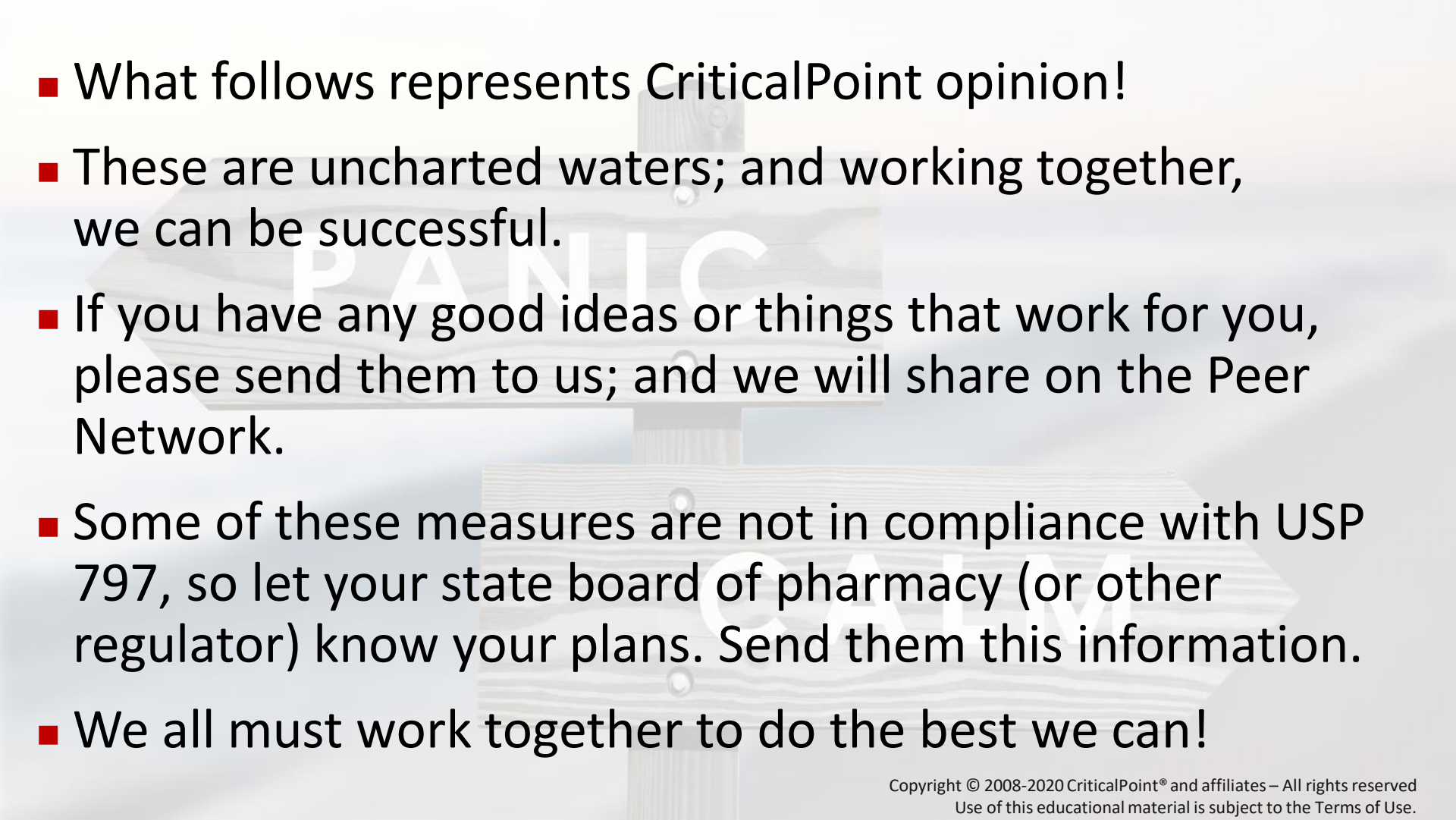


- Walk slowly and deliberately in the compounding area.
- Meticulous material transfer into PEC.
- Sanitize deck, staging cart, and other high-touch surfaces frequently (when wiping deck with sIPA, wipe staging cart and computer screen).
- Do not talk while compounding.
- Do not touch mask.
- Frequent resanitization of gloved hands.



