



## **NHIA TALK INFUSION WEBINAR**

# **COVID-19**

**What the Home and Specialty Infusion  
Community Needs to Know**

# Today's Speakers



Valerianna Amorosa, MD  
**Medical Director,**  
**Penn Home Infusion Therapy**



Abby Roth  
**Director of Learning &  
Development**  
*Critical Pointe, Inc.*



Shea McCarthy  
**Director of Government  
Affairs**  
*NHIA*



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# Today's Speakers



Bill Noyes  
**Senior Vice President  
Of Reimbursement Policy**  
*NHIA*



Connie Sullivan  
**President & CEO**  
*NHIA*



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Valerianna Amorosa, MD  
**Medical Director,**  
**Penn Home Infusion Therapy**

*Professor of Clinical Medicine,*  
Infectious Diseases Division  
**University of Pennsylvania**



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# PANDEMIC

- A disease effecting all people and populations
  - Widespread and out of control
    - Greek origin: PAN – all, DEMOS – people (the population)
- Other terms:
  - Outbreak
    - An increase in cases over usual number
  - Epidemic:
    - An outbreak over a large area
      - Greek origin: EPI – On, DEMOS – people
  - Endemic:
    - A disease that persists within a population over time
      - Greek: EN – In, DEMOS – people



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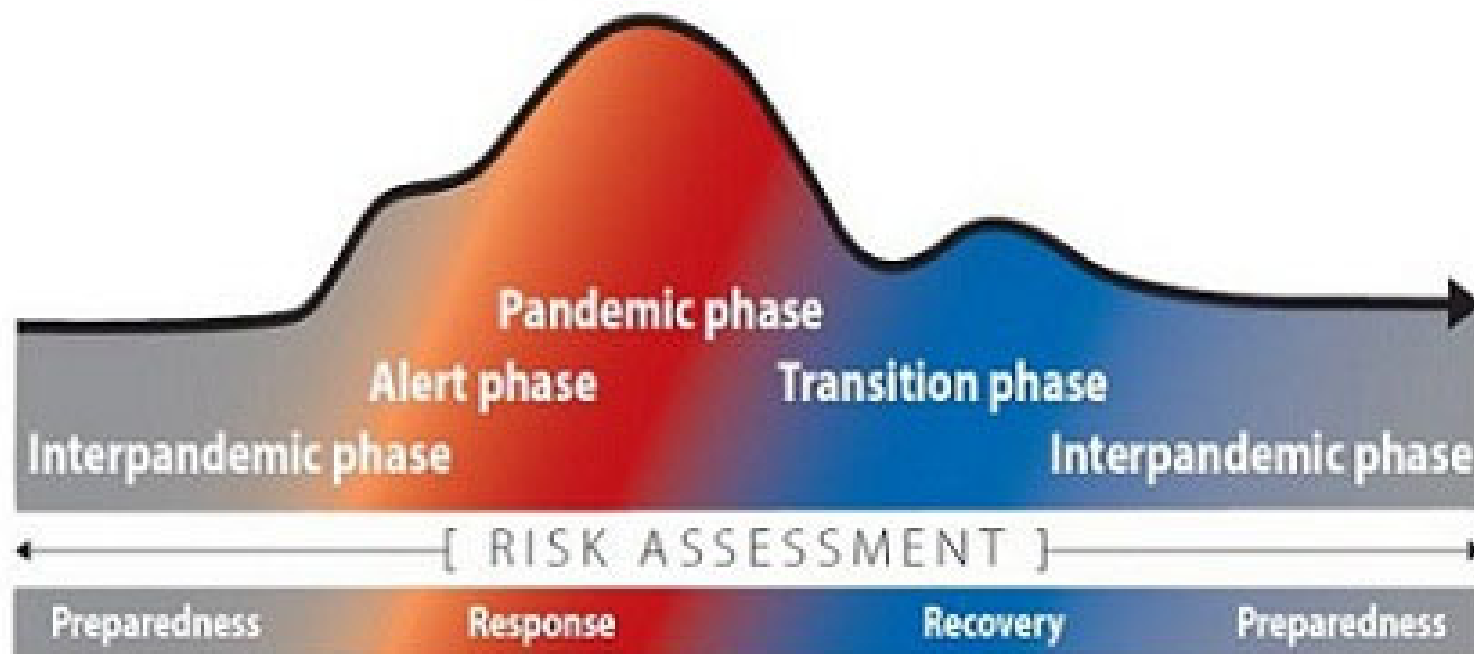
Interpandemic		Pandemic Alert			Pandemic	Post-peak	Possible new wave
Phase 1	Phase 2	Phase 3	Phase 4	Phase 5	Phase 6		
No new virus in humans Animal viruses low risk to humans	No new virus in humans Animal viruses high risk to human	New virus in humans Little/no spread among humans	Small clusters, Limited spread among humans	Larger cluster, localized Limited spread among humans	Increased and sustained spread in general human population	Levels in most countries have dropped below peak levels	Level of pandemic influenza activity rising again

## WHO Pandemic stages – PRIOR DESIGNATION (2009)



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# WHO Pandemic Framework (2018)



