

**COVID-19  
HEALTHCARE  
PROVIDER  
UPDATE**

**MAY 8, 2020**

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## DISCLAIMER

- Our understanding of COVID-19 is evolving rapidly
- This presentation is based on our knowledge as of May 7, 2020, 5 PM

COVID-19  
NYC UPDATES

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# Outline



SURVEILLANCE UPDATES



CLINICAL UPDATES



LABORATORY ISSUES



QUESTIONS AND DISCUSSION

## WHERE WE ARE

- Over two months have passed since the confirmed arrival of COVID-19 in NYC
- Over 19,000 people have died due to confirmed or probable COVID-19 in NYC
- There are signs that mitigation measures, including physical distancing, are making a difference
- The number of new daily cases, hospitalizations, and deaths due to COVID-19 continue to decline
- Some alternate care sites have closed
- Mitigation measures must be maintained until we can safely transition to suppression measures

## CURRENT ACTIVITIES

- Over 13,000 volunteers registered with the Medical Reserve Corps
  - Volunteers working in hospitals, nursing homes, mortuaries, and alternate care sites
- Hotels being used to house healthcare workers, symptomatic individuals from congregate settings, and individuals discharged from hospitals that are COVID-19+ and require an isolated setting
- Food distribution programs providing millions of free meals through the NYC Department of Education and Department for the Aging
- City to create and maintain 90-day stockpile of PPE in case of resurgence

# CUMULATIVE CASES AND DEATHS, WORLDWIDE

5/7/20 , 5:00PM

>3,860,000 cases

>270,000 deaths



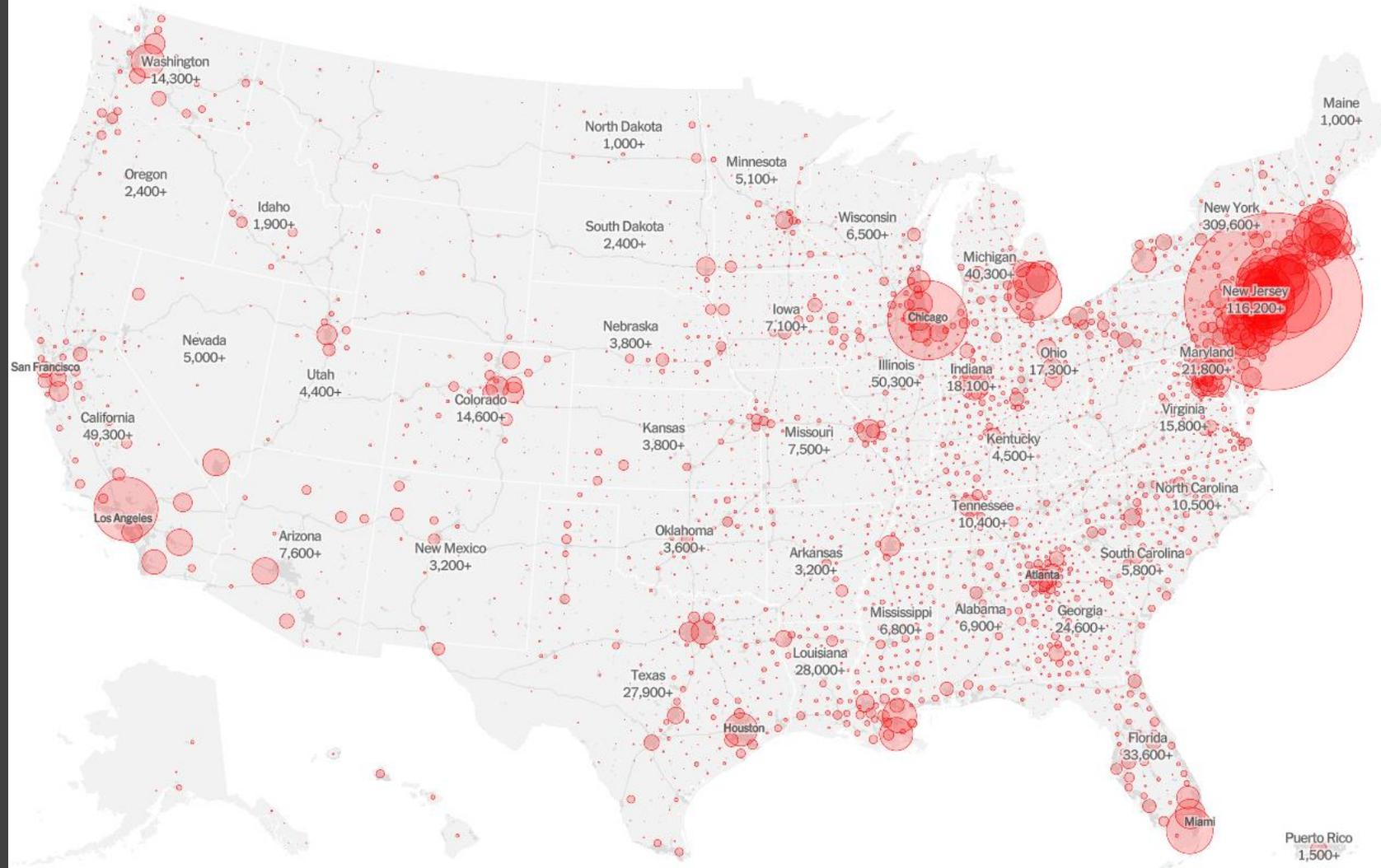
Cumulative confirmed cases, Johns Hopkins University

<https://www.arcgis.com/apps/opsdashboard/index.html#/bda7594740fd40299423467b48e9ecf6>

# CUMULATIVE CASES AND DEATHS, US 5/7/20, 5:00PM

>1,200,000 cases  
(33% of confirmed global cases)

>75,000 deaths  
(28% of reported global deaths)



Confirmed and probable cases, *New York Times*

<https://www.nytimes.com/interactive/2020/us/coronavirus-us-cases.html>

CURRENT  
STATUS OF  
OUTBREAK,  
NYC  
5/7/20

Laboratory confirmed cases	174,709
Hospitalized	43,744
Deaths total	19,540
<i>confirmed</i>	14,162
<i>probable</i>	5,378

[NYC Health Department Coronavirus Data](#)