PANIC

CALM

- 
- The background of the slide features a large, light-colored wooden signpost. The signpost has two directional arrows. The top arrow points upwards and is labeled 'PANIC' in large, white, sans-serif capital letters. The bottom arrow points downwards and is labeled 'CALM' in large, white, sans-serif capital letters. The signpost is set against a blurred background of what appears to be a road or a path.
- What follows represents CriticalPoint opinion!
 - These are uncharted waters; and working together, we can be successful.
 - If you have any good ideas or things that work for you, please send them to us; and we will share on the Peer Network.
 - Some of these measures are not in compliance with USP 797, so let your state board of pharmacy (or other regulator) know your plans. Send them this information.
 - We all must work together to do the best we can!

Remember why we wear garb...





Rationale for Garb

- Covers most of our skin and partially retains particles.
- Even when garbed with all skin covered, particles escape with movement.
- Reused garb sheds more particles.

Activity ¹	Particles Generated
Sitting quietly	100,000/minute
Walking slowly (1.9 miles/hour)	5,000,000/minute
Walking medium (3 miles/hour)	7,500,000/minute
Walking fast (5 miles/hour)	10,000,000/minute

¹Particle Measuring Systems. Basic Guide to Particle Counters and Counting. 2011.



What if we can't get garb?

- Inventory your current supply.
- If low, try to order more (regular size order since hoarding adds to the problem).
- Begin conservation measures immediately.
- Evaluate alternatives, and implement the best strategies for your organization.
- What follows are CriticalPoint recommendations for each type of garb we believe may become scarce.

Remember...



- Though the world around us is trying to prevent people from infection, we are trying to prevent workers from contaminating the environment and, therefore, the CSP and, ultimately, the patient.
- Pharmacy sterile compounding personnel are coming at this advice from a different direction than the infection preventionists.

Garb Conservation Strategy: Staffing



- Limit the number of persons entering the compounding area.
- Instead of 2 compounders entering and each compounding for an hour, send in 1 compounder for 2 hours.
- Whatever your algorithm is, just try to maximize the work for those “inside” by having others stage outside the compounding area.



Face Mask Alternatives and Strategies



- Regular face mask
- N95 respirators
 - do not need to be fit tested for this type of use
 - must fit snugly from bridge of nose to around chin without gaps
- Ideally, we would never reuse garb
- Pouch-type masks, cleanroom-grade masks, and N95-respirator masks may be more conducive to reuse

Face Mask Alternatives and Strategies (continued)



- Must put a process around reuse so reuse does not compromise microbial state of control in rooms.
- Write initials on the outside of the mask.
- Doff the mask on the dirty side of the ante-room or outside of the perimeter line of the SCA without touching the inside.
- Place each mask for reuse in its own new small paper bag and initial the outside of the bag (use a new bag each time, discarding the previous when the mask is redonned).
- Place all masks in bags in a container located where masks would normally be donned.

CDC. Pandemic Planning. [Recommended Guidance for Extended Use and Limited Reuse of N95 Filtering Facepiece Respirators in Healthcare Settings](#). March 28, 2018. Retrieved 3/4/20.

Face Mask Alternatives and Strategies (continued)



- If your sink is on the clean side of the LOD, then put on mask in normal garbing order.
- If sink is located outside of the ante-room or SCA and mask is donned after hands are washed, use alcohol-based hand rub after donning what is, essentially, a dirty mask.



Face Mask Alternatives and Strategies (continued)



It is *very important* that you do NOT touch your mask once donned!



Face Mask Alternatives and Strategies (continued)



- How long can the mask be worn before being replaced?
 - Use your best judgment
 - Based on
 - condition
 - whether it is visibly soiled
 - handling technique
- Set a procedure and relay to staff.

Shoe Covers



- We don't recommend reuse of shoe covers, nor do we recommend turning them inside out.
- If you are getting close to running out of shoe covers, we suggest implementing "facility-dedicated" shoes (already a best practice recommendation).
- "Facility dedicated" means inside the pharmacy offices not "hospital dedicated."
- Maybe shoes that are washable or cleanable, then put a process around that.



Shoe Covers for HD Settings

- Wearing facility-dedicated shoes, don one pair of waterproof, seamless shoe covers
- The materials for these shoe covers also comes from China.
- Available through
 - [Uline](#)
 - [Grainger](#)



Gowns



- Since the material for low-lint gowns generally comes from China, these are already in short supply.
- Though healthcare workers caring for infected patients use back-closing gowns, the gowns that we use are made of the same materials.
- Suppliers already seeing price pressure due to short supply.

