Closing the COVID-19 Test to Treatment Gap Webinar

February 24, 2022

Access speaker bios here:
https://files.asprtracie.hhs.gov/documents/aspr-test-to-treatment-gap-webinar-bios.pdf

Access the recording here:
https://attendee.gotowebinar.com/recording/3795092347924826383

Unclassified

T R A C I E
HEALTHCARE EMERGENCY PREPAREDNESS
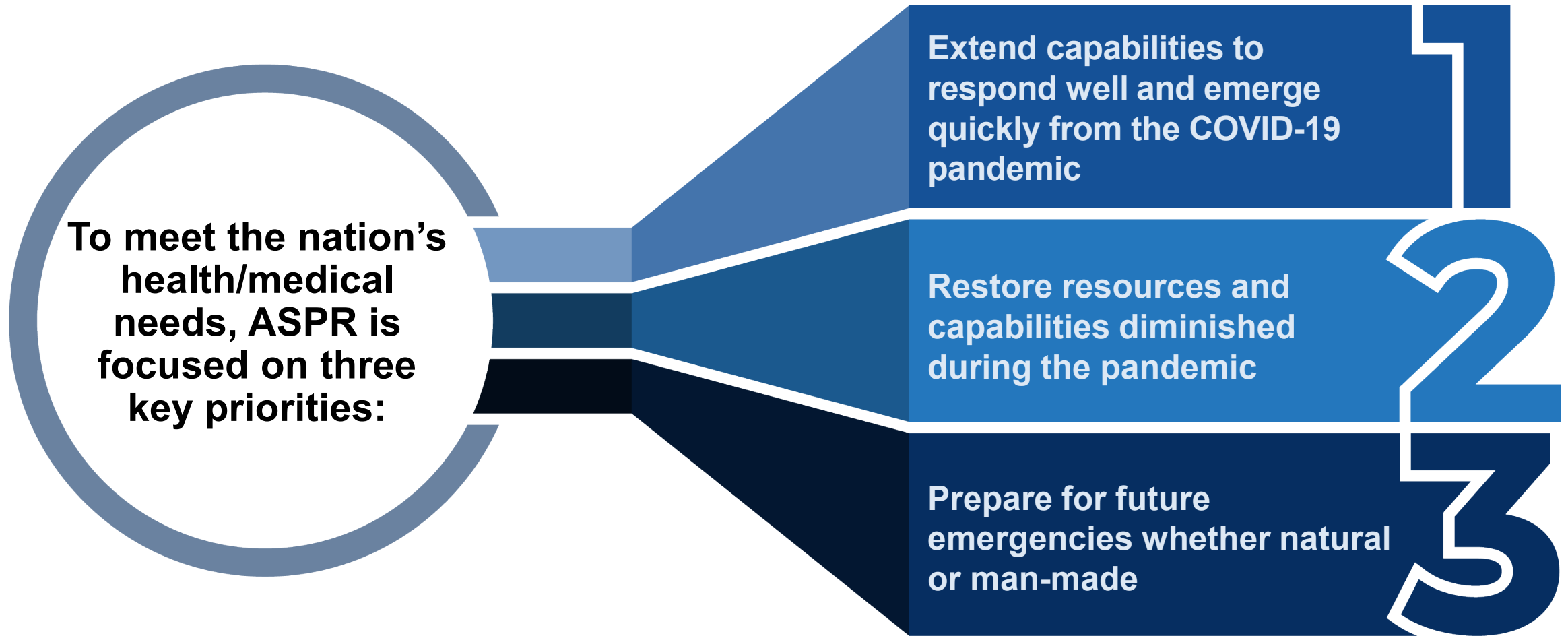INFORMATION GATEWAY

Welcome/Opening Remarks

Shayne Brannman, MS, MA
Director, ASPR TRACIE

Disclaimer

The views, opinions, and/or findings expressed are those of the author and should not be interpreted as representing the official views or policies of the U.S. Department of Health and Human Services or the U.S. Government.