NYC Health Department Data Portal – updated daily

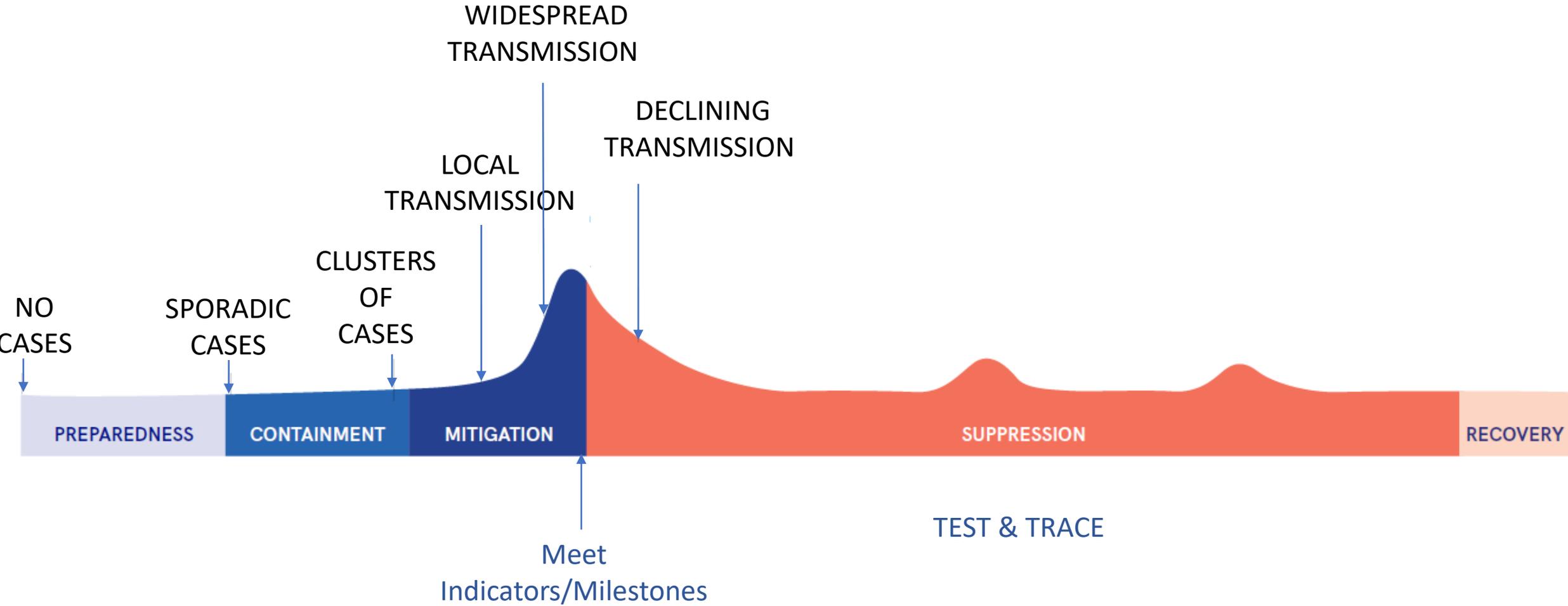
# COVID-19 RATES BY BOROUGH, NYC 5/7/20

Shows number of positive cases  
per 100,000 people in each  
borough

	▼ Rate per 100,000 people	Count
The Bronx	2,711	39,878
Staten Island	2,463	12,380
Queens	2,166	54,121
Brooklyn	1,718	46,579
Manhattan	1,153	21,662
Citywide		174,709

[NYC Health Department Coronavirus Data](#)  
NYC Health Department Data Portal – updated daily

# PHASES OF THE RESPONSE BASED ON SURVEILLANCE DATA



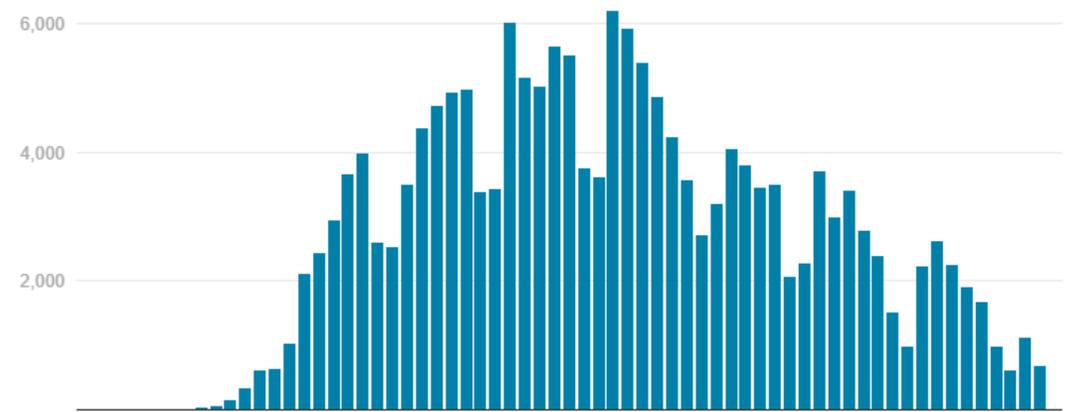
# COVID-19 CASES NYC

3/6/20 – 5/7/20

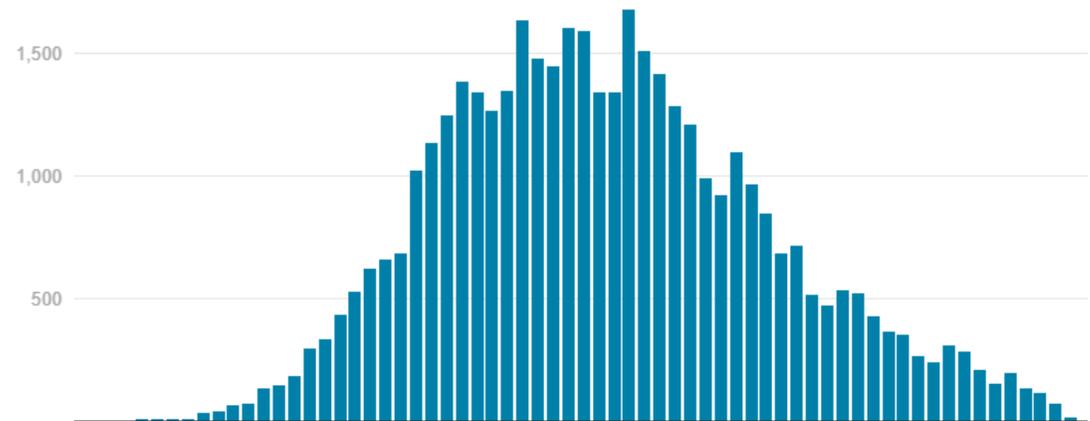
Shows number of COVID-19 cases,  
hospitalizations, and deaths based  
on a daily analysis since March 3

