Update on Emerging SARS-CoV-2 Variants and Vaccine Considerations

CDR Heather Scobie PhD, MPH
ACIP Meeting
May 12, 2021
Background
SARS-CoV-2 Variants

- Multiple SARS-CoV-2 variants circulating globally
  - Viruses constantly change through mutation, so new variants are expected
  - After emerging, some disappear; others persist

- CDC and others are studying these variants to understand whether they:
  - Spread more easily from person to person
  - Cause milder or more severe disease in people
  - Detected by available diagnostic tests
  - Respond to therapeutics currently used to treat people for COVID-19
  - Change effectiveness of COVID-19 vaccines

Variant Classifications

- Established in collaboration with the SARS-CoV-2 Interagency Group (SIG)

- **Variant of Interest (VOI):** Genetic markers associated with changes to receptor binding, reduced antibody neutralization, reduced efficacy of treatments, potential diagnostic impact, or predicted increase in transmissibility or disease severity

- **Variant of Concern (VOC):** Evidence of increased transmissibility, more severe disease, significant reduction in neutralization by antibodies, reduced effectiveness of treatments or vaccines, or diagnostic detection failures

- **Variant of High Consequence (VOHC):** Clear evidence that prevention measures or medical countermeasures have significantly reduced effectiveness [None yet]
## Variants of Interest

<table>
<thead>
<tr>
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<td>(S477N(^*)) L452R E484K</td>
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| B.1.1.7              | 10-13                  | N501Y K417N E484K N501Y           | • 50% increased transmission  
• Minimal impact on neutralization by antibody therapies, convalescent or vaccine sera  |
| B.1.351              | 10                     | K417N E484K                        | • 50% increased transmission  
• Reduced efficacy of some antibodies  
• Reduced neutralization by convalescent or vaccine sera |
| P.1                  | 11                     | K417T E484K                        | • Reduced efficacy of some antibodies  
• Reduced neutralization by convalescent or vaccine sera |
| B.1.427              | 4                      | L452R                              | • 20% increased transmission  
• Modest decrease in efficacy of some antibodies  
• Reduced neutralization by convalescent or vaccine sera |
| B.1.429              | 4                      | L452R                              | • 20% increased transmission  
• Modest decrease in efficacy of some antibodies  
• Reduced neutralization by convalescent or vaccine sera |

**SARS-CoV-2 Variants Classifications & Definitions | CDC**
# Variants of Concern

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<td>Japan / Brazil</td>
<td>California</td>
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SARS-CoV-2 Variants Classifications & Definitions | CDC
Genomic Surveillance & Epidemiology of SARS-CoV-2 Variants
6%-9% of SARS-CoV-2 positive cases sequenced weekly

CDC COVID Data Tracker
As of 5/11/21
NCBI=National Center for Biotechnology Information; GISAID, a global initiative maintaining a repository of viral sequencing data
National SARS-CoV-2 Variant Proportions, United States
January 17 – May 8, 2021 with NOWCAST

Estimates for April 25-May 8, 2021

**VOC / VOI**

- B.1.1.7 72%
- B.1.427/B.1.429 1%
- P.1 6%
- B.1.351 <1%
- B.1.526 7%
- B.1.526.1 3%
- B.1.617.2 3%

** CDC COVID Data Tracker **
As of 5/11/21; VOC=Variant of Concern; VOI=Variant of Interest

** Estimates table **

<table>
<thead>
<tr>
<th>Lineage</th>
<th>Type</th>
<th>%Total</th>
<th>95%PI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Most common lineages</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>B.1.1.7</td>
<td>VOC</td>
<td>72.4%</td>
<td>67.4-77.1</td>
</tr>
<tr>
<td>B.1.526</td>
<td>VOI</td>
<td>6.8%</td>
<td>4.2-9.6</td>
</tr>
<tr>
<td>P.1</td>
<td>VOC</td>
<td>6.2%</td>
<td>3.7-9.1</td>
</tr>
<tr>
<td>B.1.617.2</td>
<td>VOI</td>
<td>3.3%</td>
<td>1.4-5.7</td>
</tr>
<tr>
<td>B.1.526.2</td>
<td>VOI</td>
<td>3.1%</td>
<td>1.4-5.1</td>
</tr>
<tr>
<td>B.1.526.1</td>
<td>VOI</td>
<td>2.8%</td>
<td>1.1-4.5</td>
</tr>
<tr>
<td>B.1.1.519</td>
<td>VOI</td>
<td>1.2%</td>
<td>0.3-2.3</td>
</tr>
<tr>
<td>B.12</td>
<td></td>
<td>0.7%</td>
<td>0.0-1.7</td>
</tr>
<tr>
<td>B.1</td>
<td></td>
<td>0.3%</td>
<td>0.0-1.1</td>
</tr>
<tr>
<td>B.1.596</td>
<td></td>
<td>0.1%</td>
<td>0.0-0.6</td>
</tr>
<tr>
<td>B.1.427</td>
<td></td>
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<td>0.0-2.0</td>
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<tr>
<td>B.1.351</td>
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<td>0.6%</td>
<td>0.0-1.4</td>
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<tr>
<td>P.2</td>
<td>VOI</td>
<td>0.0%</td>
<td>0.0-0.3</td>
</tr>
<tr>
<td>B.1.617.3</td>
<td>VOI</td>
<td>0.0%</td>
<td>0.0-0.3</td>
</tr>
</tbody>
</table>