Gowns (continued)



- For those who do not reuse gowns (a best practice recommendation), start reusing immediately.
- Reuse for 1 day only, until there is a true shortage.
 - First cut down on the compounding personnel that enter, reducing the number of gown needed.
 - If reusing gown, do so for no longer than a week.
 - If gown is reused, then add ***nonsterile sleeves*** (not in short supply).
 - Must discard gown if:
 - visibly soiled
 - used during cleaning activities

Disposable Sleeve Covers



- If supply dwindles and gown reuse is required, we recommend use of sleeve covers.
- They do not have to be sterile if they are intended for use in cleanroom environments.
- Examples of sleeve cover materials are
 - Tyvek
 - Microporous film products with enclosed elastic

Disposable Sleeve Covers (continued)



- Don in buffer room or inside perimeter line of SCA
 1. Remove the outer package from both the sterile gloves and sleeves.*
 2. Apply alcohol-based hand rub to hands and wrists and allow to dry.
 3. Don sleeves.
 4. Don sterile gloves.



*This depends on how the sleeves are packaged.

Doffing Gowns

- Remove gowns slowly and carefully, as they are laden with particles on the skin side.
- Try to remove gown standing near a return (if the return is not located next to a sink that is in use).
- Hang gowns on clean side of ante-room far away from the sink, so that persons performing hand hygiene will not splash the gowns with water.
- **Never** reuse HD gowns.



Sterile Gloves



- The supply is not likely to be affected.
- Workers caring for infected patients do not use sterile gloves.
- Materials and production occur outside of China.
- If these countries do not become as infected as China, there should be little impact.



Alcohol-Based Hand Rub



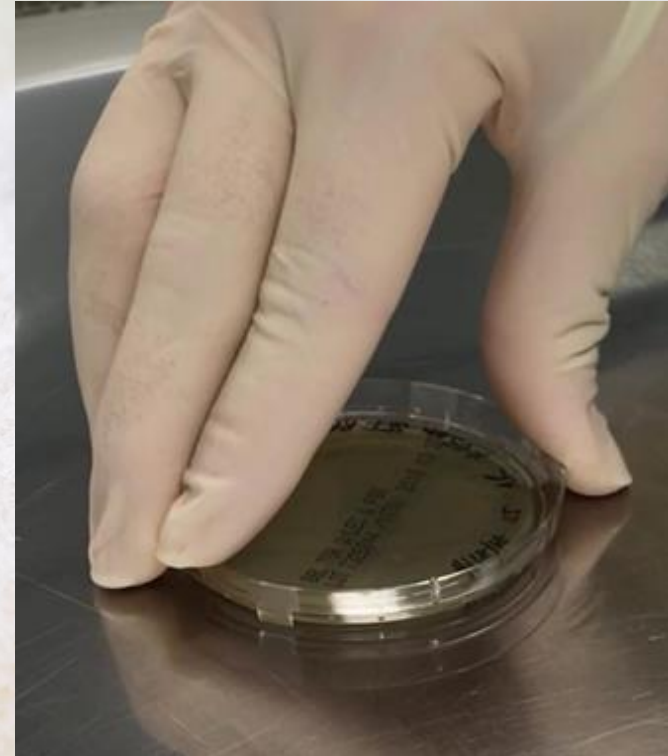
- Hand sanitizer has disappeared from retail shelves.
- Health-care hand rubs are now difficult to get as well.
- If hand rub is affected, conserve for applying during the glove change only.
- If completely unavailable, those changing gloves return to the ante-room, remove and hang their gown, and wash hands prior to donning fresh gloves.





Shall we do more EM?

- No need for air sampling (HVAC and PECs are working).
- Consider weekly surface sampling inside ISO 5 space in the direct compounding area (DCA), if following non 797-compliant, garb-conservation measures.
- Realize that if there is widespread garb reuse, there may be excursions; but the remedial actions would be to improve garbing practices, which might not be realistic or possible.





What to do?

- If excursion during surface sampling, likely due to inconsistent work practices, such as:
 - Material transfer into the PEC
 - Leaning forearms on the deck
 - Infrequent deck sanitization
- Retrain and closely monitor staff
- Resample
- Consider reduced BUDs

Summary



- Discuss options with your state board of pharmacy or other regulatory body.
- Develop a plan and start conserving garb now.
- Maintaining a state of microbial control is still the goal, so additional contamination control measures may be necessary.
- Stay calm, we are all facing this challenge together!

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about this and other
topics related to
sterile compounding?

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