Deaths lag 1-2 weeks after  
hospitalizations

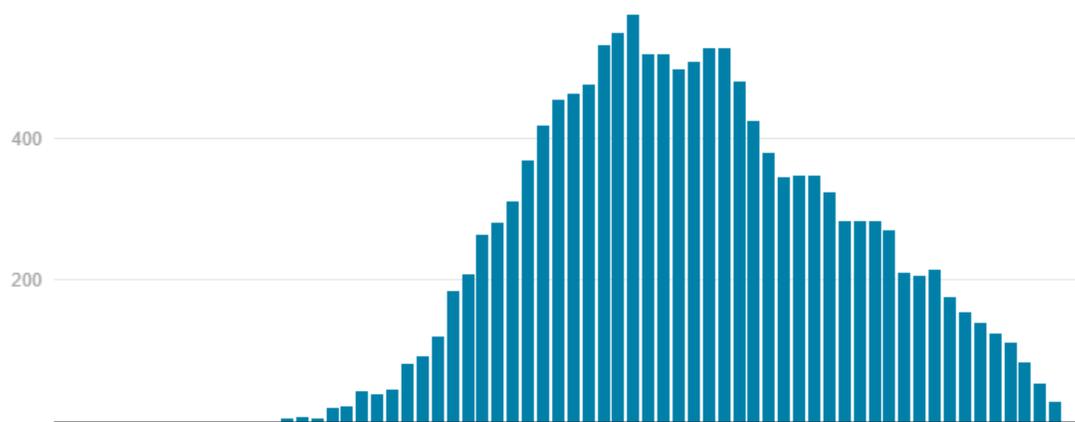
CASES



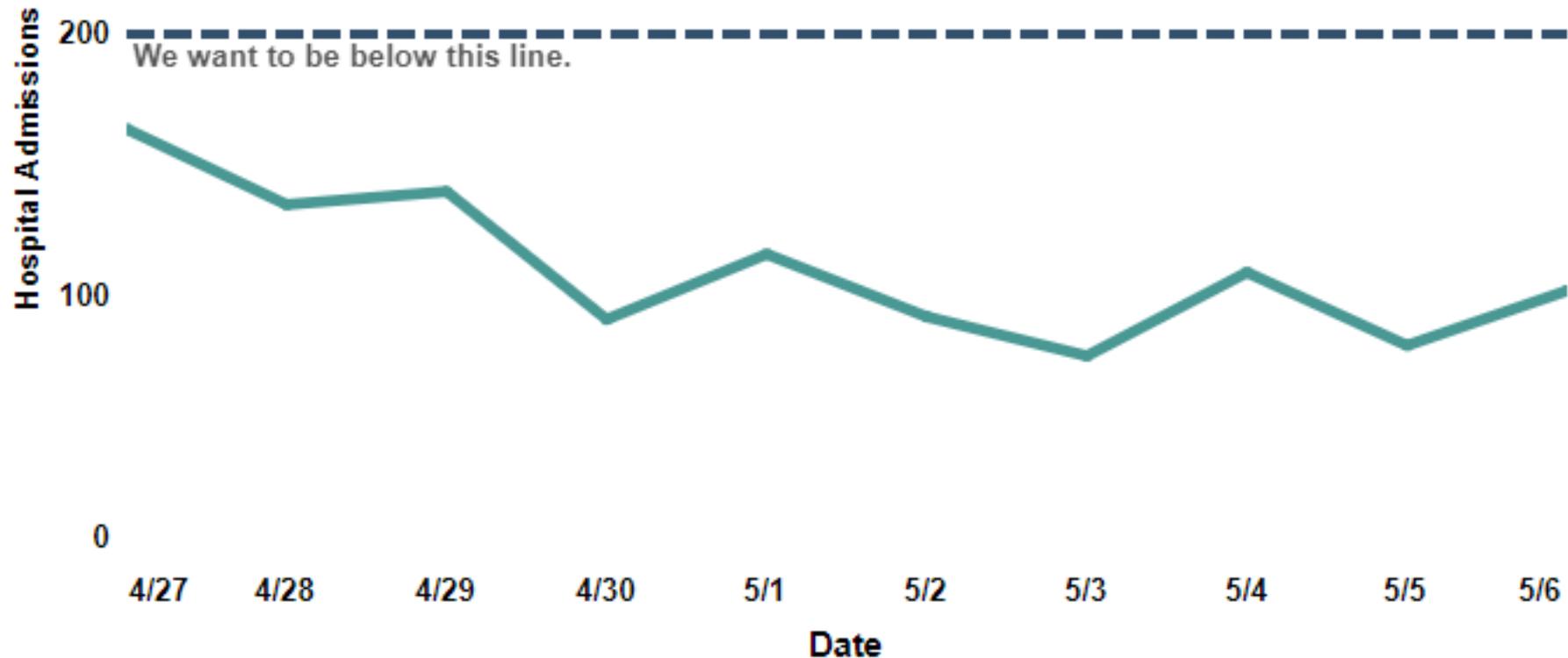
HOSPITALIZATIONS



DEATHS

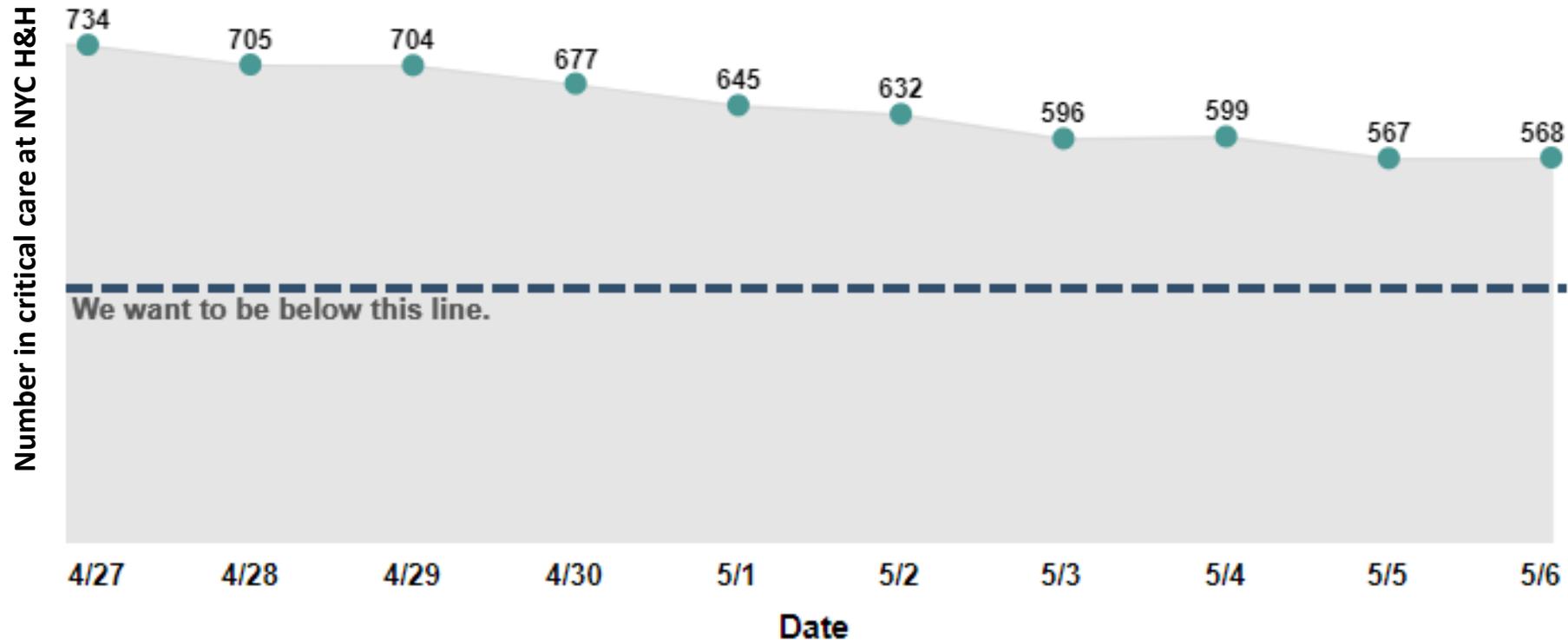


# PEOPLE ADMITTED TO NYC HOSPITALS FOR COVID-19-LIKE ILLNESS



MILESTONE: This chart may indicate when COVID-19's spread is slowing by showing 10 consecutive days when the daily number of people admitted to NYC hospitals for influenza-like illness and pneumonia is less than 200. That would be double the average for prior years in the city

# PEOPLE IN CRITICAL CARE ACROSS NYC HEALTH + HOSPITALS



MILESTONE: This chart may indicate when critical care volume is at sustainable levels by showing 10 consecutive days when the daily number of people in critical care at NYC Health and Hospitals is less than 375.

