



# Learn What Works: Successful collection and distribution processes for decontaminated respirators

June 30, 2020

# Agenda

- Welcome and Introduction: Joe Berger
- Overview of Battelle CCDS™: Joe Berger
- CCDS site process: Kevin Sayers
- Mass General Brigham: Phil Licari and Danielle Le Hals
- UPMC: Bart Wyss
- Q&A

# Guest Speakers

## Guest Speakers:

- Phil Licari, VP of Operations & Innovation, Partners HealthCare
- Danielle Le Hals, Executive Director, Radiation Oncology, Mass General Brigham
- Bart Wyss, Sr. Director Distribution, Transportation & Logistics , UPMC
- Kevin Sayers, Sr. Regulatory Specialist, Battelle

Moderator: Joe Berger, VP Sales and Marketing, Battelle

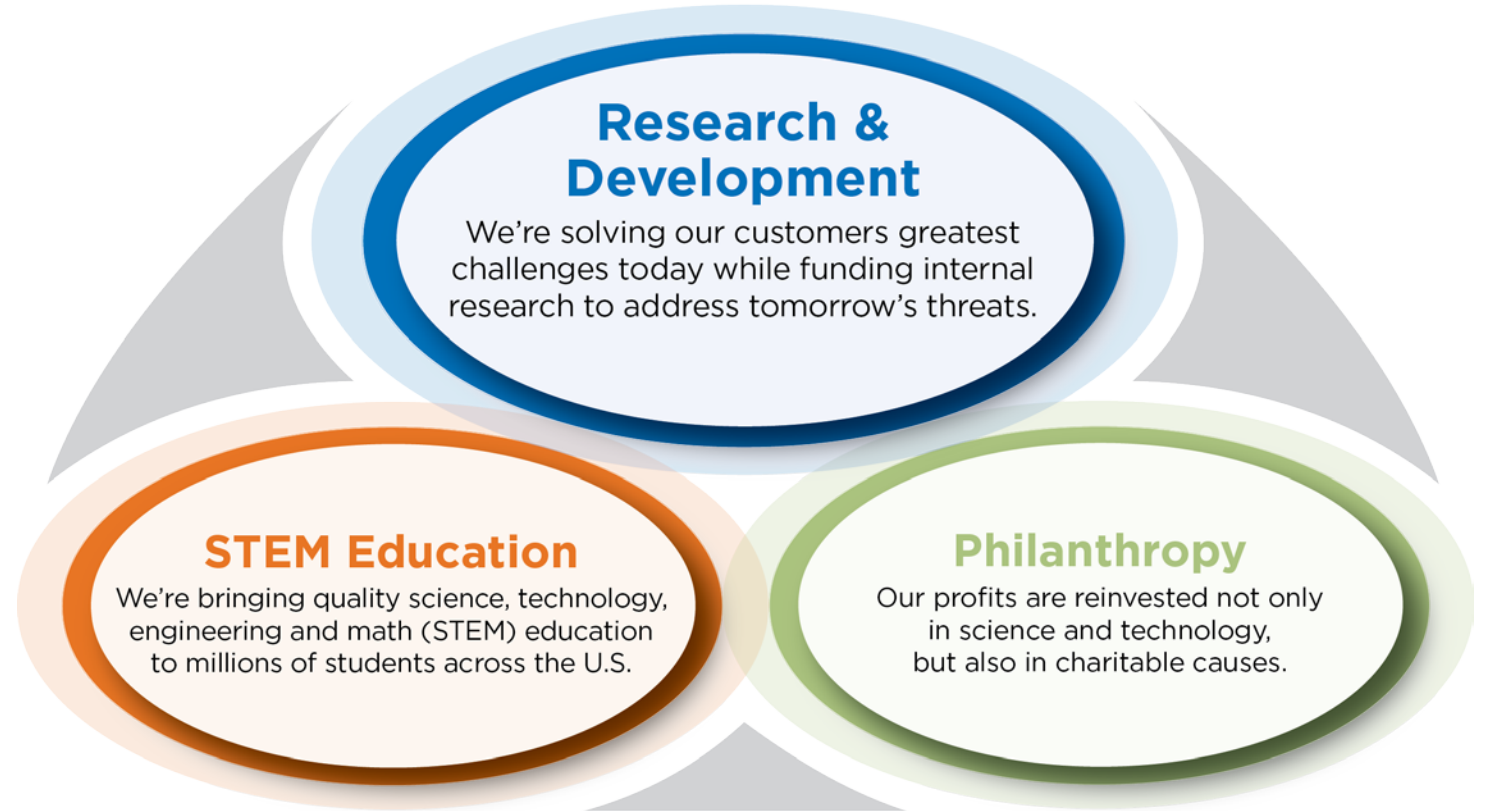
AHA WEBINAR

# Learn what Works: Battelle CCDS Critical Care Decontamination System™

Joe Berger and Kevin Sayers

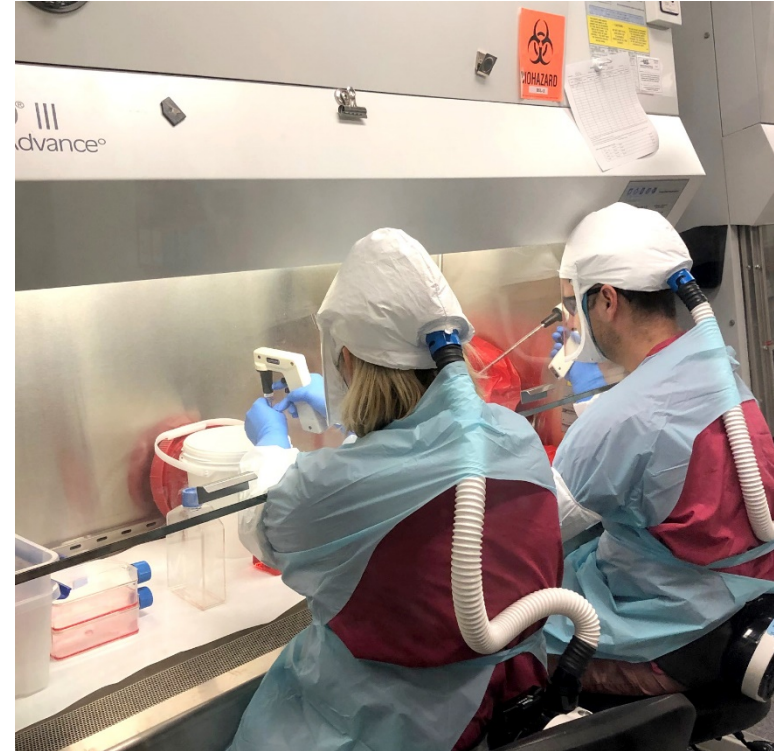
# About Battelle

- Nonprofit, charitable trust formed in 1925
- Our mission: To translate scientific discovery and technology advances into societal benefits