ASPR Key Priorities

To meet the nation's health/medical needs, ASPR is focused on three key priorities:

1 Extend capabilities to respond well and emerge quickly from the COVID-19 pandemic

2 Restore resources and capabilities diminished during the pandemic

3 Prepare for future emergencies whether natural or man-made

ASPR TRACIE: Three Domains

TECHNICAL RESOURCES

- Self-service collection of audience-tailored materials
- Subject-specific, SME-reviewed "Topic Collections"
- Unpublished and SME peer-reviewed materials highlighting real-life tools and experiences

asprtracie.hhs.gov

ASSISTANCE CENTER

- Personalized support and responses to requests for information and technical assistance
- Accessible by toll-free number (1844-5-TRACIE), email (askasprtracie@hhs.gov), or web form (ASPRtracie.hhs.gov)

1-844-5-TRACIE

INFORMATION EXCHANGE

- Area for password-protected discussion among vetted users in near real-time
- Ability to support chats and the peer-to-peer exchange of user-developed templates, plans, and other materials

askasprtracie@hhs.gov

Cicely Waters, MS
Moderator
Director, Office of External Affairs
Office of the Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human services
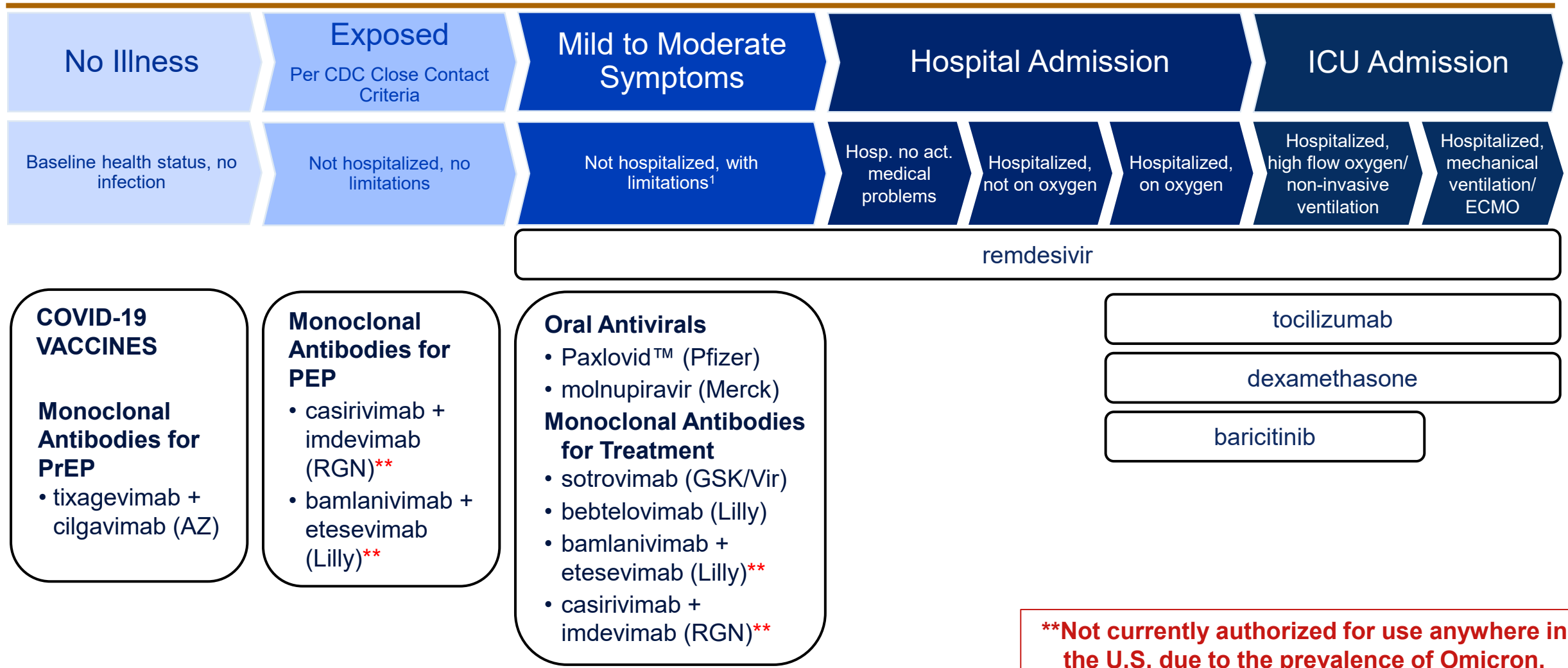
Objectives & Setting the Stage