* Other represents >200 additional lineages, which are each circulating <1% of viruses
** These data include Nowcast estimates, which are modeled projections that may differ from weighted estimates generated at later dates

CDC COVID Data Tracker As of 5/11/21; VOC=Variant of Concern; VOI=Variant of Interest
Regional SARS-CoV-2 Variant Proportions
April 25 – May 8, 2021 with NOWCAST

CDC COVID Data Tracker As of 5/11/21; VOC=Variant of Concern; VOI=Variant of Interest
Vaccine Effectiveness Against SARS-CoV-2 Variants
Vaccine-Induced Antibody Protection and Variants

- Robust correlation between vaccine efficacy (VE) versus:
  - Neutralizing titer ($\rho = 0.79$)
  - Binding antibody titer ($\rho = 0.93$)

- Correlate of protection, or threshold that protects against SARS-CoV-2, **not yet determined**

- Variants result in reduced protective antibody levels
  - Lower VE and increased breakthrough infection?
  - Shorter duration of immunity?
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**Figure Source:** Altman et al (2021): https://science.sciencemag.org/content/371/6534/1103
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Reduced Neutralization Activity of Vaccine Sera Relative to Wildtype/Dominant Strain, by Study (n=31)

Fold reduction

No effect = 1

Studies by vaccine
- mRNA
- AstraZeneca
- Novavax

Variants:
- B.1.1.7
- B.1.351
- P.1
- P.2
- B.1.1.7
- B.1.617
- B.1.617.1
- B.1.429
- B.1.526
- B.1.526
Discussion of Lab Studies

- Largest impacts: **B.1.351** (SA) > **P.1** (Brazil) > **B.1.1.7** (UK), **B.1.427/B.429** (CA)

- Difficult to estimate how results might translate to clinical protection
  - Neutralizing antibodies in sera from mRNA vaccine recipients higher than COVID-19 convalescent sera

- Variation in results may be explained by different experimental conditions
  - Neutralization assays — replicating & nonreplicating pseudovirus vs. SARS-CoV-2
  - Sera — time post-vaccination, or population (e.g., age, COVID-19 history)
  - Use of limited or full sets of spike mutations vs. clinical isolates of variants

- Limitation for all studies — small sample sizes and lack generalizability
  - Almost half of studies are preprints, not yet peer-reviewed
# Vaccine Efficacy or Effectiveness (VE) Against Variants

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<td>Janssen</td>
<td>Pre-EUA</td>
<td>• 74% in U.S.</td>
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<td>• 66% in Brazil (69% of cases from P.2)</td>
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<td>• 52% in S. Africa (95% of cases from B.1.351)</td>
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** Abu-Radad and Butt. Effectiveness of the BNT162b2 Covid-19 Vaccine against the B.1.1.7 and B.1.351 Variants | NEJM [https://www.fda.gov/media/146217/download](https://www.fda.gov/media/146217/download)

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Shinde et al. Efficacy of NVX-CoV2373 Covid-19 Vaccine against the B.1.351 Variant | NEJM

Madhi et al. Efficacy of the ChAdOx1 nCoV-19 Covid-19 Vaccine against the B.1.351 Variant | NEJM

Emary et al. Efficacy of ChAdOx1 nCoV-19 (AZD1222) vaccine against SARS-CoV-2 variant of concern 202012/01 (B.1.1.7) | The Lancet

