

## COVID-19 Response and Reactivation Update

### July 21: Vaccine Trial at NM, Restore Illinois: Actions to Combat a Resurgence

*This twice-weekly communication is intended to facilitate the sharing of important clinical information about COVID-19 pandemic response and reactivation initiatives across Northwestern Medicine.*

Today's issue features information about a new vaccine trial launching at three locations across NM, as well as state guidelines from the recently released Restore Illinois: Action to Combat a Resurgence of COVID-19.

#### **COVID-19 VACCINE TRIAL TO OPEN SOON AT NORTHWESTERN MEDICINE**

Efforts are underway to find a safe and effective vaccine for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes COVID-19. While numerous investigational vaccines have been introduced, only a few candidates have shown the combination of promising results necessary to be considered true contenders: success in animal studies, evidence of efficacy and safety in pilot human clinical trials, and characteristics amenable to production and distribution on a scale that can address the global need.

The National Institutes of Health (NIH) is advancing the most promising COVID-19 vaccine candidates into large-scale clinical trials. The first vaccine to enter this rapid phase 3 pipeline is the Moderna mRNA-1273 SARS-CoV-2 vaccine, which encodes a stabilized prefusion spike trimer, S-2P. In the phase 1 clinical trial, the mRNA-1273 vaccine induced anti-SARS-CoV-2 immune responses in all participants, and no significant safety concerns were identified ([Jackson LA, et al. An mRNA vaccine against SARS-CoV-2 — preliminary report. \*New England Journal of Medicine\*. July 14, 2020](#)). The authors noted that development of this vaccine that normally would require years were finished in about two months. The definitive phase 3 clinical trial of the Moderna vaccine is now set to launch later this month and will enroll 30,000 volunteers.

The second candidate in NIH's accelerated COVID-19 vaccine clinical trial pipeline is AZD1222, a recombinant adenovirus vaccine candidate that targets the spike protein of SARS-CoV-2. AZD1222 was developed at Oxford University and is now licensed to AstraZeneca. The results of the phase 1 safety and immunogenicity trial of AZD1222 are expected to be published in *The Lancet* very soon.

The NIH's phase 3 study of AZD1222, which NM will participate in, is in advanced planning stages through the COVID Prevention Network (CoVPN); the study at NM will be led by Babafemi O. Taiwo, MD. Participants will be enrolled and followed at several NM locations, including Northwestern Memorial Hospital, Central DuPage Hospital and Lake Forest Hospital. The goal is to

enroll at least 500 volunteers at NM out of the 30,000 expected to participate in this study. Participants will receive two injections of the vaccine and be followed for about two years. NM scientists are working with NIH and industry professionals on other COVID vaccine and immunotherapy trials that are expected to launch this summer or fall.

A registry (PI: Karen Krueger, MD) has been created to enlist potential volunteers for the upcoming AZD1222 and other COVID-19 vaccine trials. Please visit the [Northwestern COVID Prevention Trials Registry](#) page if you are interested in being contacted to assess your eligibility as the COVID vaccine trials open for enrollment.

### **RESTORE ILLINOIS: ACTIONS TO COMBAT A RESURGENCE OF COVID-19**

On July 15, Gov. J.B. Pritzker and the Illinois Department of Public Health released a modification to its Restore Illinois plan that includes several layers of mitigations to combat a resurgence of COVID-19 and prevent uncontrollable spread.

This updated guidance establishes a range of options organized by risk level. See below for more information.

#### **What could cause a region to become more restrictive?**

**One of the following two scenarios** could trigger additional restrictions:

- Sustained increase in seven-day rolling average (seven out of 10 days) in the positivity rate, **plus one of the following:**
  - Sustained seven-day increase in hospital admissions for a COVID-19-like illness
  - Reduction in hospital capacity threatening surge capabilities (ICU capacity or medical/surgical beds under 20%)
- Three consecutive days averaging greater than or equal to an 8% positivity rate

Mitigations will be applied on a regional basis based on those traditionally guided by IDPHs public health work. Expanding from four to 11 regions allows for a more targeted approach in this phase of the response to COVID-19. See the link below for more information about the regional breakdown.

#### **Tiered restrictions**

Once a region meets the resurgence criteria, a tiered menu of interventions will be considered. If sustained increases in metrics continue unabated, additional escalation of interventions may occur.

For hospitals, the following tiered actions would be put into effect:

- **Tier 1** – Reduce elective surgeries and procedures; limit visitation at hospitals; implement twice daily bed reporting
- **Tier 2** – Suspend elective surgeries and procedures; implement surge capacity; assess need to open alternate care facility
- **Tier 3** – Open alternate care facility

For offices, the following tiered actions would be put into effect:

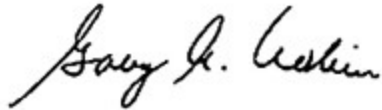
- **Tier 1** – Institute remote work for high-risk individuals; continued emphasis on telework for as many workers as possible
- **Tier 2** – Reduce office capacity with recommendations to resume remote work where possible
- **Tier 3** – Institute remote work for all nonessential workers

Please view the **Actions to Combat a Resurgence of COVID-19** report for the complete tiered menu, a breakdown of regions and additional information.

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Thank you to all NM physicians and clinicians for your ongoing support, collaboration and dedication to providing exceptional care during this unprecedented time.



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