- Throughout COVID-19 response, federal government steadfast in supporting health care community

- Environment remains dynamic

- Landscape of medical countermeasures has evolved

- Provide overview of COVID-19 therapeutics landscape

- Highlight initiatives to help close Test to Treatment gap

- Discussion

- Q/A

COVID-19 Therapeutics Landscape

Derek Eisnor, MD

Medical Officer, Division of Clinical Development,
Biomedical/Advanced Research and Development Authority (BARDA)
COVID-19 Allocation and Distribution Lead, HHS ASPR

Summary of COVID-19 Preventative Agents & Therapeutics

No Illness	Exposed Per CDC Close Contact Criteria	Mild to Moderate Symptoms	Hospital Admission			ICU Admission	
Baseline health status, no infection	Not hospitalized, no limitations	Not hospitalized, with limitations[1]	Hosp. no act. medical problems	Hospitalized, not on oxygen	Hospitalized, on oxygen	Hospitalized, high flow oxygen/ non-invasive ventilation	Hospitalized, mechanical ventilation/ ECMO

remdesivir

COVID-19 VACCINES

Monoclonal Antibodies for PrEP
- tixagevimab + cilgavimab (AZ)

Monoclonal Antibodies for PEP
- casirivimab + imdevimab (RGN)**
- bamlanivimab + etesevimab (Lilly)**

Oral Antivirals
- Paxlovid™ (Pfizer)
- molnupiravir (Merck)

Monoclonal Antibodies for Treatment
- sotrovimab (GSK/Vir)
- bebtelovimab (Lilly)
- bamlanivimab + etesevimab (Lilly)**
- casirivimab + imdevimab (RGN)**

tocilizumab

dexamethasone

baricitinib

**Not currently authorized for use anywhere in the U.S. due to the prevalence of Omicron.

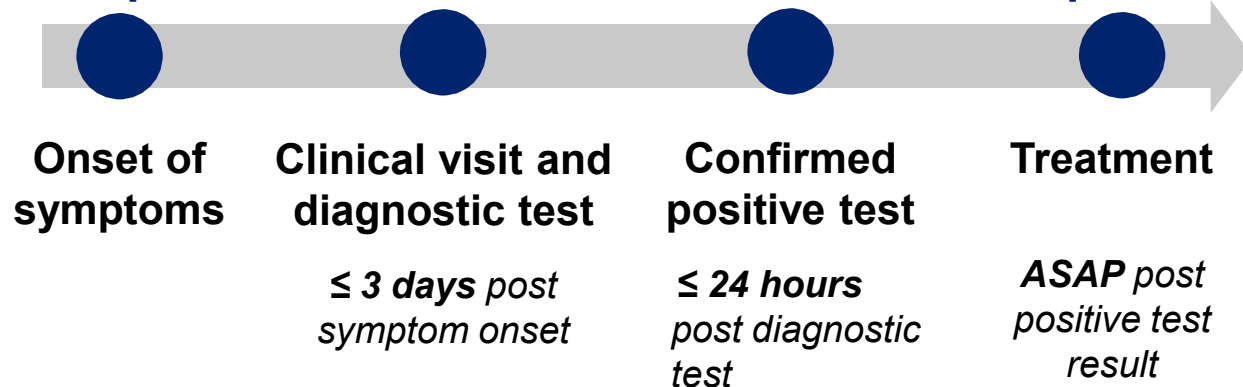[1] NIH COVID-19 Treatment Guidelines https://www.covid19treatmentguidelines.nih.gov/about-the-guidelines/whats-new/
Therapeutic Management of Nonhospitalized Adults With COVID-19 https://www.covid19treatmentguidelines.nih.gov/management/clinical-management/nonhospitalized-adults--therapeutic-management/