- World's largest, independent, not-for-profit research and development organization



# Battelle CCDS™

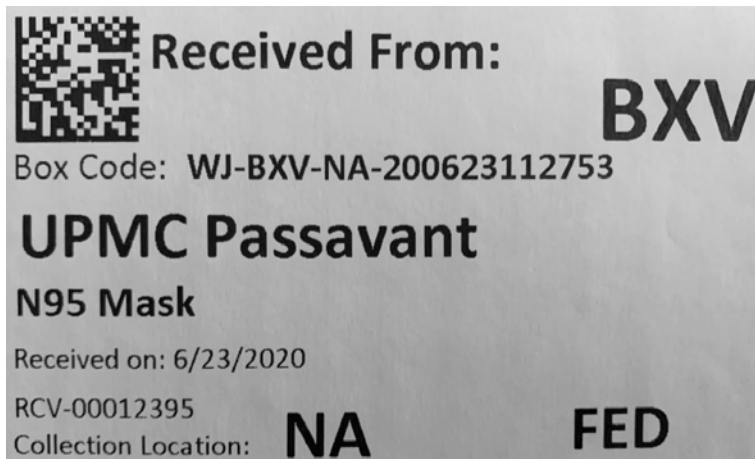
- Designed to help address the PPE shortage in the U.S.
- **Based on proven science:**
  - [2015-16 FDA study](#) - vapor phase hydrogen peroxide (VPHP) proved to effectively decontaminate N95 respirator masks
  - 2020 pandemic - proved VPHP efficacy against SARS-CoV-2 in our Bio Safety Level 3 (BSL 3) laboratories
    - Droplet/aerosol spray and recovery study
    - SARS-CoV-2 rendered non-infectious
    - Validated up to 20 decontamination cycles without degrading filter performance or fit (NIOSH, 3M, Duke and more)





# Decontamination Process: Receipt<sup>1</sup>

- Boxes of used N95s arrive to a Battelle CCDS site via FedEx or Private Courier
- CCDS Technicians review chain of custody information to ensure it matches what was received
- Each box of N95s are logged into tracking software and assigned a unique barcode number