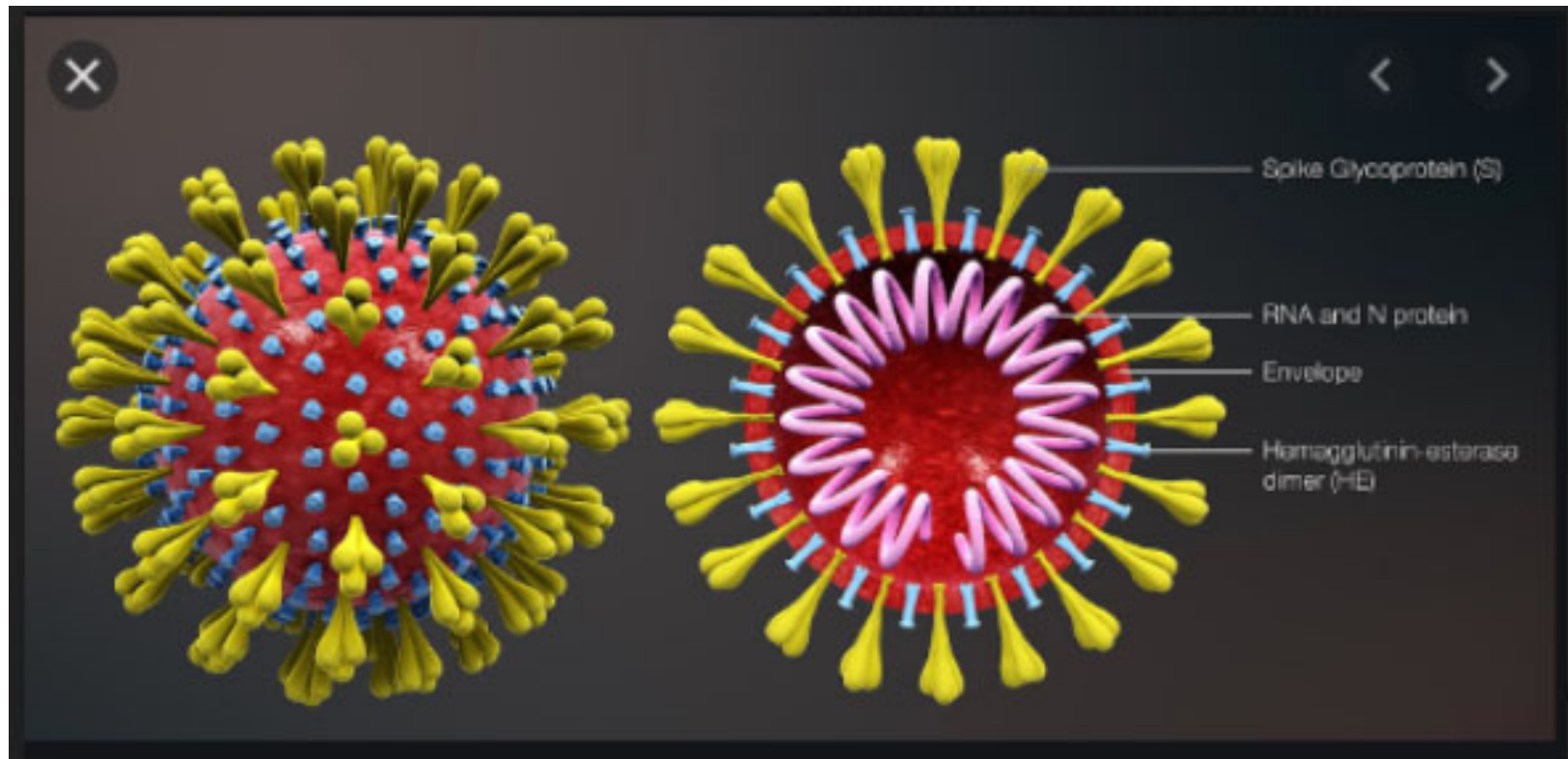
WHO, 2018



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# Coronavirus



ASM.org



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# Coronaviruses

- Corona Family are widespread in animal kingdom
  - Many species identified in BATS
- Four genera ( $\alpha, \beta, \gamma, \delta$ )
- Four coronaviruses cause common cold:
  - 2  $\alpha$ 's, 2  $\beta$ 's
- Three serious  $\beta$  coronaviruses
  - Severe Acute Respiratory Syndrome Coronavirus (SARS-CoV) [lineage B]
  - Middle Eastern Respiratory Syndrome (MERS-CoV) [lineage C]
  - NOW: SARS CoV-2 [lineage B]



# SARS CoV-2 Emergence

- Dec, 2019 Wuhan city – Severe pneumonia- Clinicians suspected viral origin
- Early suspicion for coronavirus
- BAL specimens → molecular testing – CoV-PCR primers used
- Identified a  $\beta$ -coronavirus phylogenetically close to other bat CoV
  - Genetically similar to SARS-CoV with some differences
  - Clinically much less deadly than SARS-CoV
- Person to person spread

Zhou, P., Yang, X., Wang, X. *et al.* *A. Nature* (2020).



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# SARS CoV-2

- COVID-19 (**CO**rona**V**irus Disease 2019) caused by SARS CoV-2
- Surface spike protein (S) to attaches to surface of target cells
  - S1 attaches to angiotensin converting enzyme 2 (ACE2) receptor then S is cleaved at S2 site and fusion with the cell
- ACE2 expressed in respiratory epithelial cells, intestine, kidney, blood vessels
- Virus uses host lysosomal enzymes to fuse into cell

Zhou, P., Yang, X., Wang, X. *et al.* A. *Nature* (2020); Hoffmann et al., SARS-CoV-2 Cell Entry Depends on ACE2 and TMPRSS2 and Is Blocked by a Clinically Proven Protease Inhibitor, *Cell* (2020), <https://doi.org/10.1016/j.cell.2020.02.062>; <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6258935/>

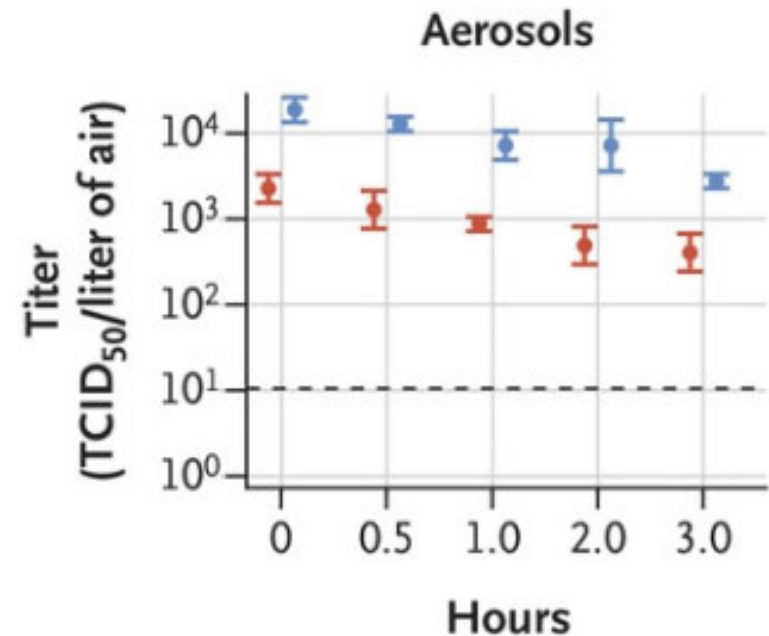


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# Spread: Transmission

- Inhalation of droplets in the air
- Touching fomites on which live virus is present in droplet
  - Then touching eyes, nose or mouth
- Concern that can remain airborne
  - Up to 3 hours when aerosolized
  - Unlike droplets that need to be projected into air
- Airborne transmission seems unlikely
  - Transmission rate would likely be greater than ~10% in household contacts
  - Caution during aerosol generation
    - (eg intubation)