Pathway to Treatment:
Patient with Confirmed COVID-19 Infection

- Treatment likely most beneficial to patients if given **early in symptom progression**
- EUA requires administration of **treatment as soon as possible after** confirmed positive test result and within **5 to 10 days of symptom onset***
- Strong **partnership and communication** between patients and HCP to get right treatment to right patients at right time
- Fast testing turnaround needed, to efficiently **identify positive tests** and **schedule for treatment**

Early administration of treatment needs fast testing turn-around and patient scheduling

Planning required for "Test to Treat" models

Example of timeline which would fulfill EUA requirements

Onset of symptoms

Clinical visit and diagnostic test
≤ 3 days post symptom onset

Confirmed positive test
≤ 24 hours post diagnostic test

Treatment
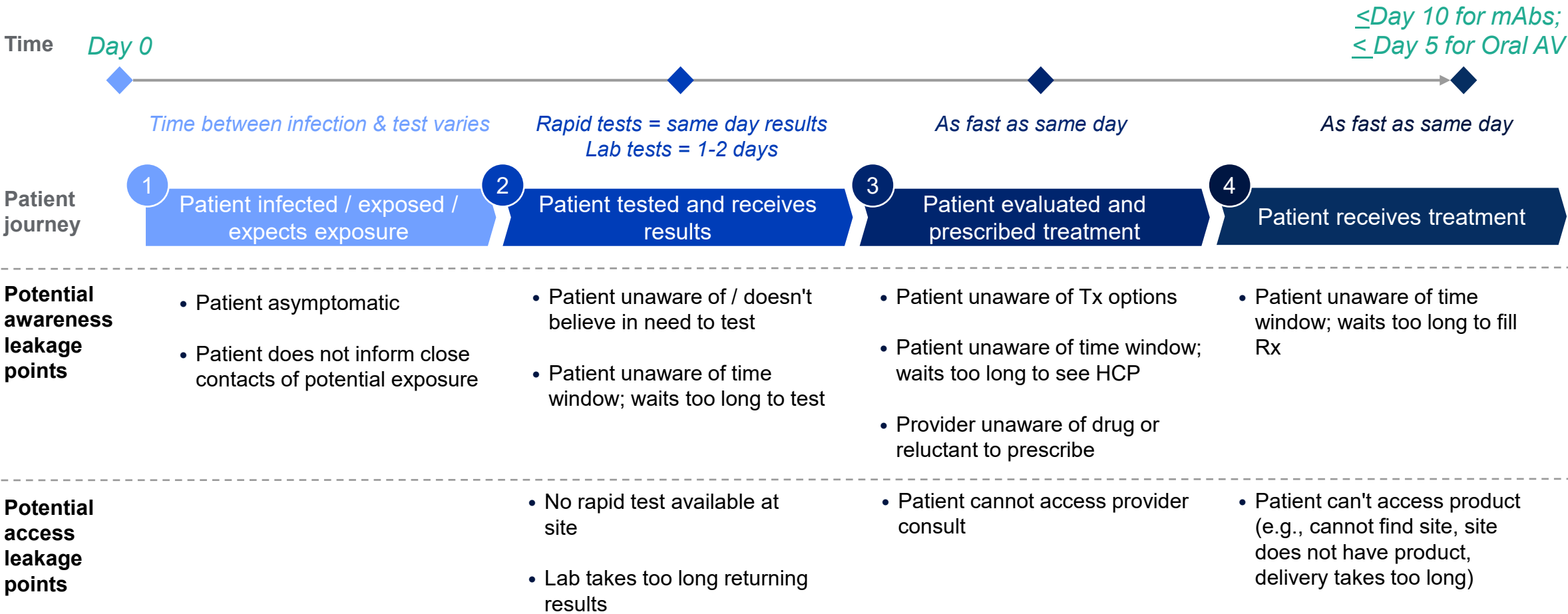*ASAP* post positive test result