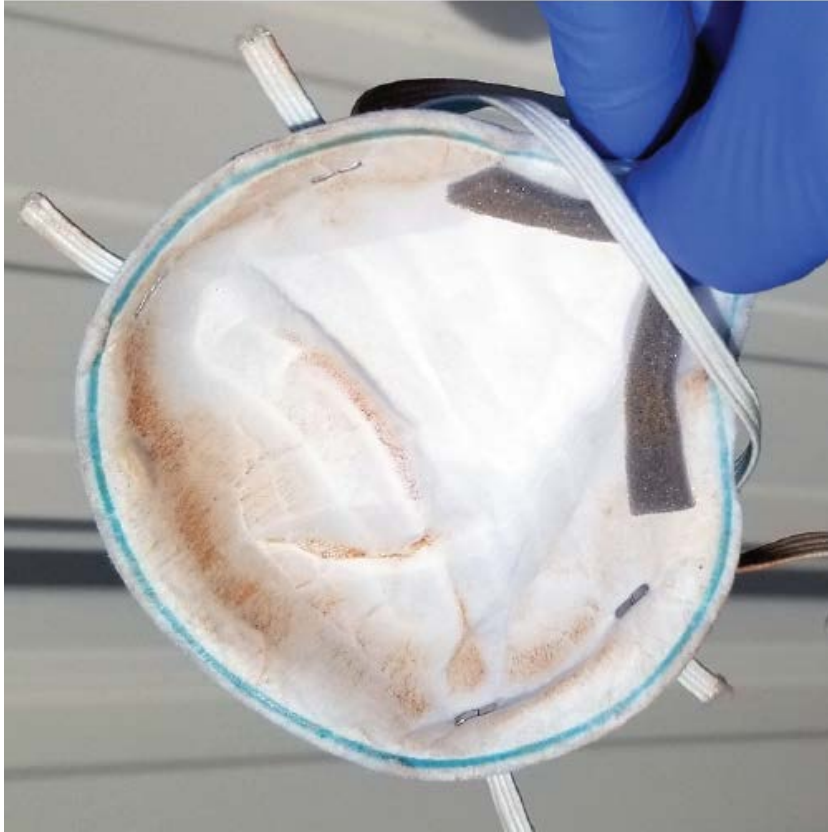
# Decontamination Process: Inspection

N95s are loaded into chamber and inspected.





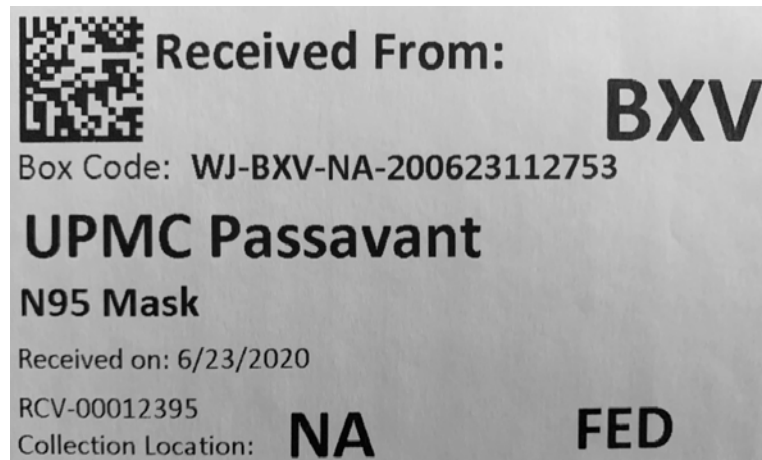
# Non-Compatible Masks are Disposed



Makeup is #1 reason

# Decontamination Process: Loading

N95s passing inspection are arranged for decontamination.





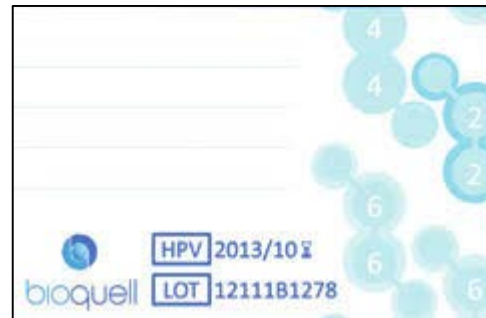
# Decontamination Process: VHP Decon<sup>1</sup>

- Decon chamber is sealed and the vapor phase hydrogen peroxide (VHP) is introduced
- Humidity increases and VHP starts to condensate on the masks
- After the appropriate length of time the VHP is evacuated from the chamber and masks are allowed to aerate



# Decontamination Process: Unloading

- Once the VHP has cleared the chamber. Masks are tested to ensure residual VHP is  $<1$  ppm (OSHA limit)
- Chemical indicators placed throughout the chamber verify the run achieved a  $>6$  log reduction
- Staff in PPE, to protect the N95s, conduct another inspection and then box the masks for shipping back to health care providers







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# Learn what Works: Mass General Brigham Experience

Danielle Le Hals and Phil Licari

# Mass General Brigham & Adoption of Battelle's CCDS

– March 30, 2020

- MGB research scientists led controlled evaluations of more than six decontamination technologies for N95 FFRs evaluated through March, 2020. Verification and selection of VHP as preferred method preceded introduction to Battelle CCDS.
- MGB's research scientists have since independently verified the effectiveness of the VHP process for: viral & bacterial “kill levels”, mask fit, filtration efficiency, and H2O2 residuals.
- Battelle System authorized under FDA's EUA process; specific conditions of EUA necessitate process requirements for Battelle and its source hospitals.