# REMDESIVIR APPROVED FOR EMERGENCY USE

- FDA authorized emergency use of remdesivir to treat hospitalized patients of all ages with severe COVID-19 (May 1, 2020)<sup>1</sup>
  - Authorization is temporary; remdesivir remains an investigational drug and has not been formally approved by the FDA for any use
  - Severe suspected or confirmed COVID-19 disease defined as oxygen saturation  $\leq 94\%$  on room air, or requiring supplemental oxygen, or mechanical ventilation or requiring extracorporeal membrane oxygenation (ECMO)
- Remdesivir must be administered intravenously; optimal dosing and duration is still unknown
  - See [FDA's emergency use fact sheet](#) for recommended use<sup>2</sup>

1. U.S. Food and Drug Administration. Letter: emergency use authorization of remdesivir for the treatment of hospitalized 2019 coronavirus disease (COVID-19) patients. May 1, 2020. <https://www.fda.gov/media/137564/download>

2. U.S. Food and Drug Administration. Fact Sheet for health care providers: emergency use authorization (EUA) of remdesivir (gs-5734™). May 2020. <https://www.fda.gov/media/137566/download>

# REMDESIVIR APPROVED FOR EMERGENCY USE

- NIH study found patients taking remdesivir recovered faster and had lower mortality rate based on preliminary results
  - Randomized, double blinded controlled trial included 1,063 hospitalized patients with confirmed COVID-19 who had lung involvement and need for supplemental oxygen or had abnormal chest x-ray, or, requiring mechanical ventilation
    - 31% faster recovery; median time to recovery was 11 days with remdesivir (vs. 15 days on placebo)
    - Recovery defined as being well enough for hospital discharge or returning to normal activity level
  - Mortality rate was 8% with remdesivir (vs. 11.6% in placebo group)

National Institutes of Health. NIH clinical trial shows remdesivir accelerates recovery from advanced COVID-19. April 29, 2020.  
<https://www.nih.gov/news-events/news-releases/nih-clinical-trial-shows-remdesivir-accelerates-recovery-advanced-covid-19>

# REMDESIVIR APPROVED FOR EMERGENCY USE

- Gilead study found similar clinical improvement for both the 5-day and 10-day treatment course
  - Randomized, multi-center clinical trials Included 397 hospitalized patients with severe COVID-19 who did not require mechanical ventilation
  - Time to clinical improvement for 50% of patients was 10 days in 5-day group and 11 days in 10-day group; more than half of patients in both treatment groups were discharged from the hospital by day 14

Gilead. Gilead announces results from phase 3 trial of investigational antiviral remdesivir in patients with severe COVID-19. April 29, 2020. <https://www.gilead.com/news-and-press/press-room/press-releases/2020/4/gilead-announces-results-from-phase-3-trial-of-investigational-antiviral-remdesivir-in-patients-with-severe-covid-19>

**PEDIATRIC  
MULTI-SYSTEM  
INFLAMMATORY  
SYNDROME**

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# PEDIATRIC MULTI-SYSTEM INFLAMMATORY SYNDROME

- Providers in United Kingdom, other countries, and some U.S. cities reporting pediatric multi-system inflammatory syndrome.
  - Patients with “overlapping features of toxic shock syndrome and atypical [incomplete] Kawasaki disease (KD)”<sup>1,2</sup>
  - Some patients positive by PCR for SARS-CoV-2
- Cases series (n=8) from the UK<sup>3</sup>
  - Age range: 4-14 years
  - Persistent fever; most with abdominal pain, rash, and conjunctivitis
  - laboratory markers of inflammation, single/multiple organ systems
  - All 8 patients had positive serologic tests for SARS-CoV-2

1. Paediatric Intensive Care Society. PICS Statement: Increased number of reported cases of novel presentation of multi-system inflammatory disease. April 27, 2020. <https://picsociety.uk/wp-content/uploads/2020/04/PICS-statement-re-novel-KD-C19-presentation-v2-27042020.pdf>

2. Jones VG, Mills M, Suarez D, et al. COVID-19 and kawasaki disease: novel virus and novel case. *Hosp Pediatr*. 2020. <https://hosppeds.aappublications.org/content/hosppeds/early/2020/04/06/hped.2020-0123.full.pdf>

3. Riphagen S, Gomez X, Gonzalez-Martinez C, Wilkinson N, Theocharis P. Hyperinflammatory shock in children during the COVID-19 pandemic. *Lancet*. May 7, 2020. [https://doi.org/10.1016/S0140-6736\(20\)31094-1](https://doi.org/10.1016/S0140-6736(20)31094-1)

# PEDIATRIC MULTI-SYSTEM INFLAMMATORY SYNDROME

- NYC Health Department Health Alert #13 describes initial outreach to NYC pediatric ICUs
  - Identified 15 cases of incomplete or typical KD (Ages: toddler – adolescent)
  - All had subjective or measured fever and more than half reported rash, abdominal pain, vomiting, or diarrhea
  - PCR results for SARS-CoV-2: 4 positive, 10 negative, and 1 indeterminate
  - More than half required blood pressure support; five required mechanical ventilation
  - No fatalities
- Relationship to COVID-19 infection not yet defined

NYC Health Department. Health alert #13: pediatric multi-system inflammatory syndrome potentially associated with COVID-19. May 4, 2020. <https://www1.nyc.gov/assets/doh/downloads/pdf/han/alert/2020/covid-19-pediatric-multi-system-inflammatory-syndrome.pdf>

# PEDIATRIC MULTI-SYSTEM INFLAMMATORY SYNDROME

- Immediately refer suspected cases to specialist in pediatric infectious disease, rheumatology, and critical care, as indicated
- Early diagnosis and treatment of patients meeting full or partial criteria for Kawasaki disease is critical to preventing end-organ damage and other long-term complications
  - Patients meeting criteria for Kawasaki disease should be treated with intravenous immunoglobulin and aspirin
- Report by calling the Provider Access Line: **(866) 692-3641** any patient who meets the following criteria;
  - <21 years old, with persistent fever (4 or more days), and incomplete Kawasaki disease, typical Kawasaki disease, and/or toxic shock syndrome-like presentation
  - AND**
  - No alternative etiology identified that explains the clinical presentation (Note: patients should be reported regardless of SARS-CoV-2 PCR test result)

## COAGULOPATHY AND COVID-19

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# COAGULOPATHY AND COVID-19

- Several observational and case reports from Asia, Europe, and the U.S. suggest high rate of thrombotic complications in COVID-19<sup>1-7</sup>
- Spiezia et al. found **fibrinogen and D-dimer levels were significantly higher in COVID-19 patients** than controls ( $p < 0.0001$  in both comparisons)<sup>8</sup>
  - Based on data collected from 22 consecutive patients admitted over 12 days to ICU with COVID-19, associated respiratory failure compared to 44 healthy non-CVOID-19 patients matched controls
- Most common among severe cases (e.g., patients admitted to the ICU)

