Policy on Pre-Procedure Testing
Amongst Fully Vaccinated Individuals
(Effective May 3, 2021. Updated May 11, 2021)

Nebraska Medicine

Situation:

With falling COVID-19 rates and increasing public vaccination, the risk of asymptomatic carriage decreases. With the majority of UNMC/NM healthcare workers now being vaccinated, the risk of patient-to-provider transmission has also decreased. *See data at the end of document for further support.*

Policy Update:

1. **As of May 3, pre-procedural COVID testing is no longer necessary for patients who have been fully vaccinated and report no symptoms consistent with COVID-19 and report no close contact with persons with COVID19 in the last 14 days.**
    a. Close contact as defined by the CDC is as follows: Being within 6 feet of someone who has COVID-19 for a total of 15 minutes or more, providing care at home to someone who is sick with COVID-19, having direct physical contact with the person with COVID-19 (hugged or kissed them), sharing eating or drinking utensils, being directly exposed to sneeze, cough, or getting respiratory droplets on your person.
    b. Fully vaccinated is defined as 14 or more days from the terminal vaccination (2nd dose for Pfizer or Moderna, single dose for J&J).
    c. Please note, for patients not meeting these strict criteria (fully vaccinated, asymptomatic, no close exposure) they should continue to be tested prior to procedure and follow all current precautions.
    d. Testing is still at provider discretion and in some cases, based on perceived risk, testing may be performed on persons who meet the above criteria.

Frequently Asked Questions - Answered:

1. For vaccinated patients being admitted to the hospital for their procedure, no pre-procedural test is required prior to admission (if all above criteria are met). If a vaccinated patient is admitted with a scheduled, or unanticipated admission post procedure, they will require admission testing on the day of admission, post-procedure, as per the universal admission screening policy that remains in place.
2. Inpatient COVID screening policies remain in place for all unvaccinated persons. For those who are vaccinated, if no new symptoms or exposures occur during the procedural index hospitalization, no further pre-procedure COVID testing would be required for subsequent procedures.
3. Patients are still expected to follow all guidelines (wear a mask, distancing, handwashing).
4. Vaccination documentation is required and is the responsibility of the proceduralist and/or their team to ensure this is completed prior to the scheduled procedure.
    a. Vaccination status may be documented in the EMR or via state documentation via NESIIS). (Tips on how to conduct a NESIIS query: https://updates.nebraskamed.com/onechart/tip-sheet/automatic-nesiis-query/)
    b. If not, recorded, the vaccination card would need to be **visualized** (no verbal reporting accepted) AND then documented in EMR/state database.

5. Employees are still expected to follow all standard PPE (masks, eyewear).
6. Visitation policies are not adjusted for vaccination at this time.

Asymptomatic Infection or Shedding & Transmission After Receiving COVID-19 vaccination

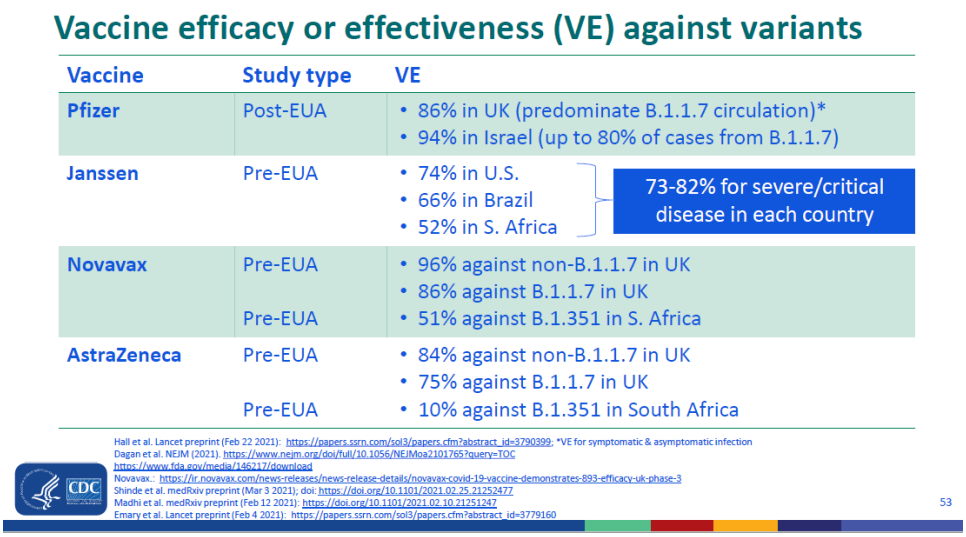
With COVID-19 vaccination on the rise, there is increasing data regarding the rate of asymptomatic shedding/infection and risk of viral transmission to others. (1) Data is still evolving. However, based on existing data, re-assessment of the need for continued pre-procedure testing for asymptomatic, vaccinated adults, in the setting of widespread healthcare provider vaccination, is appropriate. The current vaccines are highly effective at preventing symptomatic COVID-19 infections ($\geq$ 90%), and almost uniformly prevent severe disease, hospitalization, and mortality. However, less data was initially reported on asymptomatic infection. The Moderna trial demonstrated a reduction in asymptomatic persons (from 0.3% to 0.1%), and the reported efficacy of the Janssen vaccine for prevention of asymptomatic infection was 74%.(1) A prospective study in the UK amongst HCWs demonstrated a 85% efficacy in preventing asymptomatic and symptomatic infection, at 7-days post 2nd dose (day 28 or later). (2) A US HCW study demonstrated 0.05% infection rate amongst vaccinated staff.(11) Data from Israel also has demonstrated a similar decreased risk of asymptomatic COVID-19 infection (92% effectiveness) for $\geq$ 7 days post 2nd dose. (3) Viral loads, per CT assessment, are also shown to decrease post-vaccine, amongst those infected, therefore likely reducing transmissibility (based upon pre-vaccine data showing decreased transmissibility with lower viral loads). (4,5)