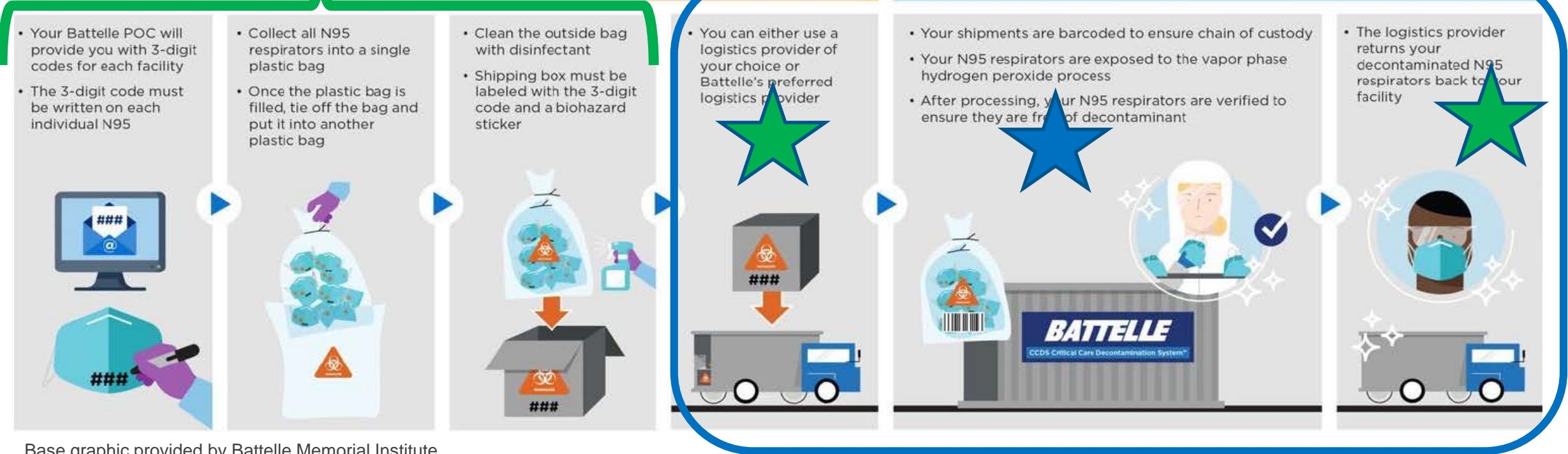
N95 Masks in VPHP Cycle



# Consideration of End-to-End Process | Aim to Supplement new N95 Mask Inventory

Manage your facilities' adoption, process & cadence

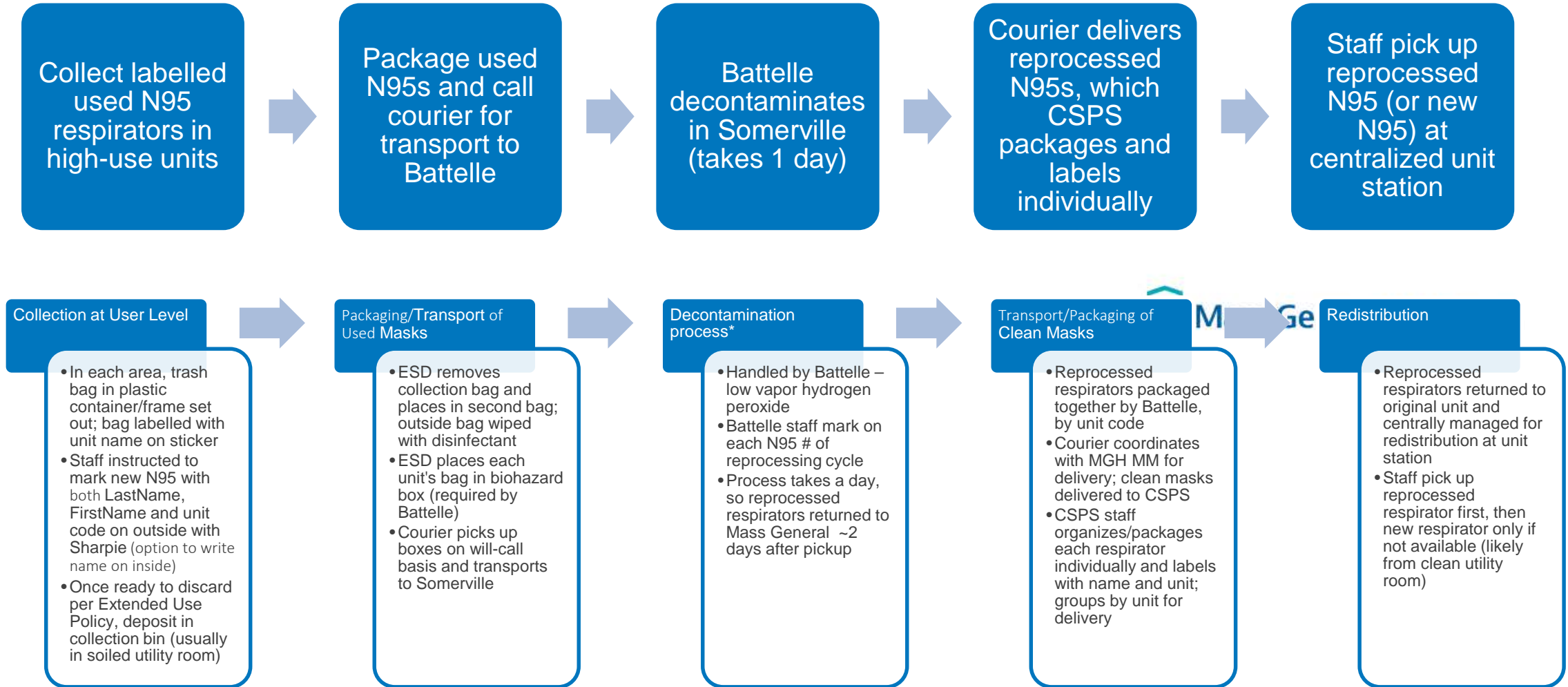
- ★ - Hospital manages others' Process & cadence
- ★ - Battelle manages Process & cadence