<https://www.nejm.org/doi/10.1056/NEJMc2004973>



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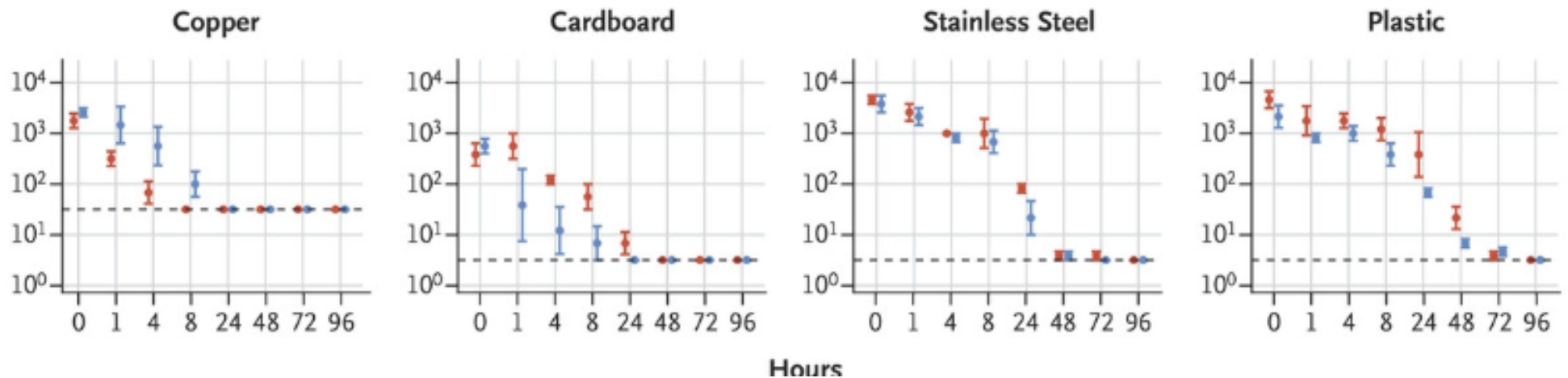
# COVID-19 Spread

- Droplet spread (though can be aerosolized by aerosol generating procedures)
- Many factors contribute transmissibility
  - Severity of illness in the patient
  - Extent of shedding
    - Can also have prolonged shedding
  - Timing of exposure in relation to symptoms
  - Duration and type of exposure
- Characterizations of 'high risk', 'medium risk', 'low risk' contact



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## Fomite transmission: Duration of survival of virus on various surfaces



<https://www.nejm.org/doi/10.1056/NEJMc2004973>



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# Incubation Period

- Time between exposure and symptom onset
  - Average 5 days
  - Can happen within 2-3, rarely as long as 14 days

Exposure	No. patients	Mean, d	Median, d	Interquartile range, d	Range, d
Contact with confirmed symptomatic case-patient	33	6.1	5	3–8	1–16
Traveled to Wuhan and stayed $\leq 1$ day	25	6.0	5	3–8	1–15
Total	58	6.0	5	3–8	1–16

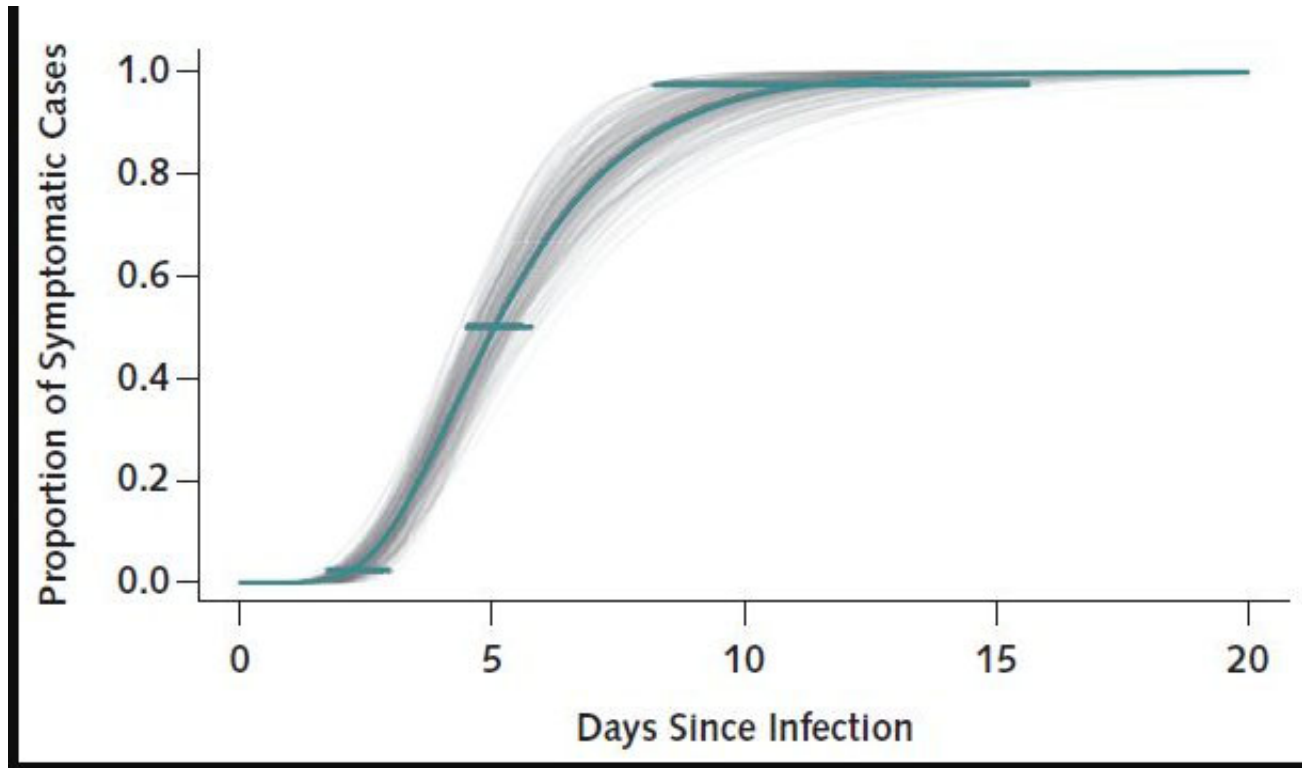
Liu J, Liao X, Qian S, Yuan J, Wang F, Liu Y, et al. Community transmission of severe acute respiratory syndrome coronavirus 2, Shenzhen, China, 2020. Emerg Infect Dis. 2020 Jun [date cited].