# COAGULOPATHY AND COVID-19

## REFERENCES

1. Klok FA, Kruij MJHA , van der Meer NJM, et al. Confirmation of the high cumulative incidence of thrombotic complications in critically ill ICU patients with COVID-19: an updated analysis. *Thromb Res.* April 30, 2020. <https://doi.org/10.1016/j.thromres.2020.04.041>
2. Lodigiani C, Lapichino G, Carenzo L, et al. Venous and arterial thromboembolic complications in covid-19 patients admitted to an academic hospital in Milan, Italy. *Thromb Res.* April 23, 2020. <https://doi.org/10.1016/j.thromres.2020.04.024>
3. Ziehr DR, Alladina J, Petri CR, et al. Respiratory pathophysiology of mechanically ventilated patients with COVID-19: a cohort study. *Am J Respir Crit Care Med.* April 29, 2020. <https://doi.org/10.1164/rccm.202004-1163LE>
4. Llitjos JF, Leclerc M, Chochois C, et al. High incidence of venous thromboembolic events in anticoagulated severe COVID-19 patients. *J Thromb Haemost.* April 22, 2020. <https://doi.org/10.1111/jth.14869>
5. Cui S, Chen S, Li X, et al. Prevalence of venous thromboembolism in patients with severe novel coronavirus pneumonia. *J Thromb Haemost.* April 9, 2020. <https://doi.org/10.1111/jth.14830>
6. Poissy J, Goutay J, Caplan M, et al. Pulmonary embolism in COVID-19 patients: awareness of an increased prevalence. *Circulation.* April 24, 2020. <https://doi.org/10.1161/circulationaha.120.047430>
7. Goyal P, Choi JJ, Pinheiro LC, et al. Clinical characteristics of COVID-19 in New York City. *N Engl J Med.* April 17, 2020. <https://doi.org/10.1056/nejmc2010419>
8. Spiezia L, Boscolo A, Poletto F, et al. COVID-19-related severe hypercoagulability in patients admitted to intensive care unit for acute respiratory failure. *Thromb Haemost.* April 21, 2020. <https://doi.org/10.1055/s-0040-1710018>

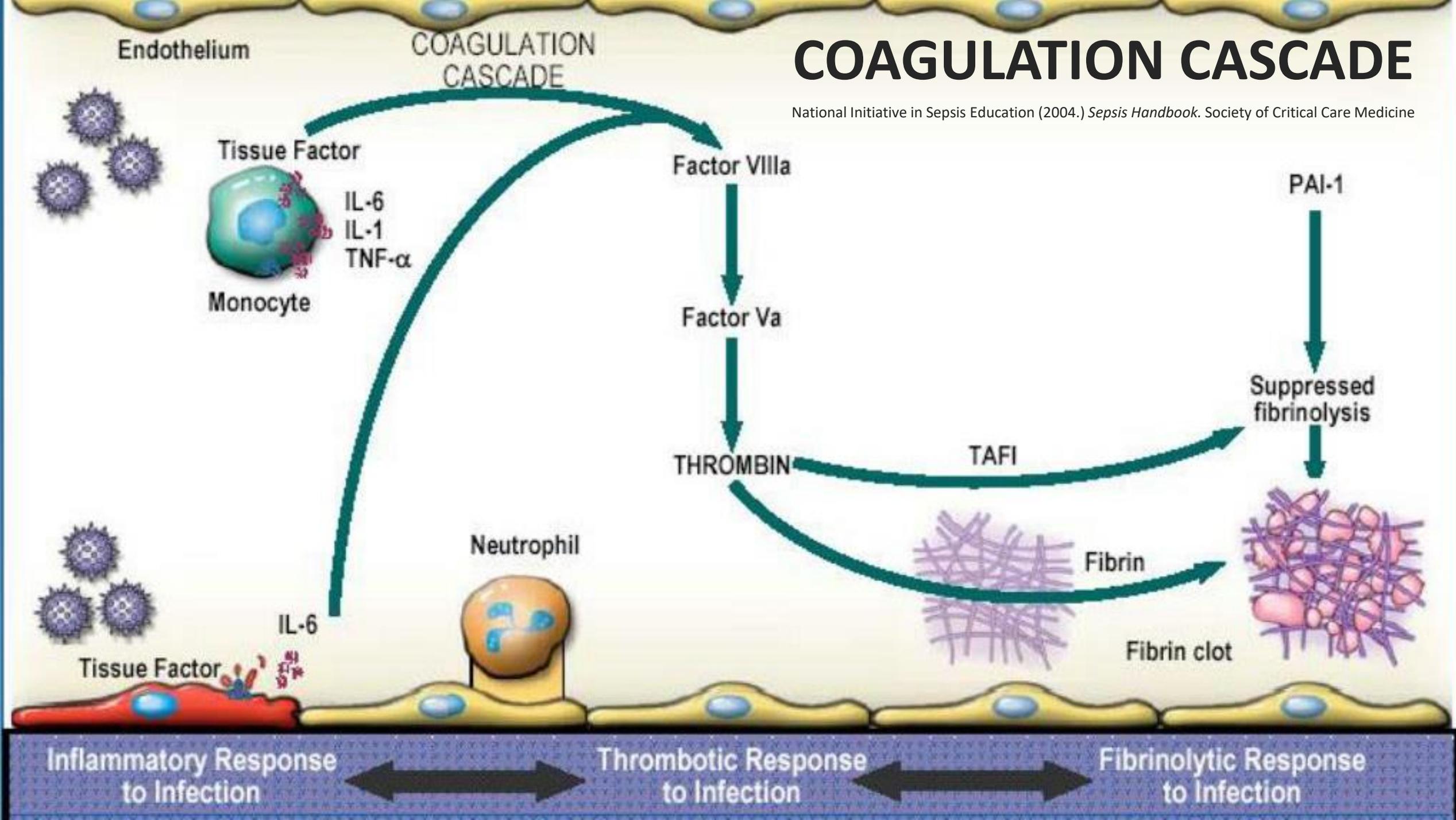
# COAGULOPATHY AND COVID-19

- Sepsis – especially with lung injury – can predispose to coagulopathy
  - Many types of microbes can cause sepsis, including bacteria, fungi, and viruses, including SARS-CoV-2
- Acute Respiratory Distress Syndrome (ARDS) is a pattern of lung injury that can occur in severe sepsis, and also occurs in severe COVID-19
  - **Prophylactic anticoagulation** is generally recommended in ARDS
    - Prophylactic = lower dose anticoagulant medication in patients without current thrombotic disease to prevent the formation of clots
  - Therapeutic anticoagulation (unless otherwise indicated) has **not** been shown to improve mortality in ARDS
    - Therapeutic = higher dose (therapeutic intensity) anticoagulant medication to prevent the propagation of and promote dissolution of existing clots.
- Is the coagulopathy seen in COVID-19 just a feature of ARDS or sepsis?

National Initiative in Sepsis Education (2004.) *Sepsis Handbook*. Society of Critical Care Medicine.

