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Novavax / Sanofi
2025-2026 COVID-19 Vaccine Update

Vaccines and Related Biological Products Advisory Committee
May 22, 2025

Robert Walker, MD
Senior Vice President
Chief Medical Officer
Novavax

Tonya Colpitts, PhD
Associate Vice President
Global Project Head, Vaccines
Sanofi

JN.1 Lineage Selection Facilitates Platform Diversity for Patient Choice and Timely Vaccine Access

US COVID-19 Situation

COVID-19 continues to cause severe illness in the US

COVID-19 vaccination rates remain low

Protein-based vaccine is an important choice for the US population due to its tolerability and acceptability profile

Current Surveillance

Circulating variants are within JN.1 lineage

JN.1 lineage strains have few sequence differences in spike protein

Recent strains have emerged in non-linear fashion with no common predecessor after JN.1

Immunogenicity Data

Preclinical data confirm JN.1 strain vaccination induces immunity across JN.1 lineage strains

Substantial cross reactivity is shown between strains within a lineage

Human studies confirm JN.1 strain vaccination neutralizes current and emerging variants

Data confirm JN.1 strain is an appropriate choice for 2025/26 season

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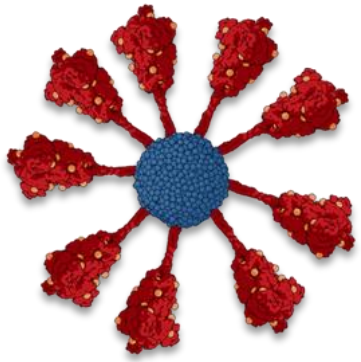
Novavax COVID-19 Vaccine: Built on Well-Established Protein Platform



Recombinant protein nanoparticle

Matrix-M®

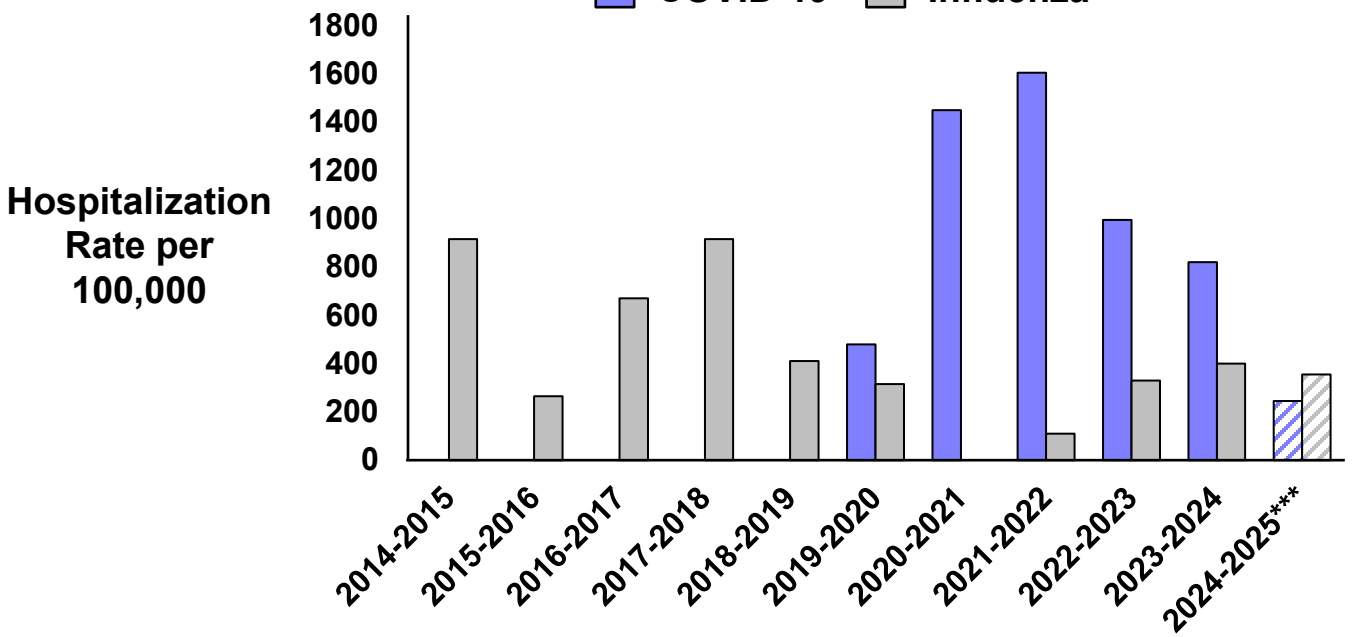
- Recombinant protein vaccine is a proven technology (e.g., influenza, HepB), safe and effective[1]
- Adjuvanted to enhance immunity response resulting in a larger, broader and more durable response[2]
- Favorable reactogenicity and excellent efficacy profile in large, diverse patient population[3]

1. Cox MMJ. Recombinant protein vaccines produced in insect cells. Vaccine. 2012;30(10):1759-1766
2. Stertman L, et al. Hum Vaccin Immunother.2023;19(1):2189885
3. Novavax COVID-19 vaccine, adjuvanted (2024-2025 formula) [US EUA fact sheet]. Gaithersburg, MD: Novavax, Inc.; Oct 2024