<https://doi.org/10.3201/eid2606.200239>



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# Incubation Period



<https://annals.org/aim/fullarticle/2762808/incubation-period-coronavirus-disease-2019-covid-19-from-publicly-reported>



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# Presymptomatic and Asymptomatic Transmission

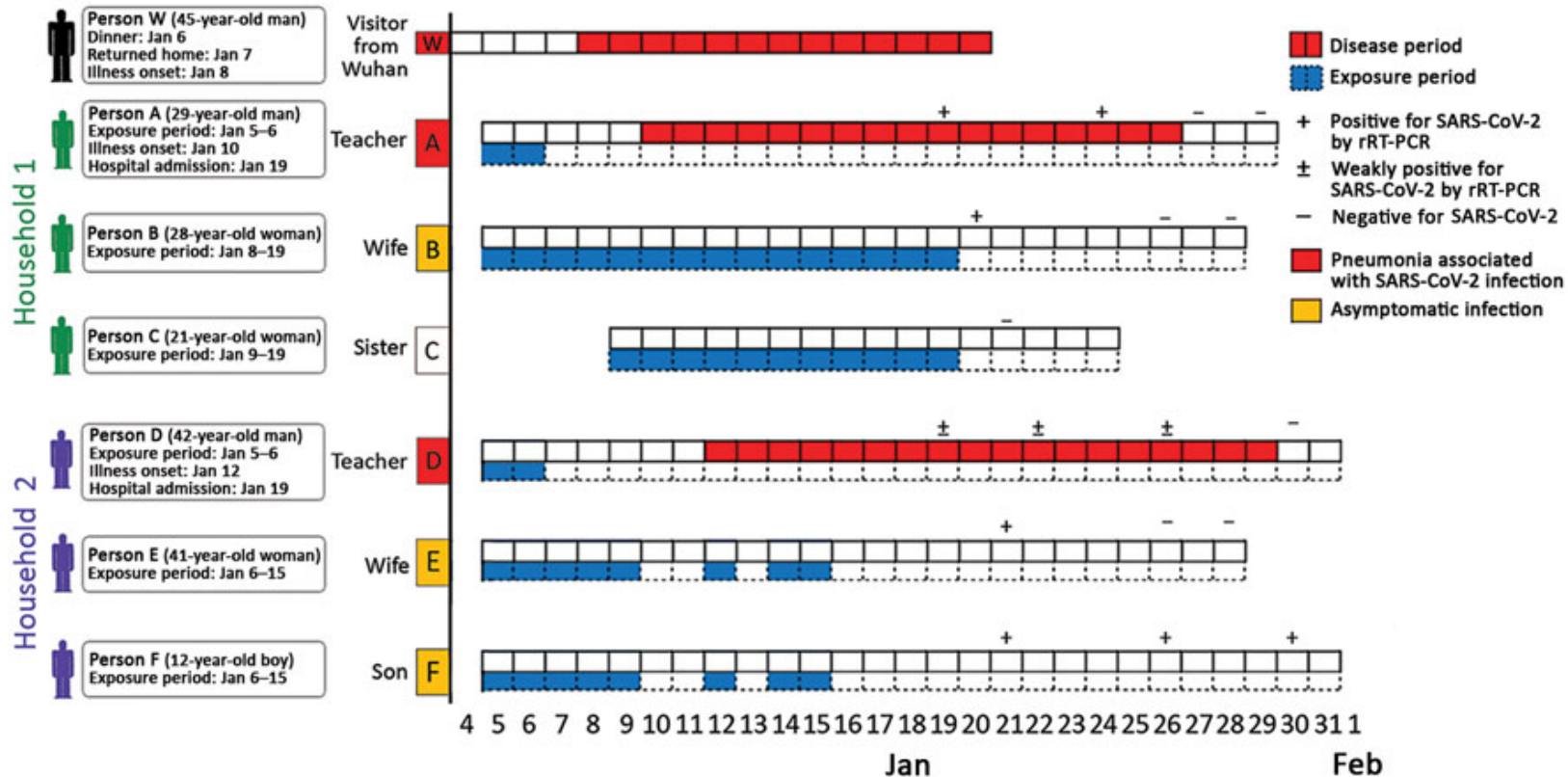
- Transmission prior to symptomatic or during asymptomatic infection
- Has been documented to occur
- Makes control more difficult
  - Relying on isolating and quarantining symptomatic persons would be inadequate to prevent asymptomatic and presymptomatic spread

Tong Z-D, Tang A, Li K-F, Li P, Wang H-L, Yi J-P, et al. Potential presymptomatic transmission of SARS-CoV-2, Zhejiang Province, China, 2020. Emerg Infect Dis. 2020 May [date cited]. <https://doi.org/10.3201/eid2605.200198>



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# Presymptomatic Transmission



Tong Z-D, Tang A, Li K-F, Li P, Wang H-L, Yi J-P, et al. Potential presymptomatic transmission of SARS-CoV-2, Zhejiang Province, China, 2020. *Emerg Infect Dis.* 2020 May [date cited]. <https://doi.org/10.3201/eid2605.200198>



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# Signs & Symptoms Range

- ASYMPTOMATIC
- MILD
  - Nonspecific respiratory symptoms
  - Fever (44% admission, 90% all), dry cough, dyspnea, headache, pneumonia, sore throat
    - Nausea, vomiting, diarrhea <5%
- SEVERE
  - Pneumonia, respiratory failure and shock
    - Alveolar damage and acute respiratory distress syndrome (ARDS)
  - Lab abnormalities include lymphopenia

[https://www.nejm.org/doi/full/10.1056/NEJMoa2002032?query=recirc\\_mostViewed\\_railB\\_article](https://www.nejm.org/doi/full/10.1056/NEJMoa2002032?query=recirc_mostViewed_railB_article)



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# High Risk Categories

- AGE risk factor for severity
- Other conditions associated with higher severity
  - HTN
  - DM
  - CAD
  - Other: COPD, renal, malignancy, immunocompromise

[https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(20\)30566-3/fulltext#tbl1](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)30566-3/fulltext#tbl1)

Age	Confirmed Cases	Mortality Rate
0-9	416	0.0%
10-19	549	0.2%
20-29	3619	0.2%
30-39	7600	0.2%
40-49	8571	0.4%
50-59	100008	1.3%
60-69	8583	3.6%
70-79	3918	8.0%
>80	1408	14.8%
Data from Chinese CDC Feb 11, 2020		



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# Diagnosis

- Overlapping features with other respiratory viruses
- Clinical characteristics, epidemiology (potential exposure, community circulation) → lab testing
- LAB TESTING - Molecular assay
  - Real Time Polymerase chain reaction (RT-PCR) – genetic amplification
- Highly sensitive (detects few copies) if appropriate sample taken
  - Nasopharyngeal, oropharyngeal swabs, nasal aspirate, sputum, BAL
  - In exposed asymptomatic, negative test does not rule out
- Delays in ramp up in US as of yet