Specific to pre-procedure testing, in a retrospective cohort study of asymptomatic adults undergoing pre-procedure PCR testing for SARS-CoV-2, positive tests were less common amongst mRNA vaccinated persons (1.4% (of 3,006 vaccinated) vs 3.2% (of 45,327 unvaccinated); with a RR of 0.21 (95% CI 0.12-0.37) at > 10 days from the first dose and RR if 0.20 (95% CI 0.09-0.44) at >0 days after the second dose. (6) *Of note, this study included primarily Pfizer vaccine)*. (6)

When evaluating risk for nosocomial transmission, it is also important to consider the site and risk of the procedure for aerosolization. Prior to the emergence of the data cited above concern was raised regarding possible shedding in high-risk upper airway tissues and some have suggested that that high-risk ENT AGPs continue to use precautions pending further data on vaccine efficacy. (7). The currently published data is very encouraging that many procedures are low risk and vaccination decreases this risk even further but in an abundance of caution a tiered approach to roll-back pre-procedure testing is preferred.

Variants and vaccine breakthrough

Vaccine breakthrough with infections have been reported as the vaccines are not 100% effective. Viral variants may render vaccines less effective, but encouraging data suggests immune responses are generally maintained for currently available US vaccines, although somewhat variable depending on the variant. (8,9) Vaccines have been shown to effectively prevent COVID including severe disease even when variants were the predominant strains in countries like the UK and S. Africa. These data are encouraging but further studies are ongoing regarding risk of transmission of disease in these settings. There is ongoing research on booster doses, if needed, and impact on clinical disease. Any rollbacks of testing require ongoing monitoring for all of the above, with consideration for resumption of all pre-procedure testing, should clinically significant changes arise.



1) https://www.cdc.gov/coronavirus/2019-ncov/more/fully-vaccinated-people.html

2) Hall A, Foulkes S, Saei A, et al. Effectiveness of BNT162b2 mRNA Vaccine Against Infection and COVID-19 Vaccine Coverage in Healthcare Workers in England, Multicentre Prospective Cohort Study (the SIREN Study). Lancet (preprint). 2021;https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3790399external icon [Access date: March 4, 2021].

3) Dagan N, Barda N, Kepten E, Miron O, Perchik S, Katz MA, et al. BNT162b2 mRNA Covid-19 Vaccine in a Nationwide Mass Vaccination Setting. N Engl J Med. 2021.

4) Levine-Tiefenbrun M, Yelin I, Katz R, et al. Decreased SARS-CoV-2 viral load following vaccination. medRxiv. 2021;https://www.medrxiv.org/content/10.1101/2021.02.06.21251283v1.full.pdfpdf iconexternal icon [Access date: March 4, 2021].

5) Marks M, Millat-Martinez P, Ouchi D, Roberts CH, Alemany A, Corbacho-Monne M, et al. Transmission of COVID-19 in 282 clusters in Catalonia, Spain: a cohort study. Lancet Infect Dis. 2021 https://europepmc.org/article/PMC/PMC7906723

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7) Bleier, Benjamin S., Murugappan Ramanathan Jr, and Andrew P. Lane. "COVID-19 vaccines may not prevent nasal SARS-CoV-2 infection and asymptomatic transmission." *Otolaryngology–Head and Neck Surgery* 164.2 (2021): 305-307. https://journals.sagepub.com/doi/full/10.1177/0194599820982633?casa_token=6VpR5UsIVmkAAAAA%3AurZU_uzA1148FUrc09cpgctaVx3-CApZY36nTCAcPwENtDZnzIhyTx3Y-ftU-mBuoTRKMaqhww3FsA

8) Wu, Kai, et al. "Serum Neutralizing Activity Elicited by mRNA-1273 Vaccine." *New England Journal of Medicine* (2021). https://www.nejm.org/doi/full/10.1056/NEJMc2102179

9) Antibodies elicited by SARS-CoV-2 infection and boosted by vaccination neutralize an emerging variant and SARS-CoV-1

10) Leonidas Stamatatos, Julie Czartoski, Yu-Hsin Wan, Leah J. Homad, Vanessa Rubin, Hayley Glantz, Moni Neradilek, Emilie Seydoux, Maedeline F. Jennewein, Anna J. MacCamy, Junli Feng, Gregory Mize, Stephen C. De Rosa, Andrés Finzi, Maria Lemos, Kristen W. Cohen, Zoe Moodie, M. Juliana McElrath, Andrew T. McGuire

medRxiv 2021.02.05.21251182; doi: https://doi.org/10.1101/2021.02.05.21251182

11) Daniel et al.Early Evidence of the Effect of SARS-CoV-2 Vaccine at One Medical Center. NEJM. March 23, 2021. https://www.nejm.org/doi/full/10.1056/NEJMc2102153?query=featured_home