Base graphic provided by Battelle Memorial Institute



# MGH N95 Re-Use Program - Logistics Process Flow | Mass General Index User Version)



# Mass General N95 Respirator Collection and Distribution Signage

## N95 Respirator Re-Use Program

The goal of this innovative program is to grow our total supply of N95 respirators during a time in which supply availability is limited. This re-use strategy is just one of several personal protective equipment (PPE) building tactics being actively pursued by Mass General and Partners.

**This initiative only works with YOUR participation.** Please help us ensure that we are as well prepared as can be for the weeks to come.

### COLLECTION OF USED N95

**When ready to discard, place your used N95 in the collection bin here.** All brand types of N95 are being collected.

**Important!** This code is specific to pickup location:

Front of Mask  
**MGH-**  
Last Name, First Name



**Please Note:** If you float through various clinical areas please label your N95 respirator with your home unit/dept. code (see corresponding unit code grid). The N95 will be returned to the distribution location, according to your unit/dept. code.



N95 respirators that are visibly soiled, damaged, or wet cannot be reprocessed; please throw these in the regular trash.



Your reprocessed N95 should be available for pick up at a distribution station (desk or clean utility room) in this unit within 2-3 days.



Please do not deposit trash or other PPE items in this collection bin; it is **only** for used N95 respirators for reprocessing.

Thank for participating in Mass General's innovative N95 Respirator Re-Use Program!

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**This initiative only works with YOUR participation.** Please help us ensure that we are as well prepared as can be for the weeks to come.

### LABEL EVERY NEW N95



When picking up a new N95 respirator, **PLEASE LABEL** the front using the provided Sharpie. Before donning, please label using the convention below:

**MGH-**  
Last Name, First Name

**Important!** This code is specific to pickup location:



**Please Note:** If you float through various clinical areas please label your N95 respirator with your home unit/dept. code (see corresponding unit code grid). The N95 will be returned to the distribution location, according to your unit/dept. code.

### REMINDER: SEAL CHECK

When donning a new or reprocessed respirator, **please be sure to do a seal check.**

### COLLECTION OF USED N95

**When ready to discard, place your used N95 in any collection bin** (likely in a soiled utility room). **Any brand of N95** may be deposited into any designated collection bin. Your N95 will be reprocessed via an **FDA-approved (under Emergency Use Authorization) method** and returned to this location within 2-3 days.

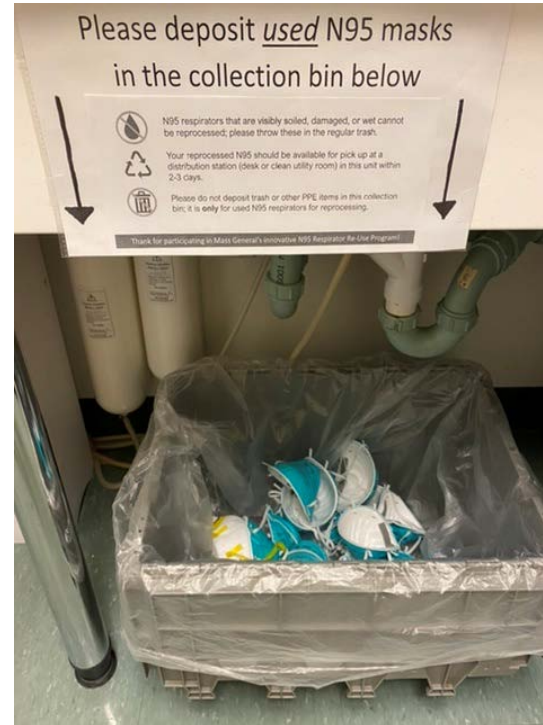
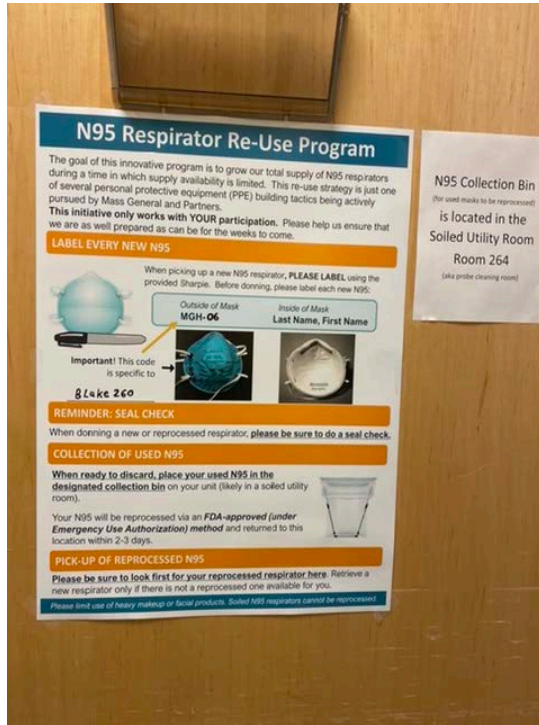