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# Prevention

- Prevent all non-essential contact with patients
  - ‘Triage’, utilize telehealth resources
- Each provider (Including drivers, allied health) screen every patient by phone prior to every visit
  - Screening questions evolving
    - Travel, contact with a person with known or suspected COVID-19, symptom screen (cough, feverish/chills)
    - Screen HOUSEHOLD MEMBERS as well as patient
- Robust protocols (in evolution!) how to manage ‘positive’ screens
- Ask patient preferences regarding non-vital services
- Anticipate other scenarios
  - If positive screen emerges in the home, guidance for clinician



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# Personal Protective Equipment (PPE)

- DROPLET/CONTACT PRECAUTIONS in SYMPTOMATIC patient
  - Widespread supply chain shortages
  - Airborne precautions - If generating aerosol (suctioning, intubation, airway management), N95 or PAPR
- Surgical masks (droplet)
  - Looser fit
  - Prevents droplet particles
- N95 masks (airborne)
  - Close fitting, prevents 95% of 3 micron particles
- Face shield or goggles as eye protection
- Gown/gloves for contact



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# Prevention: Scenario

- Patient is living with COVID-19 positive patient
- Effectively this is a 'self-quarantined' patient
  - ~10% of household members become infected
- Limit any nonessential contact (and keep 6 feet away if possible)
- Educate family on limiting spread within household (CDC.gov)
- Continue to screen patient for symptoms prior to contacts
- If asymptomatic, wear surgical mask, goggles (or face shield), gloves
  - Ideally self-quarantined family member is not in the room (sometimes essential)
- If patient becomes symptomatic, consider test and wear gown as well
  - N95 vs. surg. Mask in suspected vs. diagnosed patient (evolving guidance)

<https://www.cdc.gov/coronavirus/2019-ncov/php/guidance-evaluating-pui.htm>



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# CDC Guidance

- Personal protective equipment caring for patients in the HOME
  - <https://www.cdc.gov/coronavirus/2019-ncov/php/guidance-evaluating-pui.html>
- Guidance on exposed healthcare workers
  - <https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assessment-hcp.html>



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# Hand Hygiene

- Vital given fomite spread
- Frequent alcohol based hand sanitizer
- Soap and water (20 seconds)
- Avoiding touching face – eyes, nose, mouth



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# Treatment

- Current protocols based on Chinese experience, in vitro data, SARS experience – EVOLVING and rapidly changing
- What IS recommended and what's NOT
- Treatment recommendations based on
  - China experience
  - In vitro efficacy
  - SARS experience from 2002



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# Treatment Decisions

- Base on severity of disease AND presence of risk factors for severe disease
- Generally don't treat mild disease, without risk factors for poor outcomes

Stratification to guide treatment decisions

Mild illness – outpatient or hospitalized

- No hypoxia or radiographic evidence of pneumonia
- With or without risk factors for severe disease

Hospitalized, hypoxia, not critical

Hospitalized, intubated

Critical, intubated with multiorgan damage



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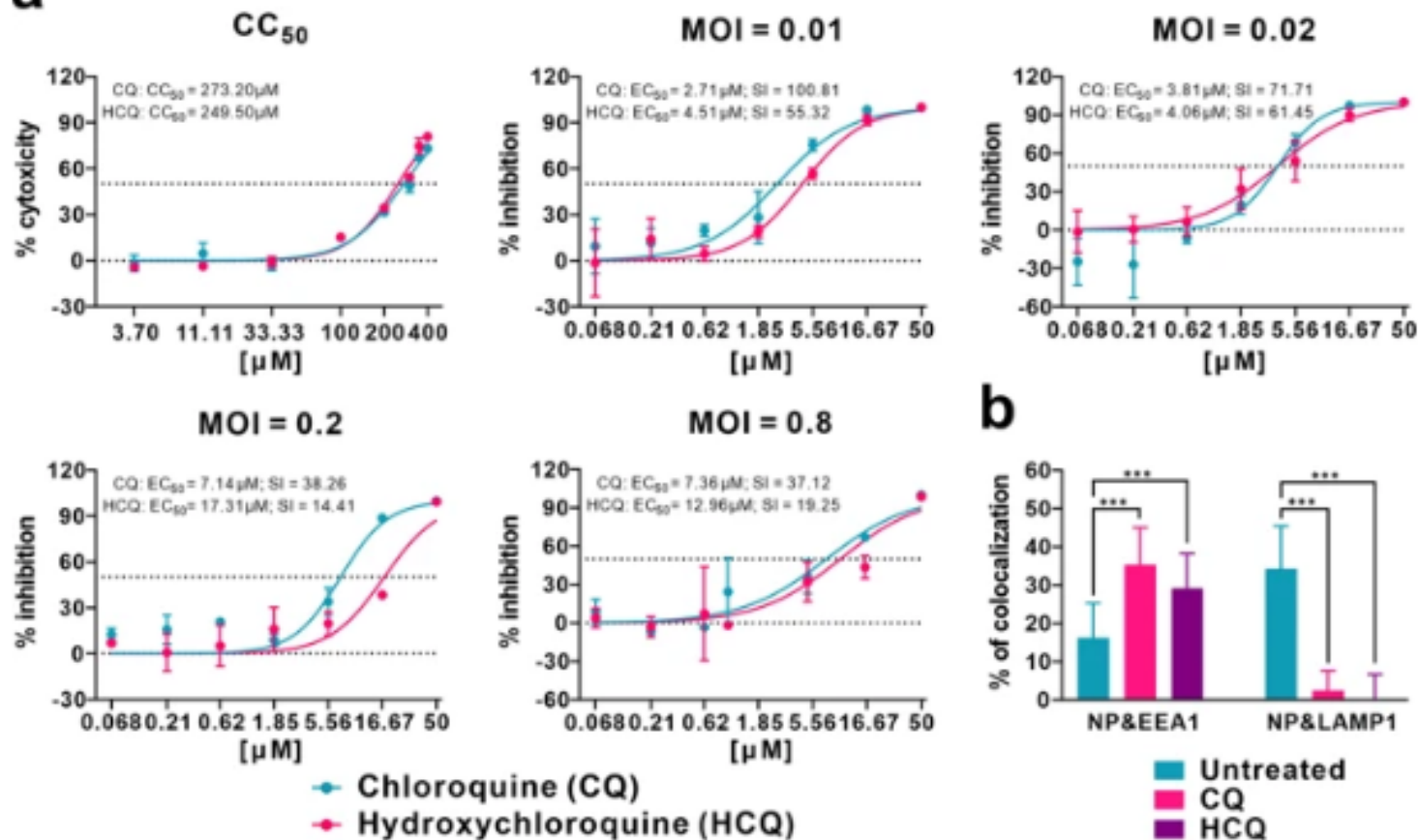
# Several Agents Being Used