Treatment required within 5 to 10 days of symptom onset *Testing sites should recommend COVID+ patients that are high risk confer with their HCP on potential suitability for Tx*

*Please reference EUA factsheet for specific treatment guidelines including recommended treatment window

Minimize Leakages in the Patient Journey Around Awareness & Access

Time

Day 0

<u><Day 10 for mAbs;</u>
<u>< Day 5 for Oral AV</u>

Time between infection & test varies

Rapid tests = same day results
Lab tests = 1-2 days

As fast as same day

As fast as same day

Patient journey

1 Patient infected / exposed / expects exposure

2 Patient tested and receives results

3 Patient evaluated and prescribed treatment

4 Patient receives treatment

Potential awareness leakage points

- Patient asymptomatic
- Patient does not inform close contacts of potential exposure

- Patient unaware of / doesn't believe in need to test
- Patient unaware of time window; waits too long to test

- Patient unaware of Tx options
- Patient unaware of time window; waits too long to see HCP
- Provider unaware of drug or reluctant to prescribe

- Patient unaware of time window; waits too long to fill Rx

Potential access leakage points

- No rapid test available at site
- Lab takes too long returning results

- Patient cannot access provider consult

- Patient can't access product (e.g., cannot find site, site does not have product, delivery takes too long)

Test to Treat

Meg Sullivan, MD, MPH
Acting Chief Medical Officer, HHS ASPR

COVID-19 Test to Treat Strategy: Overall Goals

- Facilitate **early diagnosis and rapid linkage to treatment** for individuals with COVID-19 who are at **high risk for complications.**

- Prevent disease progression and transmission through early diagnosis and treatment of high-risk individuals, thereby **reducing morbidity and mortality** caused by COVID-19

- **Reduce disparities in COVID-19 outcomes** through equitable strategies that prioritize access to tests and reduce barriers to treatments for high-risk individuals disproportionately impacted by COVID-19

Test to Treat Overview

- ***Test to Treat efforts aim to address challenges with patients obtaining therapeutics, <u>including</u>:***
  - Consumer knowledge of "test to treat" guidance

  - Access to tests upon symptom onset

  - Access to healthcare provider (or treatment site for mAbs) within timeframe for treatment effectiveness

  - Provider knowledge of and comfort level with prescribing therapeutics

  - Equitable distribution of therapeutics, especially in the setting of limited supply

  - Provider/consumer locating site with medication in-stock

COVID-19 Test to Treat Strategy: Overall Goals

- **Increase COVID-19 test and treat health literacy.**
- **Ensure Access to Tests** for early diagnosis, with a specific focus on high-risk individuals.
- **Facilitate Rapid Linkage to Care after Positive Result**, with a specific focus on high-risk individuals.
- **Ensure Access to Therapeutics,** with a focus on equitable distribution.

Increase COVID-19 Test to Treat Health Literacy

- Include Test to Treat language on testing websites

Self-Testing

Updated Feb. 1, 2022   Languages ▾   Print

CDC has updated isolation and quarantine recommendations for the public, and is revising the CDC website to reflect these changes. These recommendations do not apply to healthcare personnel and do not supersede state, local, tribal, or territorial laws, rules, and regulations.

Free At-Home COVID-19 Tests: Order 4 free tests now so you have them when you need them.

If you test positive for COVID-19 and have one or more health conditions that increase your risk of becoming very sick, treatment may be available. Contact a health professional right away after a positive test to determine if you may be eligible, even if your symptoms are mild right now. Don't delay: Treatment must be started within the first few days to be effective.

What if you test Positive?

A **positive** at-home test result means that the test found the virus, and you very likely have COVID-19.

If you test positive, follow the latest CDC guidance for isolation ⤢.

If you test positive and have a weakened immune system or other health conditions ⤢, talk to a doctor as soon as possible about available treatment options ⤢.

What if you test Negative?

A **negative** at-home test result means that the test did not find the virus, and you may have a lower risk of spreading COVID-19 to others. Check your test kit's instructions for specific next steps. If you test negative, you should test again within a few days with at least 24 hours between tests.