# COAGULATION CASCADE

National Initiative in Sepsis Education (2004.) *Sepsis Handbook*. Society of Critical Care Medicine



# COAGULOPATHY AND RESPIRATORY CORONAVIRUSES

- Dysregulation of coagulation cascade and subsequent formation of intra-alveolar or systemic fibrin clots are prominent findings in SARS, MERS, and COVID-19<sup>1</sup>
  - Demonstrated in both humans and animal models
  - Attributed to prothrombotic response which attempts to prevent diffuse alveolar hemorrhage, but can instead result in overt clot formation
- Coronaviruses may cause direct liver injury<sup>2</sup>

1. Giannis D, Ziogas IA, Gianni P. Coagulation disorders in coronavirus infected patients: COVID-19, SARS-CoV-1, MERS-CoV and lessons from the past. *J Clin Virol*. 2020;127:104362. <https://doi.org/10.1016/j.jcv.2020.104362>

2. Xu L, Liu J, Lu M, Yang D, Zheng X. Liver injury during highly pathogenic human coronavirus infections. *Liver Int*. 2020;40:998-1004. <https://doi.org/10.1111/liv.14435>

# COAGULOPATHY AND COVID-19: PROPHYLACTIC ANTICOAGULATION

- Tang et al. found a survival benefit for **prophylactic anticoagulation** using low molecular weight heparin vs. no anticoagulation in an observational study of patients with severe COVID-19 disease<sup>1</sup>
- Found lower 28-day mortality among prophylactically anticoagulated patients with higher **sepsis-induced coagulopathy score and D-dimer** levels
- Heparin may have additional benefits in COVID-19 beyond anticoagulation<sup>2</sup>
  - Direct antiviral effects?
  - Anti-inflammatory effects?
  - Endothelial protection?

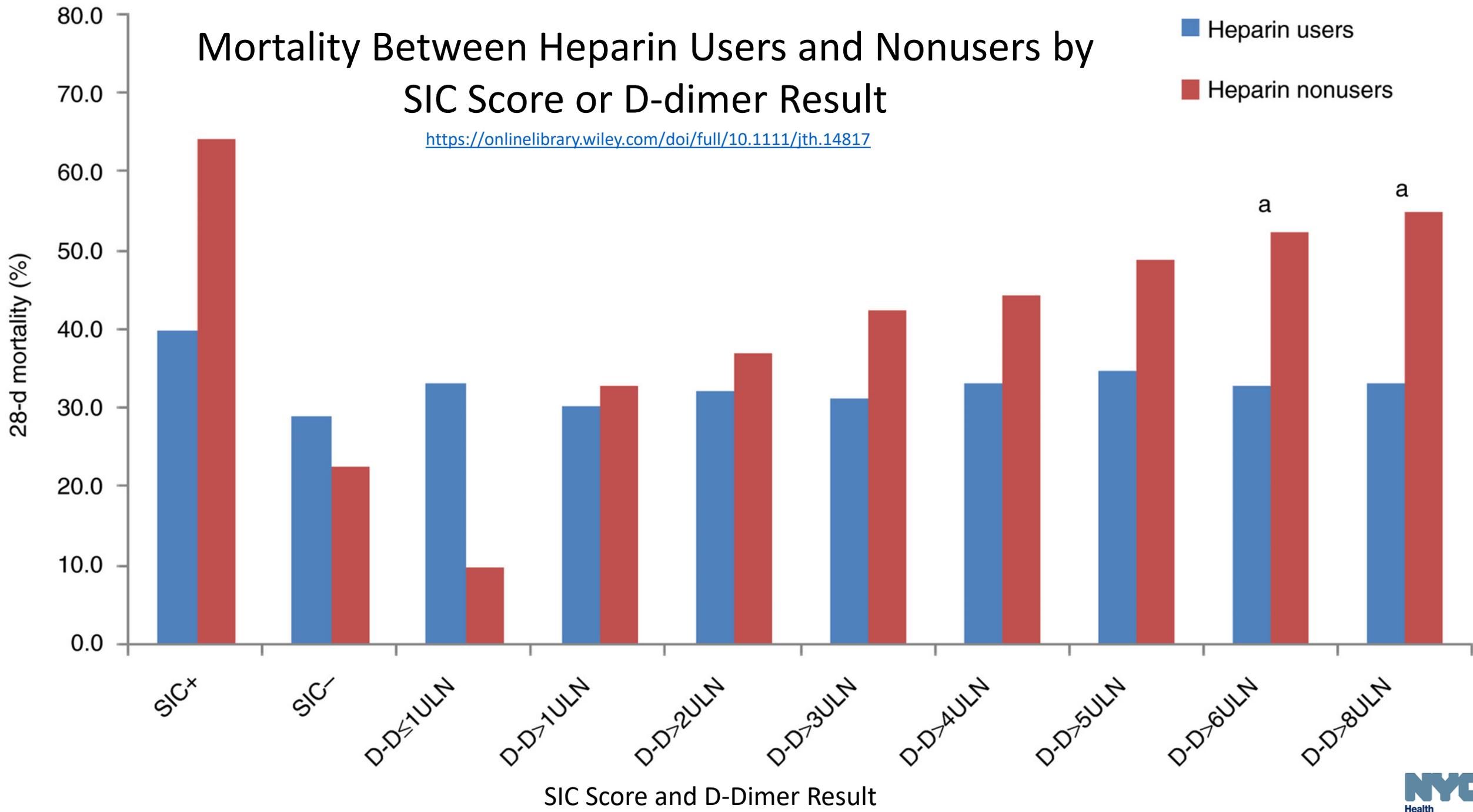
1. Tang N, Bai H, Chen X, Gong J, Li D, Sun Z. Anticoagulant treatment is associated with decreased mortality in severe coronavirus disease 2019 patients with coagulopathy. *J Thromb Haemost.* 2020;18:1094-1099. <https://doi.org/10.1111/jth.14817>

2. Thachil J. The versatile heparin in COVID-19. *J Thromb Haemost.* 2020;18:1020-1022. <https://doi.org/10.1111/jth.14821>

# Mortality Between Heparin Users and Nonusers by SIC Score or D-dimer Result

<https://onlinelibrary.wiley.com/doi/full/10.1111/jth.14817>

■ Heparin users  
■ Heparin nonusers



# COAGULOPATHY AND COVID-19: HIGH RISK OF THROMBOSIS

- Helms et al. did a multi-institutional, prospective cohort study of 150 COVID-19 patients with ARDS admitted to ICU
- Sixty-four clinically relevant thrombotic complications while on **prophylactic anticoagulation**
  - Low incidence of bleeding complications (2.7%)
  - Most patients (>95%) had elevated D-dimer and fibrinogen
- COVID-19 ARDS patients developed more thrombotic complications and had coagulation parameters different than what is usually seen in non-COVID-19 ARDS patients
- Consider higher level of anticoagulation than in usual critically ill patients

Helms J, Tacquard C, Severac F, et al. High risk of thrombosis in patients with severe SARS-CoV-2 infection: a multicenter prospective cohort study [published online ahead of print, 2020 May 4]. *Intensive Care Med.* 2020;1-10. <https://10.1007/s00134-020-06062-x>

# COAGULOPATHY AND COVID-19: HIGH RISK OF THROMBOSIS

- Sixty-four clinically relevant thrombotic complications while on **prophylactic anticoagulation**
  - Pulmonary emboli (most common)
  - Stroke (ischemia/hemorrhage)
  - Thrombotic occlusion of ECMO pump
  - Renal replacement therapy circuit clot (common amongst patients on CRRT)
  - Acute limb ischemia
  - Mesenteric ischemia



Pro Time	13.8 *	▲
I.N.R.	1.2 *	▲
PTT	25	▼
D-Dimer	8,573 *	▲
Fibrinogen	712	▲

Coagulation studies from patient with COVID-19 whose blood immediately clotted within a newly placed central line (I withdrew blood into all lumens of the central line and then flushed the lumens about a minute later. Flushing the line revealed small clots adherent to the clear portion of the catheter).