- Remdesivir
  - Intravenous nucleoside analog (Gilead)
  - Clinical trial or IND application for compassionate use
- Hydroxychloroquine
  - Metabolite of chloroquine
  - Inhibition of intracellular lysosomal acidification
- Chloroquine
- Lopinavir/ritonavir –
  - Sill may have role for combination with ribavirin (SARS data)
  - ?Monotherapy OUT
    - No clear benefit with severe disease as monotherapy
    - March 18, 2020 - DOI: 10.1056/NEJMoa2001282
- Tocilizumab
  - IL-6 inhibitor – for cytokine storm associated with severe disease

<https://www.nature.com/articles/s41421-020-0156-0>



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## **Penn Medicine Treatment Guidelines for SARS-CoV-2 Infection**

**Treatment of Adult Patients with Laboratory-Confirmed  
SARS-CoV-2 (COVID-19) Infection**

<http://www.uphs.upenn.edu/antibiotics/COVID19.html>



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Clinical Situation	Treatment Considerations	Special Considerations
<p>Mild illness, not requiring hospitalization</p> <p>OR</p> <p>Hospitalized patient with mild illness (no hypoxia or radiographic evidence of pneumonia) and no risk factors<sup>1</sup></p>	<p>Symptomatic treatment and monitoring</p>	<p>Not applicable</p>
<p>Hospitalized or non-hospitalized patients with mild illness (no hypoxia or radiographic evidence of pneumonia) <u>and risk factors<sup>1</sup> for progression to severe disease</u></p> <p>OR</p> <p>Hospitalized with hypoxia or radiographic evidence of pneumonia but not critically ill</p>	<p>Consider treatment with:</p> <p>Hydroxychloroquine 400 mg PO q12h x 1 day then 200 mg q12h<sup>2</sup> for total 5-10 days (depending on clinical improvement)</p>	<p><u>Hydroxychloroquine:</u></p> <ul style="list-style-type: none"> <li>• Check EKG prior to initiation given risk of QT prolongation. Risk is increased in patients on other QT-prolonging agents.</li> <li>• Other risks include but are not limited to arrhythmia, cardiomyopathy, bone marrow suppression, and hypoglycemia and patients should be monitored for these side effects.</li> </ul>



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# What's NOT Recommended – Evolving...

- Corticosteroids
  - May increase shedding, not recommended unless another compelling reason
- Ibuprofen?
  - May increase the ACE2 receptor expression on airway
    - World Health Organization first recommended avoiding then JUST redacted
- Antibiotics
  - Unless clear evidence bacterial superinfection
- ACE Inhibitors and Angiotensin receptor blockers?
  - Controversy if ACEI could increase ACE2 expression further poor outcomes in DM, HTN
  - [https://www.thelancet.com/journals/lanres/article/PIIS2213-2600\(20\)30116-8/fulltext](https://www.thelancet.com/journals/lanres/article/PIIS2213-2600(20)30116-8/fulltext)



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# Special Populations

- China's Guidelines for Cancer Management in COVID19 infected
- Early stage cancer patients
  - Post pone surgery/radiation if able
  - Psychological counseling around treatment delay to patient and family via telemedicine
- Patients infected with COVID19 can resume care after 2 weeks of clinical stability
- Defer any unnecessary infusions (ie- zoledronic acid)





# Summary

- Unique considerations in terms of protecting healthcare workers and patients from infection in the home
- Increasing access and rapid diagnostic testing will aid in quarantine and PPE conservation ideally
- More nuanced understanding of predictors of severe disease and appropriate treatments and interventions continues
- <https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-guidance-management-patients.html>



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Abby Roth

**Director of Learning &  
Development**

*Critical Pointe, Inc.*



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# Compounding Garb

- Inventory your current supply
- Order for HD use
- 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.

\*Content and images from CriticalPoint's Webinar COVID-19: Downstream Implications for Sterile Compounding (March 4, 2020)



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# 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

- Prioritize masks for front line health care personnel
- Regular face mask if available
- N95 respirators if available
  - do not need to be fit tested for this type of use
  - must fit snugly from bridge of nose to around chin without gaps

From USP guidance released March 18, 2020

- Not advised to re-use masks
- Use clean fabric (e.g., polyester) to cover nose and mouth (e.g., bandana, washable face mask). Don a clean face cover each time before entering the compounding area.



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# 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.



# Gowns

- 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***
  - Must discard gown if:
    - visibly soiled
    - used during cleaning activities



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# Gown Alternatives

From USP guidance released March 18, 2020

- Use clean, washable, dedicated non-disposable garments (e.g., gowns, lab coats). Long-sleeved garments are preferred, and if not available, wear sleeve covers.
- Preferably, wash garments after each shift or sooner when visibly soiled.



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# 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

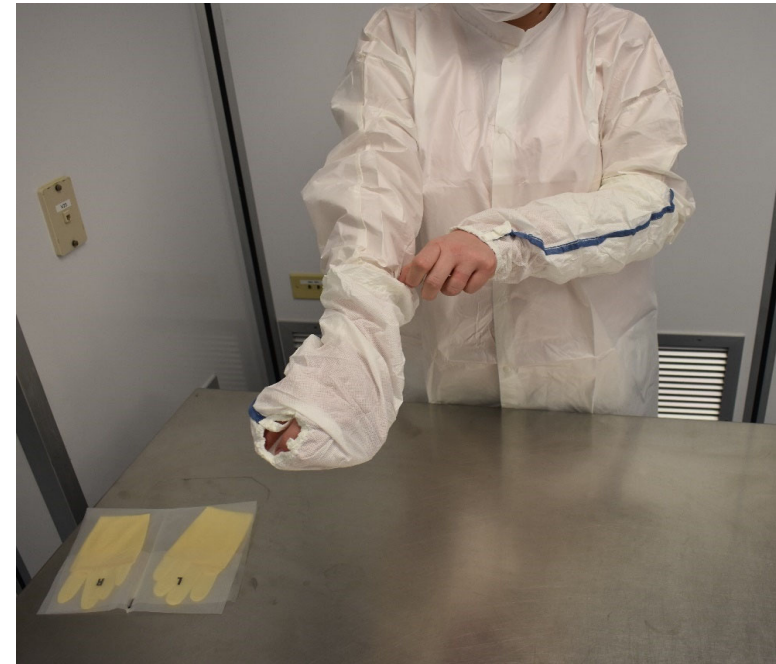


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# Disposable Sleeve Covers

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.