If you test negative, follow the latest CDC guidance for self-testing ⤢.

https://www.cdc.gov/coronavirus/2019-ncov/testing/self-testing.html

https://www.covidtests.gov/

Increase COVID-19 Test to Treat Health Literacy

https://www.cdc.gov/coronavirus/2019-ncov/downloads/communication/print-resources/Test-Soon-Treat-Early.pdf

Increase COVID-19 Test to Treat Health Literacy

Increase COVID-19 Test to Treat Health Literacy/Ensure Access to Therapeutics

- Amplify existing resources, and develop additional resource for linkages to therapeutics for healthcare providers

https://covid-19-therapeutics-locator-dhhs.hub.arcgis.com/
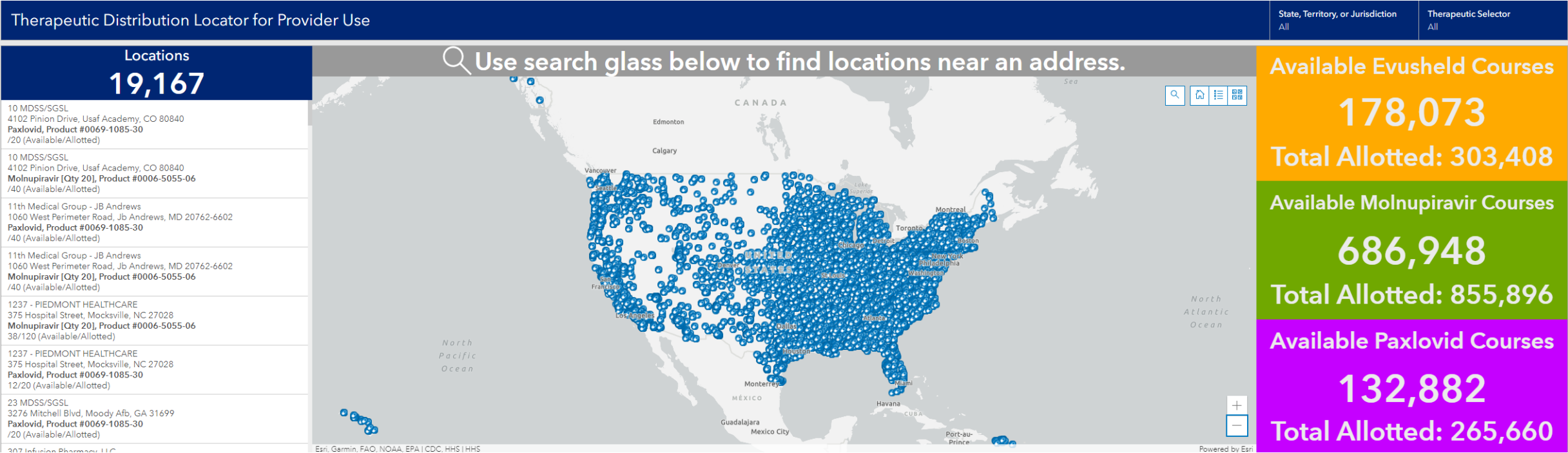
Weekly Stakeholder Engagements

- **Office Call Sessions**: HHS/ASPR Distribution and Administration of COVID-19 Therapeutics
  - Tuesdays (2:00-3:00PM ET)
  https://hhsasproea.zoomgov.com/j/1604329034?pwd=dGRwZTBETTJzWFIiQW83TXZSOFVNQT09
- **Stakeholder Call: Federal Retail Pharmacy Therapeutics Program (FRPTP) Participants**
  - Every other Tuesday (12:00-12:30PM ET); Next meeting March 8
- **Stakeholder Call: State and Territorial Health Officials**
  - Wednesdays (2:00-3:00PM ET)
- **Stakeholder Call: National Health Care and Medical Orgs and Associations**
  - Wednesdays (3:15-4:15PM ET)
  https://hhsasproea.zoomgov.com/j/1617766329?pwd=SEVPMzlQWDQyYWo2KzcxVU01THluQT09
- **Health Partners Ordering Portal (HPOP) Office Hours**
  - Thursdays (4:00-5:00PM ET)
  https://hhsasproea.zoomgov.com/j/1603047233?pwd=V3R4OG1LSDhUZ2I0Y0NhZkUxVlkxdz09
- **Federal COVID-19 Response: COVID-19 Therapeutics Clinical Webinar**
  - Every other Friday (12:00-1:00PM ET); Next meeting March 4
  https://hhsasproea.zoomgov.com/j/1617536991?pwd=NjFMcnJOUENuSFhtRFFtaWltejYzZz09