**mild/moderate illness
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<td><strong>100% for severe/critical disease</strong></td>
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**Emary et al. Efficacy of ChAdOx1 nCoV-19 (AZD1222) vaccine against SARS-CoV-2 variant of concern 202012/01 (B.1.1.7): The Lancet.**

**mild/moderate illness**
Investigating COVID-19 Vaccine Breakthrough Cases

- Despite high vaccine efficacy, vaccine breakthrough cases* expected
  - Some will be caused by variants, even if vaccine has similar effectiveness against variants

- Among 95 million fully vaccinated in U.S., 9,245 breakthrough infections** reported by state & territorial health departments to passive surveillance
  - Case investigation and whole genome sequencing to identify variants

- Starting soon – CDC project with Emerging Infections Program sites on frequency of SARS-CoV-2 variants among vaccinated and unvaccinated people

*Vaccine breakthrough case:* Person with SARS-CoV-2 RNA or antigen detected in respiratory specimen collected ≥14 days after completing primary series of an FDA-authorized COVID-19 vaccine

**COVID-19 Breakthrough Case Investigations and Reporting | CDC as of 4/26/21
Tehran et al. https://www.cdc.gov/mmwr/volumes/70/wr/mm7017e1.htm
Do SARS-CoV-2 Variants Cause More Breakthrough Cases?

- One preprint study from Israel assessed variants of concern (VOC) in infections of Pfizer-vaccinated cases vs. unvaccinated matched controls
- Context: B.1.1.7 dominant strain; B.1.351 <1% of all specimens
- At least a week after 2nd dose — matched OR = 8.0 for B.1.351
  - Among 149 pairs, 8 vaccinated and 1 unvaccinated persons had B.1.351
- 2 weeks after 1st dose to 1 week after 2nd dose — matched OR = 2.6 for B.1.1.7
  - Among 245 pairs, 221 vaccinated and 205 unvaccinated persons had B.1.1.7
- Conclusion: breakthrough infection more frequent with VOCs
- Limitations: not yet peer-reviewed, small sample sizes (especially B.1.351)

Summary of Preliminary Data: Implications of SARS-CoV-2 Variants of Concern on Vaccine Effectiveness

- **B.1.1.7**
  - Exponential increase in prevalence in United States
  - Minimal impact on VE; attention needed for additional substitutions in receptor binding domain (RBD), such as E484K

- **B.1.351**
  - Currently low prevalence in United States
  - Moderate impact on VE for some vaccines, though may still provide protection against severe disease

- **P.1**
  - Increasing prevalence in United States; same 3 RBD mutations as B.1.351
  - Additional data needed on potential impact on VE
Boosters and Second-Generation Vaccines Against SARS-CoV-2 Variants

- Manufacturers launching booster studies of current vaccines and/or developing second-generation vaccines against B.1.351

- Moderna — preliminary phase 2 results of single 50 µg booster of authorized (mRNA-1273) and variant-specific vaccine (mRNA-1273.351)
  - 6-8 months after primary series (pre-booster), low/undetectable neutralizing antibody titers for B.1.351 and P.1, but titers against wild-type still likely protective
  - Both vaccines — acceptable safety; boosted immunity to all types (wild-type, B.1.351, P.1)
  - mRNA-1273.351 booster more effective than mRNA-1273 at neutralizing B.1.351
  - In progress — bivalent vaccine with 1:1 mix of original & variant vaccine (mRNA-1273.211)

Wu et al. medRxiv preprint (May 6, 2021): https://doi.org/10.1101/2021.05.05.21256716
Updates to Vaccines to Address SARS-CoV-2 Variants

- Periodic update of SARS-CoV-2 vaccines likely needed
- FDA defined data needed to support EUA amendment for a vaccine addressing emerging SARS-CoV-2 variants — immunogenicity studies
- U.S. SIG* developing an evaluation and risk assessment framework
  - Evidence needed to recommend whether modified vaccine needed
- WHO has role in global coordination, developing risk assessment framework

*SARS-CoV-2 Interagency Group (SIG)
Variants: Implications for Vaccine Policy

- Current prevention measures and authorized vaccines offer protection against SARS-CoV-2 variants
  - Efforts needed to increase uptake

- Continue to monitor evidence:
  - Emergence and spread of SARS-CoV-2 variants
  - Vaccine effectiveness
  - Breakthrough infections in vaccinated or previously infected persons
  - Ability of postvaccination serum to neutralize emerging variant viruses

- ACIP will review evidence submitted for any next generation vaccines
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