### PICK-UP OF REPROCESSED N95

**Look first for your reprocessed N95 respirator at the distribution location associated with your unit/dept code.** Retrieve a new respirator only if there is not a reprocessed one available for you.

*Please limit use of heavy makeup or facial products. Soiled N95 respirators cannot be reprocessed.*





Photos of N95 Reuse Process

- Collection and Packaging to Battelle





- Sorting, Data Collection, and Redistribution



# Key Observations – Implementation

- Hospital preparation is complex and must be developed properly with key stakeholders; this is an FDA authorized process; instructions must be followed
- Clinician/user acceptance and engagement are vital:
  - Take time to develop communications plan
  - Engage champions; make the VHP effectiveness research visible
  - Respond and adapt to feedback in real-time
- Multiple factors in the process will drive overall N95 inventory (New +Decon'd):
  - Dependable offset of new mask consumption
  - Time intervals and variability between pick-ups
  - Transportation (both ways!) becomes another key element to success
- Post-implementation surveillance (involving users) is another key to continued participation

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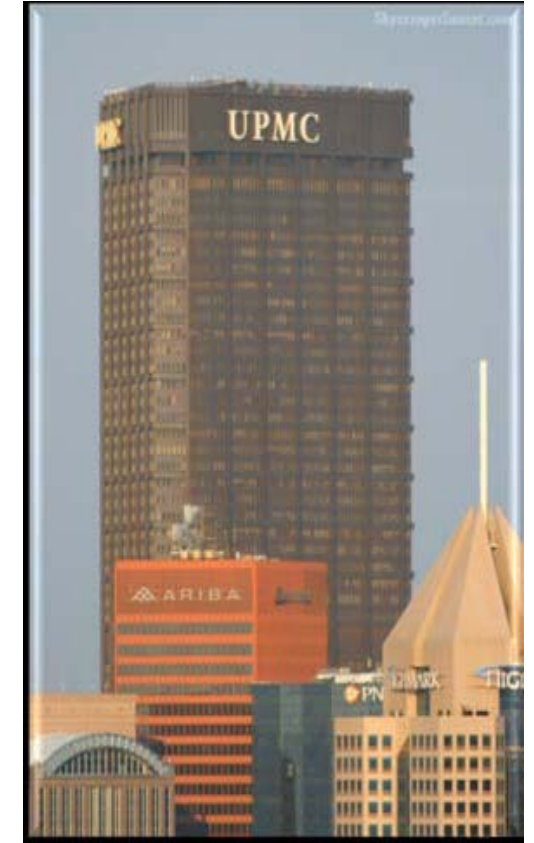
# Learn what Works: University Pittsburgh Medical Center (UPMC) Experience