-@PulmCrit

Helms J, Tacquard C, Severac F, et al. High risk of thrombosis in patients with severe SARS-CoV-2 infection: a multicenter prospective cohort study [published online ahead of print, 2020 May 4]. *Intensive Care Med.* 2020;1-10. <https://10.1007/s00134-020-06062-x>

## COAGULOPATHY AND COVID-19: QUESTIONS

- What **labs** should be drawn on suspected COVID-19 patients?
- Should all **hospitalized** COVID-19 patients be anticoagulated?
- Should there be **empiric use of therapeutic anticoagulation and alternative therapies** (including tissue plasminogen activator and post-discharge thromboprophylaxis) for patients with severe COVID-19?
- Should patients receive anticoagulation on **discharge**?

# COAGULOPATHY AND COVID-19: INTERIM GUIDELINES

## International Society for Haemostasis and Thrombosis Interim Guidelines

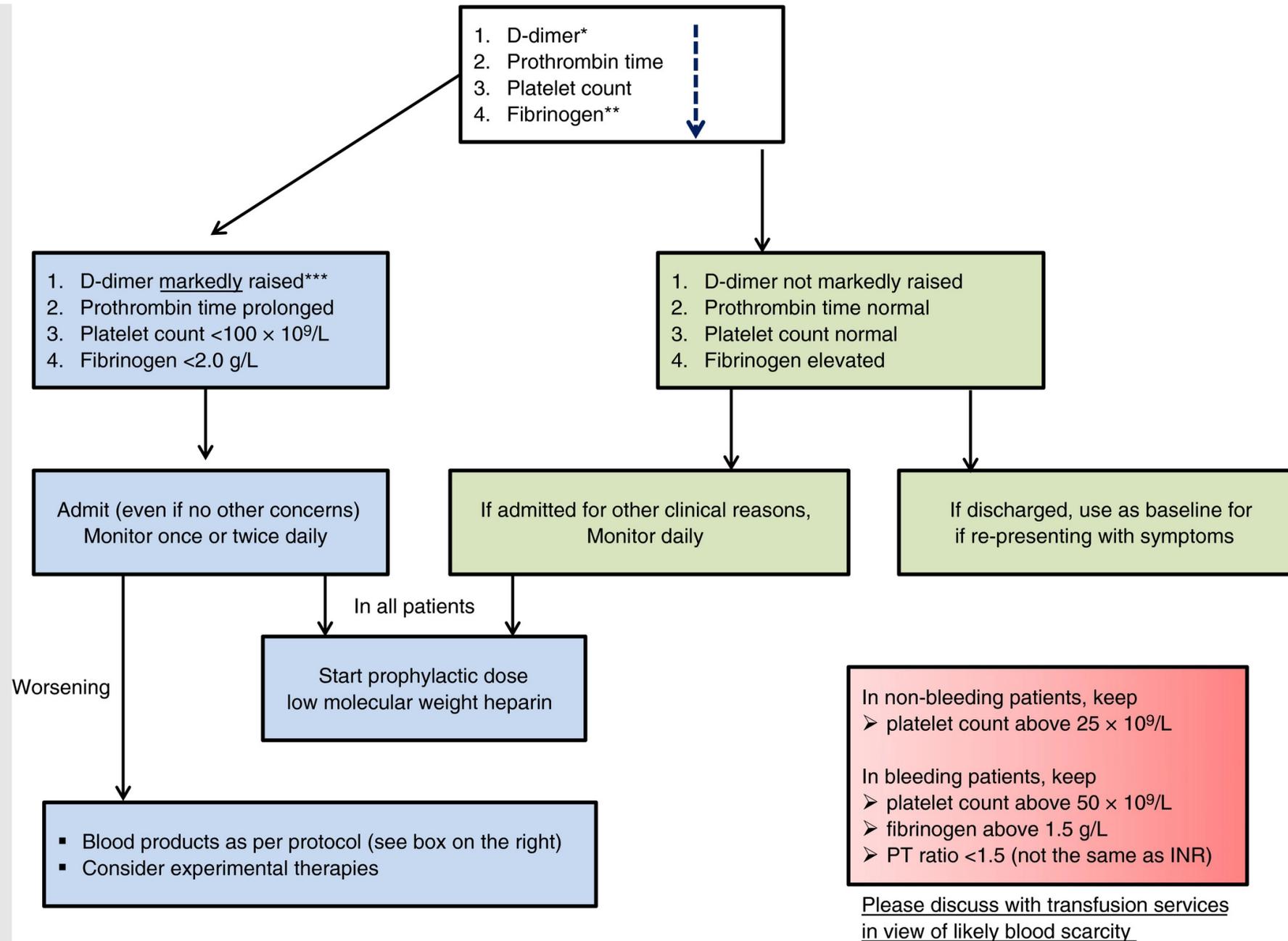
- Draw D-dimers, prothrombin time, and platelet count (in decreasing order of importance) in all patients with suspected COVID-19
- Administer prophylactic heparin for all hospitalized patients (unless there is a contraindication)

Thachil J, Tang N, Gando S, et al. ISTH interim guidance on recognition and management of coagulopathy in COVID-19. *J Thromb Haemost*. 2020;18:1023-1026. <https://doi.org/10.1111/jth.14810>

# COAGULOPATHY AND COVID-19: GUIDELINES

Thachil J, Tang N, Gando S, et al. ISTH interim guidance on recognition and management of coagulopathy in COVID-19. *J Thromb Haemost.* 2020;18:1023-1026.

<https://doi.org/10.1111/jth.14810>



# COAGULOPATHY AND COVID-19: EMERGING GUIDELINES

- Cohoon et al. developed interim guidance for anticoagulation in COVID-19
  - Reviewed institutions' anticoagulation protocols for COVID-19 patients in the USA and France
  - Protocols for management of thrombotic disease for COVID-19 patients are evolving based on anecdotes and individual expertise
- Most protocols advocated for prophylactic to intermediate intensity or multimodal anticoagulation in hospitalized patients
- Many protocols advocated for extended post-hospital discharge anticoagulation of COVID-19 patients

Cohoon KP, Mahé G., Tafur AJ, Spyropoulos AC. Emergence of institutional antithrombotic protocols for coronavirus 2019. *Res Pract Thromb Haemost.* April 28, 2020. <https://doi.org/10.1002/rth2.12358>

LABORATORY  
TESTING  
COVID-19

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# LABORATORY TESTING COVID-19: TEST TYPES

## **Detection of VIRAL NUCLEIC ACID:** nucleic acid amplification test (NAAT)

- Molecular test detect viral genetic material (SARS-CoV-2 RNA)
- Best test to diagnose acute infection, inform clinical evaluation and direct infection prevention and control practices
- Performed on respiratory specimens (e.g., nasopharyngeal or oropharyngeal swab, nasal swab, sputum, saliva)