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# 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.



# 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.



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# 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.



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# Enforce Existing SOPs and Practices

- 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.



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Shea McCarthy  
**Director of Government  
Affairs**  
*NHIA*



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# Protecting Vulnerable Seniors

- Home infusion treats patients with serious health conditions who need IV medications but don't otherwise need to be hospitalized.
- This service keeps vulnerable seniors away from the threat of infectious diseases.
  - **COVID-19:** CDC has issued [warnings](#) that healthcare facilities should keep these types of patients from being admitted if it's at all possible to treat them in other care settings.
- Home infusion providers have the capacity to treat hundreds-of-thousands of patients, especially as the risk intensifies that hospitals and nursing facilities will be pushed to capacity in the weeks ahead.



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# Patient Preference, Cost Effectiveness

- Up to [95 percent](#) of patients prefer to receive their treatments at home.
- Commercial payers have long recognized that home infusion is an incredibly efficient and cost-effective site of care.
  - [GAO](#): “Providing infusion therapy at home generally costs less than treatment in other settings... and is largely free from inappropriate utilization and problems in quality of care.”
- Cost savings are passed on to the patient in the form of lower copays and reduced out-of-pocket costs.
  - This is especially important in Medicare Part B, where patients pay 20% coinsurance.

GAO

United States Government Accountability Office  
Report to Congressional Requesters

June 2010

## HOME INFUSION THERAPY

Differences between  
Medicare and Private  
Insurers' Coverage




GAO-10-426




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# Legislative History and Implementation











Historically, Medicare Part B infusion drugs were reimbursed at the Average Wholesale Price (AWP) with the expectation that the difference would be sufficient to offset the cost of extensive professional pharmacy services needed to administer the drugs.



Congress included provisions in the 21st Century Cures Act and the Bipartisan Budget Act of 2018 to lower the drug reimbursement rate from AWP to the Average Sales Price (ASP), while also requiring CMS to create a professional services benefit for Medicare Part B home infusion drugs, similar to benefits provided by Medicare Advantage and commercial plans.



In 2018, CMS undermined the policy created by Congress by issuing restrictive regulations that limit reimbursement to days when a nurse is physically present in the patient's home, rather than each day the drug is infused.

	Before 2017	21st Century Cures + BBA	CMS Implementation	Most Commercial Payers
 Drugs	95% of AWP	 ASP+6%	 ASP+6%	A percentage of AWP
 Nursing Services		Every day drug is infused	Only when a nurse is in the home	Reimbursed separately
 Pharmacy Services		Every day drug is infused		Every day drug is infused



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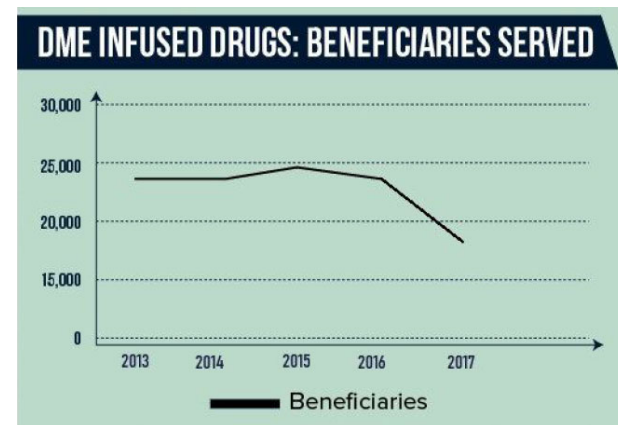
# Impact on Patient Access

This physical presence requirement contradicts our intent in drafting and enacting this legislation and makes the reimbursement required by the bill inadequate.

[Senate Letter to CMS](#)

[House Letter to CMS](#)

- Based on a review of publicly available data, an alarming **20 percent** fewer Medicare beneficiaries received DME infused drugs in 2017 compared to 2016.
- Many providers are holding on in hopes that this issue is resolved before CMS implements the “permanent” home infusion benefit in 2021.



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# The Preserving Patient Access to Home Infusion Act

As introduced in the [House](#) and [Senate](#):

1. Require payment to be made every day a medication is infused, regardless of whether a skilled professional is present in the patient's home.
2. Enumerate the specific services to be included in the reimbursement, including the extensive pharmacy services that are performed remotely.
3. Takes effect in 2021.

G:\M16\ENGEL\ENGEL\_114.XML

(Original Signature of Member)

116TH CONGRESS  
2D SESSION **H. R.**

To amend title XVIII of the Social Security Act to clarify congressional intent and preserve patient access to home infusion therapy under the Medicare program, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. ENGEL introduced the following bill, which was referred to the Committee on \_\_\_\_\_

**A BILL**

To amend title XVIII of the Social Security Act to clarify congressional intent and preserve patient access to home infusion therapy under the Medicare program, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*  
3 **SECTION 1. SHORT TITLE.**  
4 This Act may be cited as the "Preserving Patient Ac-  
5 cess to Home Infusion Act".

g:\M16\CON\2021\2021\116.xml (7542075)  
February 21, 2020 (1:48 p.m.)



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# CBO Scoring Implications

[CBO Score](#): Home Infusion Provisions in 21<sup>st</sup> Century Cures:

(Millions of dollars, by fiscal year)	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2017-2021	2017-2026
Sec. 5004 - Reducing Overpayments of Infusion Drugs												
Estimated Budget Authority	-30	-50	-55	-60	-65	-70	-75	-80	-85	-90	-260	-660
Estimated Outlays	-30	-50	-55	-60	-65	-70	-75	-80	-85	-90	-260	-660
Sec. 5012 - Medicare Coverage of Home Infusion Therapy												
Estimated Budget Authority	0	0	0	0	-12	-33	-49	-67	-86	-125	-12	-372
Estimated Outlays	0	0	0	0	-12	-33	-49	-67	-86	-125	-12	-372

[CBO Score](#): Home Infusion Provisions in the BBA of 2018:

(Outlays in millions of dollars, by fiscal year)	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2018-2022	2018-2027
50401. Home infusion therapy services temporary transitional payment	0	-260	-490	-160	0	0	0	0	0	0	-910	-910

The Moran Company Score: Cost Estimate of the PPAHI Act:

	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2020-2029
Change in Direct Federal Spending	-	(1.0)	(2.8)	(4.1)	(5.6)	(7.2)	(10.4)	(14.3)	(19.5)	(28.3)	(93.1)



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# Our Ask

- Congress should include the provisions of S. 3457/H.R. 6218 in the next coronavirus legislative package.
- Since this bill is limited to approximately 30 Part B DME infused drugs and doesn't go into effect until 2021, Congress should expand it to provide the Secretary with authority to both **expedite implementation** *and* extend professional services reimbursement to the **+100 Part D drugs** that can be infused in the home.
  - Similar to telehealth provisions in the first COVID-19 package.
- These additional measures will reduce the burden on other parts of the healthcare system and save lives in the immediate future.