Bart Wyss

# UPMC Implementation of Battelle's CCDS

## UPMC's innovative approach in pandemic preparedness

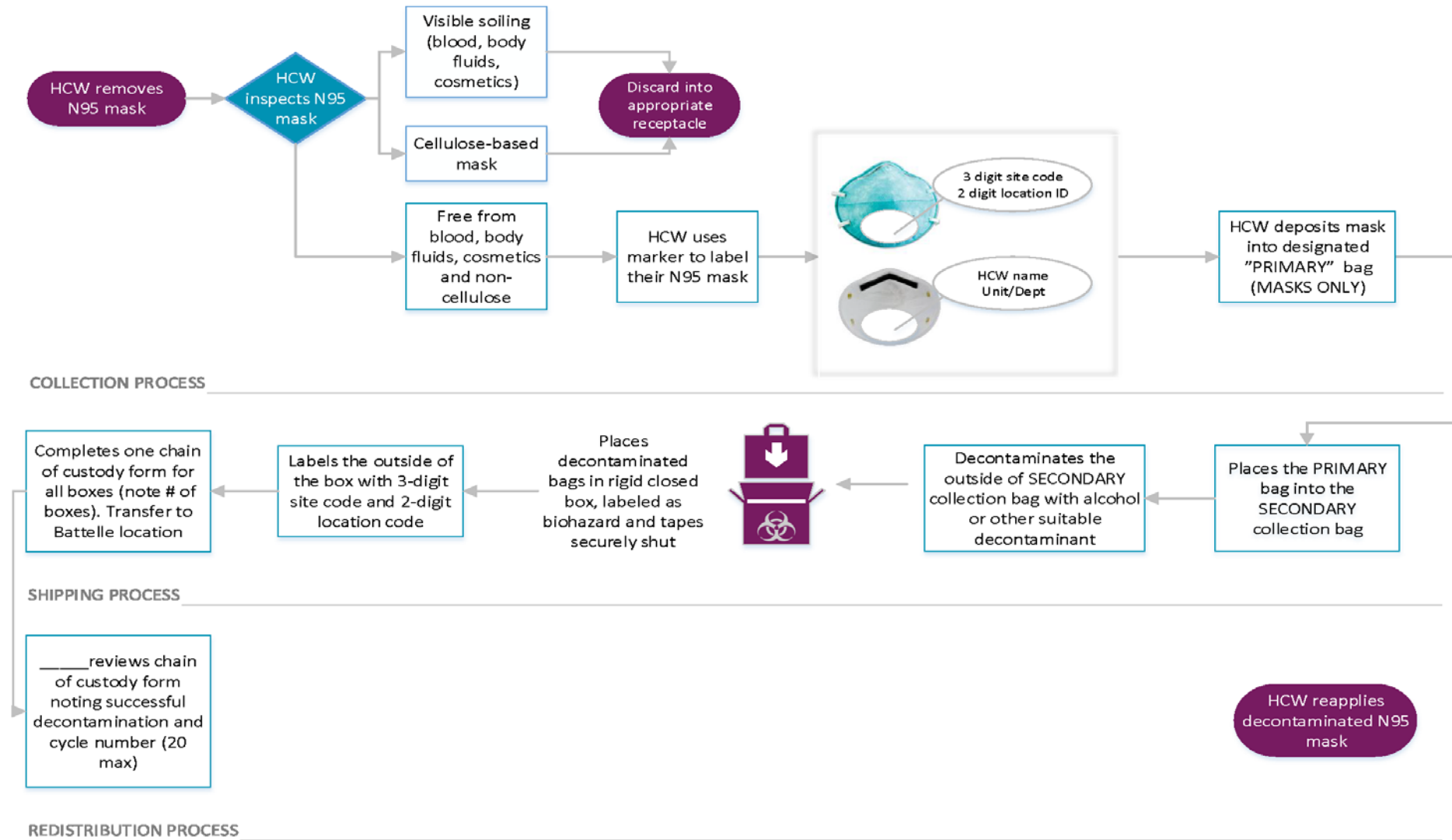
- Program that would allow us to grow our mask supply during a time of limited availability
- This only works with full participation from executive leadership down to the front-line health care provider





# Planning & Implementation

- **Preparation developed properly with key stakeholders; FDA authorized process; instructions Have to be followed.**
- **Clinical & Materials Management engagement:**
  - o Lead communications & plan
  - o Respond and feedback
  - o Logistics
- 24 • **Follow-up & Reporting**



The FDA has authorized decontamination of the N95 masks (maximum of 20 times) under the Emergency Use Authorization Act for the duration of the COVID-19 declaration

# Facility Checklist

## Microsoft TEAMS site

Communication Point

File & Information availability

Follow-up

News & Changes

Tracking

### UPMC N95 Reprocessing

We will start reprocessing N95s.

**FOR REPROCESSING TO BE EFFECTIVE – NO MAKEUP CAN BE WORN**

Units included in reprocessing are:

- PUH OR, MUH OR, IR, Cath Lab, EP, Echo, GI lab, 6G, 9G, 7G, CTICU, 10F, 9F, 8N, Rapid Response Team, Same Day Surgery Montefiore and Respiratory.
- Each unit will be responsible for taking their used N95s to the Central Supply Decontamination area on Monday's and Thursday's by 9:00 AM.

Collection starts today, for the first shipment out on Thursday.

- Pick up days will be Monday's and Thursday's.
- Return days are Wednesday's and Friday's.

Staff wearing N95s need to write on their mask:

- Hospital 3 Digit Code B X X
- Name (Outside)
- Two Digit Unit \_ \_



Unit	Code	Comments
PUH OR	PR	
MUH OR	MR	
IR	IR	
Cath Lab	CL	
EP	EP	
Echo	EC	
GI lab	GI	
6G	6G	
9G	9G	
7G	7G	
CTICU	CT	
10F	M0	MICU - 10
9F	M9	MICU - 9
8N	8N	
RRT	RR	
SDSM	SD	
Respiratory	RT	
<i>Lower Volume - phase 2 if needed</i>		
Imaging	IM	
Bronch Suite	BR	
EVS	EV	
Dental Clinic	DC	

1. A log will need to be completed with the nurse's name and the number of masks entered. **Attachment A**
2. A Ziplock bag will be used for collecting the used masks.
3. Place used mask in Ziplock bag.
4. When preparing for pick up, wipe outside of bag with PDI or Clorox wipe and then place in second master bag wipe outside of 2<sup>nd</sup> bag with PDI or Clorox wipe (masks will then be double bagged).
5. Once bags are delivered to Central Supply, the Central Supply Logs will need to be completed. **Attachment B**