## **Detection of IMMUNE RESPONSE to virus:** Antibody/Serology tests

- Detect SARS-CoV-2 specific antibodies – present 1-3 weeks after infection
- Evidence of a previous infection, NOT for diagnostic purposes
- Serosurvey, identification of candidate plasma donors
- Performed on blood (serum, dried blood spot)

# LABORATORY TESTING COVID-19: MOLECULAR TESTS

- NAAT used to detect viral RNA
  - Usually rRT-PCR
- NAAT tests are extremely sensitive and able to detect minimal amounts of virus or viral fragments of RNA
  - It cannot distinguish between viable virus or RNA shed
- Viral shedding may occur for days to weeks
  - A positive NAAT does not necessarily mean the person is infectious

# LABORATORY TESTING COVID-19: SEROLOGIC TESTS

- Serologic tests are intended to detect SARS CoV-2 antibodies
  - Tests can be for a specific antibody type (e.g., IgG, IgA, IgM) or a combination
- A **positive** result indicates the presence of antibodies that likely resulted from an infection with SARS-CoV-2
  - **Some tests may cross react with related coronavirus**
- A **negative** result is interpreted as NO previous infection
  - However, it may take 1 to 3 weeks for antibodies to reach a detectable level following infection
  - For persons who are currently or recently infected, rRT-PCR is indicated
  - Repeat testing may be indicated in persons with recent illness

# LABORATORY TESTING COVID-19: SEROLOGIC TESTS

- At this time, it is **NOT** known if antibodies provide protection against re-infection
  - If there is immunity, it is also not known how long immunity lasts (months to years or lifelong)
  - As such, **a positive test should not be used for return-to-work decisions or relaxation of other precautions**
- Serology testing can be used to:
  - Determine prevalence of SARS-CoV-2 infection among a population
  - Identify individual patients who may be candidates to donate plasma for therapeutic purposes
  - Verification of vaccine response once antibody correlate(s) of protection identified

1. NYC Health Department. Health alert #11: current status of SARS-CoV-2 serologic testing. April 22, 2020.  
<https://www1.nyc.gov/assets/doh/downloads/pdf/han/alert/2020/covid-19-status-of-serologic-testing.pdf>

2. Infectious Diseases Society of America. IDSA COVID-19 antibody testing primer. May 4, 2020.  
<https://www.idsociety.org/globalassets/idsa/public-health/covid-19/idsa-covid-19-antibody-testing-primer.pdf>

3. World Health Organization. “Immunity passports” in the context of COVID-19: scientific brief. April 24, 2020.  
<https://apps.who.int/iris/handle/10665/331866>

# LABORATORY TESTING COVID-19: FDA EMERGENCY USE AUTHORIZATION

- Normal test approval process requires extensive and rigorous evaluation by U.S. Food and Drug Administration (FDA)
- During a public health emergency, FDA can issue emergency use authorization (EUA) to expedite review process and grant temporary approval
- CLIA (Clinical Laboratory Improvement Amendments) used to determine allowable setting for tests (e.g., laboratory, doctor's office)
- Many NAATs for SARS-CoV-2 have received EUA and most are designed to be performed in a laboratory setting
  - A small number (those with “w” in the authorized setting column on the linked website) are called Point of Care (POC) tests, designed for patient settings such as urgent care centers, doctor's offices, and Emergency Departments
  - If the FDA grants an EUA for a POC test, it may be classified as “waived” by CLIA. For the duration of the national emergency declaration for COVID-19, such tests can be performed in a patient care setting with a certificate of waiver from CLIA

U.S. Food and Drug Administration. Emergency use authorizations (EUA) for COVID-19. <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/medical-devices-and-covid-19-pandemic#EUA>

# LABORATORY TESTING COVID-19: SEROLOGY TESTS AND FDA

- NEW: FDA POLICY CHANGE as of May 4, 2020
- All commercial manufacturers of serology tests must submit EUA requests with validation data within 10 business days of notification to the FDA of their validation testing (or 10 business days from the policy approval, 5/4/2020) or **remove the test from the market**
- Specific performance thresholds for sensitivity and specificity of serology tests recommended by FDA
- Streamlined process for EUA submissions for serology tests introduced
- “The FDA will continue to take steps to appropriately balance assurances that an antibody test is accurate and reliable with timely access to such tests as the continually evolving circumstances and public health needs warrant.”

1. U.S. Food and Drug Administration. Emergency use authorizations (EUA) for COVID-19. <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/medical-devices-and-covid-19-pandemic#EUA>
2. U.S. Food and Drug Administration. Insight into FDA’s revised policy on antibody tests: prioritizing access and accuracy. <https://www.fda.gov/news-events/fda-voices/insight-fdas-revised-policy-antibody-tests-prioritizing-access-and-accuracy>
3. U.S. Food and Drug Administration. Policy for coronavirus disease 2019 tests during the public health emergency (revised). May 2020. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised>

# LABORATORY TESTING COVID-19: NYC PUBLIC HEALTH LABORATORY

- NYC Public Health Laboratory (PHL) now accepting nasal swabs and saliva for COVID-19 testing
  - This is in addition to previously accepted specimens, including combined nasopharyngeal and oropharyngeal swabs, and lower respiratory specimens
- Use synthetic fiber swabs with plastic shaft; flocked swabs preferred
  - Dacron or rayon swabs also acceptable
  - Do not use calcium alginate swabs, cotton swabs, or swabs with wooden shafts
- PHL testing only offered for hospitalized patients with acute lower respiratory illness
- To obtain approval, contact the NYC Health Department Coronavirus Testing Call Center by calling the Provider Access Line (PAL) at 866-692-3641 866-692-3641

NYC Public Health Laboratory. Guidance for clinical laboratories handling specimens for COVID-19 testing. April 17, 2020.  
<https://www1.nyc.gov/assets/doh/downloads/pdf/labs/guidance-lab-2019-ncov-specimen-testing.pdf>

# LABORATORY TESTING COVID-19: MOVING FORWARD

- Use of testing in the coming months, as we begin to relax mitigation policies
  - Extensive viral NAAT testing will be critical to finding people with COVID-19
  - Contact tracing will be used to curb spread of COVID-19
- How serosurvey testing data will be used
  - Determine how widespread COVID19 was within NYC
  - Provide insight into the immune response to the virus

# RESOURCES ON COVID-19

## NYC Health Department:

- Provider page: [on.nyc.gov/covid19provider](https://on.nyc.gov/covid19provider)
- Data page: [on.nyc.gov/covid19data](https://on.nyc.gov/covid19data)
- Weekly webinars: Fridays, 2 PM (sign up on provider page)
- Dear Colleague COVID-19 newsletters (sign up for *City Health Information* subscription at: [nyc.gov/health/register](https://nyc.gov/health/register))
- NYC Health Alert Network (sign up at <https://www1.nyc.gov/site/doh/providers/resources/health-alert-network.page>)
- Provider Access Line: **866-692-3641**

## Other sources:

- CDC: <https://www.cdc.gov/coronavirus/2019-ncov/index.html>
- Vital Strategies/Resolve to Save Lives: <https://www.vitalstrategies.org/covid>
- ASTHO: <https://www.astho.org/COVID-19>
- NACCHO: <https://www.naccho.org/programs/our-covid-19-response>

QUESTIONS?

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