Questions or need the Zoom link for identified engagements?
Email us at COVID19Therapeutics@hhs.gov.

Increase COVID-19 Test to Treat Health Literacy/Ensure Access to Therapeutics

Health Resources & Services Administration

Explore +

HRSA
Health Center Program

Program Requirements	Quality Improvement	Program Opportunities	Health Center Data	Federal Tort Claims Act	About the Health Center Program

HRSA Health Center COVID-19 Therapeutics Program

i Engaging HRSA-Supported Health Centers

View participating health centers.

The Biden-Harris Administration is committed to ensuring our nation's underserved communities and those disproportionately affected by COVID-19 have equitable access to FDA-authorized or approved COVID-19 treatments, such as oral antiviral pills.

Test to Treat Models

- **Goal of Test to Treat:** Facilitate **early diagnosis and rapid linkage to treatment** for individuals with COVID-19 who are at **high risk for complications**, thereby **reducing morbidity and mortality** caused by COVID-19 and r**educing disparities in COVID-19 outcomes.**

- **Requirements for successful Test to Treat model for Oral Antivirals:**
  - Awareness by patient and provider of current testing and treatment guidance and availability.
  - Rapid access to test and results after symptom onset.
  - Timely access to a healthcare provider for evaluation and prescription.*
  - Timely access to medication (within a few days after symptom onset.)

Different requirement for mAbs

Test to Treat Initiative

- **Promote and support a variety of existing and new pathways for increased public and provider awareness, rapid access to tests, and/or linkage to treatment, including:**
  - Public education campaign and enhanced patient/consumer education and messaging
  - Provider outreach to increase knowledge of and comfort level with prescribing therapeutics
  - Ensuring access to and prepositioning tests in high priority settings & populations
  - Ensuring access to and prepositioning therapeutics in high priority settings and populations
    - HRSA-funded health centers
    - Working with states/territories to support efforts re: distribution to high priority locations
    - Prioritize other settings in which end-to-end test to treat model can be provided and/or disease burden is high
  - Ongoing efforts to increase supply of therapeutics
  - Exploring further opportunities for telehealth and other options for linkage to care and treatment

The Reliable Acquisition of Pharmaceuticals for Immediate Distribution (RAPID) Program for Long-Term Care Facilities

To facilitate early diagnosis and a rapid link to treatment options for high-risk individuals in long-term care facilities (LTCFs), HCORE is working on the RAPID initiative to increase access of oral antivirals (OAVs) to the long-term care community.

Guiding Principles

- RAPID would involve a separate federal cache that would not impact current partners allocations.

- Current data on OAVs shows only a ~62% utilization of Paxlovid and ~14% utilization of molnupiravir.

- Initially, this channel would utilize molnupiravir, which is in abundant supply, and potentially add Paxlovid when supply is not constrained.

- Aid states by identifying long-term care supporting pharmacies (LTCPs) within their jurisdictions.

- Identified LTCPs would have the ability to open order with guard rails, closely tied to utilization.

- Ensure maximum visibility by the states and jurisdictions on product supplies in LTCPs and LTCFs.

- Ensure equitable distribution of therapeutics.

- Provide an efficient and flexible logistical and distribution structure to meet the current and future demand for therapeutics when and where needed.

Panel Roundtable Discussion and Q&A

COVID19Therapeutics@HHS.gov

ASPR.HHS.gov

Contact ASPR TRACIE

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