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# How Can You Help?

- Write a letter to your Member of Congress and both senators.
- Send that letter via email to their health care staffer(s) and copy Shea McCarthy ([shea.mccarthy@nhia.org](mailto:shea.mccarthy@nhia.org)).



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Bill Noyes  
**Senior Vice President  
Of Reimbursement Policy**  
*NHIA*



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# COVID-19 Related Policies

- Expansion of Telehealth
- Adds COVID-19 lab codes
- Waivers
  - Fee-for Service
  - Medicare Advantage and Part D PDP
- FAQ's
- NHIA Advocacy



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# Telehealth

- CMS expands coverage for telehealth visits.
- HHS Office for Civil Rights (OCR) announced it will waive potential HIPAA penalties for good faith use of telehealth during the emergency. (common non-public video tech)
- OIG allows for waived or reduced co-pay for telehealth visits.



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# CMS COVID-19 Lab Codes

On March 6, the agency released an update to the Clinical Laboratory Fee Schedule (CLFS) to add the following HCPCS codes for the COVID-19 diagnostic tests:

- U0001 (CDC 2019 novel coronavirus [2019-nCoV] real-time RT-PCR diagnostic panel)
- U0002 (2019-nCoV coronavirus, SARS-CoV-2/2019-nCoV [COVID-19], any technique, multiple types or subtypes [includes all targets], non-CDC)



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# Section 1135 Waivers

On March 13, 2020 CMS issued blanket waivers consistent with those issued for past PHE declarations. These waivers prevent gaps in access to care for beneficiaries impacted by the emergency. You do not need to apply for an individual waiver if a blanket waiver is issued.

- Waivers are retro to March 1, 2020
- Apply to Medicare & Medicaid
- Details in [MLN Matters SE 20011](#)



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# FFS Waivers

- Skilled Nursing Facility: Waive 3 day hospital stay
- Critical Access Hospitals: Waive 25 bed limit & 96hr stay
- Home Health: Relax OASIS transmission timelines
- Durable Medical Equipment: Replacement of Equipment
- Medicare Advantage: Contact MA plan for details



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# CMS memo to Medicare Part C and D (3/10/2020)

- Waiving cost-sharing for COVID-19 tests
- Waiving cost-sharing for COVID-19 treatments in doctor's offices or emergency rooms and services delivered via telehealth
- Removing prior authorizations requirements
- Waiving prescription refill limits
- Relaxing restrictions on home or mail delivery of prescription drugs
- Expanding access to certain telehealth services

These waivers break down barriers to beneficiaries accessing care and allow plans to work with pharmacies and providers to treat patients without burdensome requirements limiting their options during this outbreak.



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# CMS COVID-19 Related FAQ

Topics covered in the FAQ include payment and billing for:

- Ambulance services
- Diagnostic laboratory tests
- Drugs and vaccines under Part B
- Hospital services
- Physicians' services

Link to FAQ <https://www.cms.gov/files/document/03092020-covid-19-faq-508.pdf>



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- **Question:** Will Medicare Part B cover a 90-day supply of drugs in the event that a pandemic occurs, when such drugs are needed for a patient's chronic condition?
- **Answer:** With respect to drugs covered under Part B, with the exception of immunosuppressive drugs --which are generally limited to a 30-day supply – but including drugs that need to be administered through Durable Medical Equipment, local MACs have discretion to pay for a greater-than-30-day supply of drugs. When considering whether to pay for a greater-than-30day supply of drugs, MACs will take into account the nature of the particular drug, the patient's diagnosis, the extent and likely duration of disruptions to the drug supply chain during an emergency, and other relevant factors that would be applicable when making a local determination as to whether, on the date of service, an extended supply of the drug was reasonable and necessary.



# NHIA Advocacy Efforts

- Linking the need for a comprehensive HIT benefit to current PHE.
- Pushing to get legislation considered in COVID19 bills.
- Seeking COVID19 guidance/education from DME MACs.
- Letter to HHS with recommendations to lessen administrative burden and enhanced HIT coverage in both Part B and Part D.



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# HHS Letter

- Relax POD signature requirements
- Allow for HIT services to be billed each day drug is infused
- Delay roll of PA, WOPD and Face-to-Face lists
- Waive ENT and PN LCD qualifying criteria
- Suspend audits and extend response time
- Extend HIPAA waivers beyond hospitals
- Delay Round 2021 of Competitive Bidding
- Allow for billing of the Part B daily HIT services for Part D drugs



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# Future Guidance

- Expect additional guidance in the coming days, weeks, months.



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Connie Sullivan  
**President & CEO**  
*NHIA*



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# Preparing for COVID-19

- Start now! Develop a plan.
  - Staffing
  - Infection control and safety
  - PPE conservation
  - Compounding modifications
  - Evaluate nursing capacity
  - Suite vs. home
  - Surge response



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# Nursing Conservation Strategies

- IVIG to SCIG
- Tele-visits? Remote teaching and monitoring?
- Leverage highly skilled caregivers
- Partner with home health agencies, offer training



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# Compounding Modifications

- Be conservative with BUDs
- Considerations
  - Staffing
  - Exposure frequency of delivery staff
  - Compounding conditions
  - Complexity of the compounded sterile product
    - Use more binary connectors, pre-mixes where available
  - Drug shortages



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# Expect the Unexpected

- IV Access Challenges
- Unfamiliar referral sources
- Quickly changing reimbursement policy
- Unpredictable supply chain
- New treatments



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# Any Questions?



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# NHIA Membership

- Become a part of a community that is committed to serving patients in the home and alternate site infusion space
- We are here to advocate and provide the valuable information you need to know as a home and specialty infusion organization

For information about NHIA membership please contact:

Crissy O'Donnell, Director of Member Services – [crissy.odonnell@nhia.org](mailto:crissy.odonnell@nhia.org) | 703-838-2646

Ash Oberholtzer, VP of Membership and Business Development – [ashlan.oberholtzer@nhia.org](mailto:ashlan.oberholtzer@nhia.org) | 571-814-3755



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