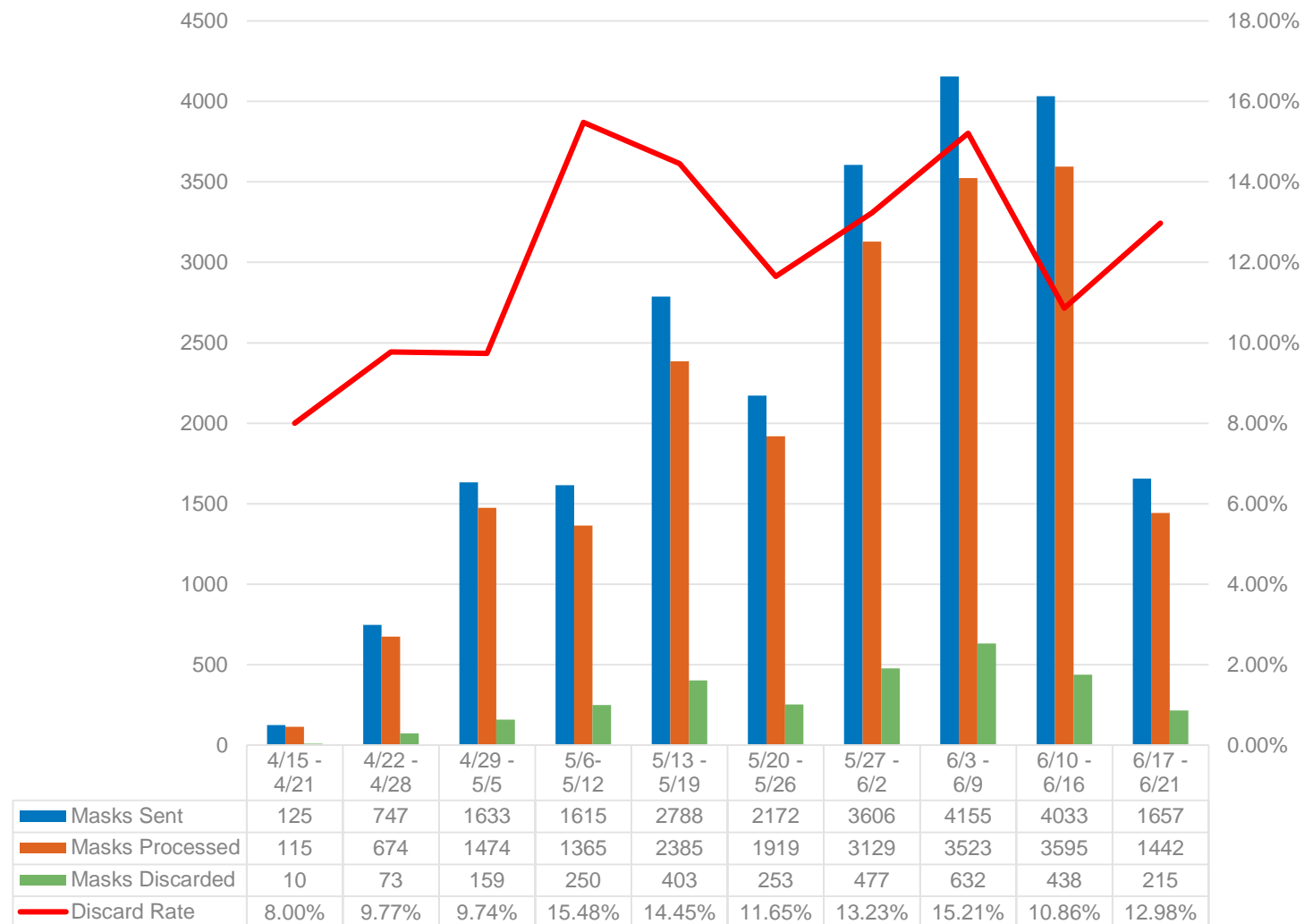
**NOTE: Each unit will need to have a designated area in their Dirty Utility Room.**



# Reporting

**UPMC Site** ☰ 🔍

- Susquehanna Valley Surgery Center
- UPMC Altoona
- UPMC Bedford
- UPMC Bethel Park Surgery Center
- UPMC Childrens Hospital of Pittsburgh
- UPMC East
- UPMC EMS
- UPMC Hamot
- UPMC Horizon
- UPMC Jameson
- UPMC Magee
- UPMC McKeesport



# Q&A

# Thank you!

More helpful information about CCDS can be  
found at: [www.battelle.org/N95](http://www.battelle.org/N95)



# Appendix

# Independent Validation<sup>1</sup>

- **NIOSH:** [completed testing](#) of CCDS process and validated efficacy through 20 cycles of decontamination
- **3M:** [validated](#) the VPHP process through 20 cycles
- **CDC:** [posted test results](#) for the CCDS VPHP process that confirmed performance and fit
- **NIH:** [study](#) found the VPHP process is the most effective for decontamination
- **Massachusetts General Hospital:** [research](#) confirmed the safety of VPHP process
- **Duke:** [validated](#) the VPHP process and post-decontamination performance