While COVID-19 Continues to Cause Severe Illness and Deaths, Vaccination Rates Remain Low

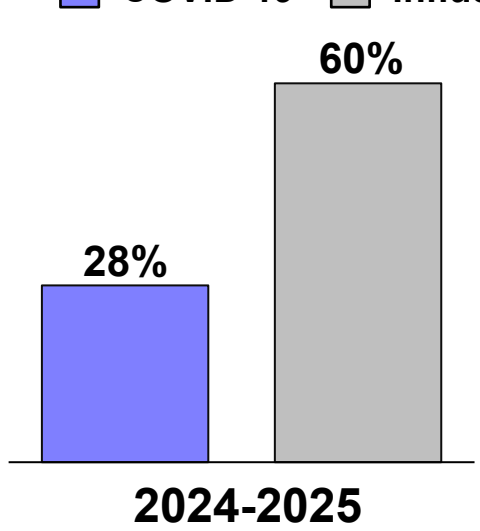
Cumulative COVID-19 hospitalizations
~75% higher than flu over past two seasons[1]
with **>40,000 US deaths** in 2023/24[2]

Hospitalization rates among US adults 65+ years[2]



COVID-19 vaccine coverage rates
<50% of flu vaccines

Vaccination rates among US adults 65+ years[3]



1. Respiratory Virus Hospitalization Surveillance Network (RESP-NET)
2. Link-Gelles R. ACIP April 15 – 16, 2025. Workgroup considerations for use of 2025-2026 COVID-19 vaccines

***Data for 2024-2025 show data for October 2024 – March 2025 only as season is ongoing

3. Based on US Census Population & IQVIA Claims sourced from AMA physicians claims database until Feb 25.

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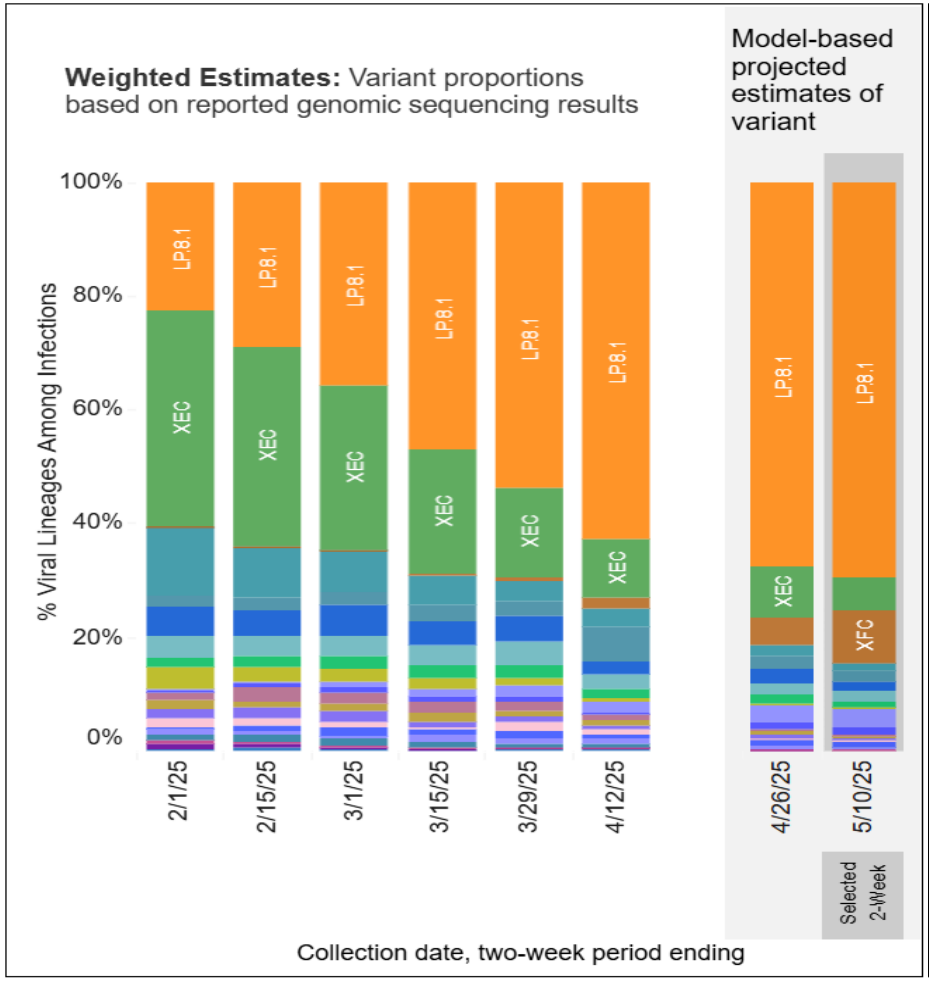
Surveillance and Immunogenicity Data Support JN.1 Lineage Level Strain Selection

- Strain prevalence and emergence patterns
- Preclinical and clinical immunological evidence

Currently Circulating COVID-19 Variants
All JN.1 Lineage

Weighted and Nowcast Estimates in US
2 Week Periods 1/19-5/10/2025

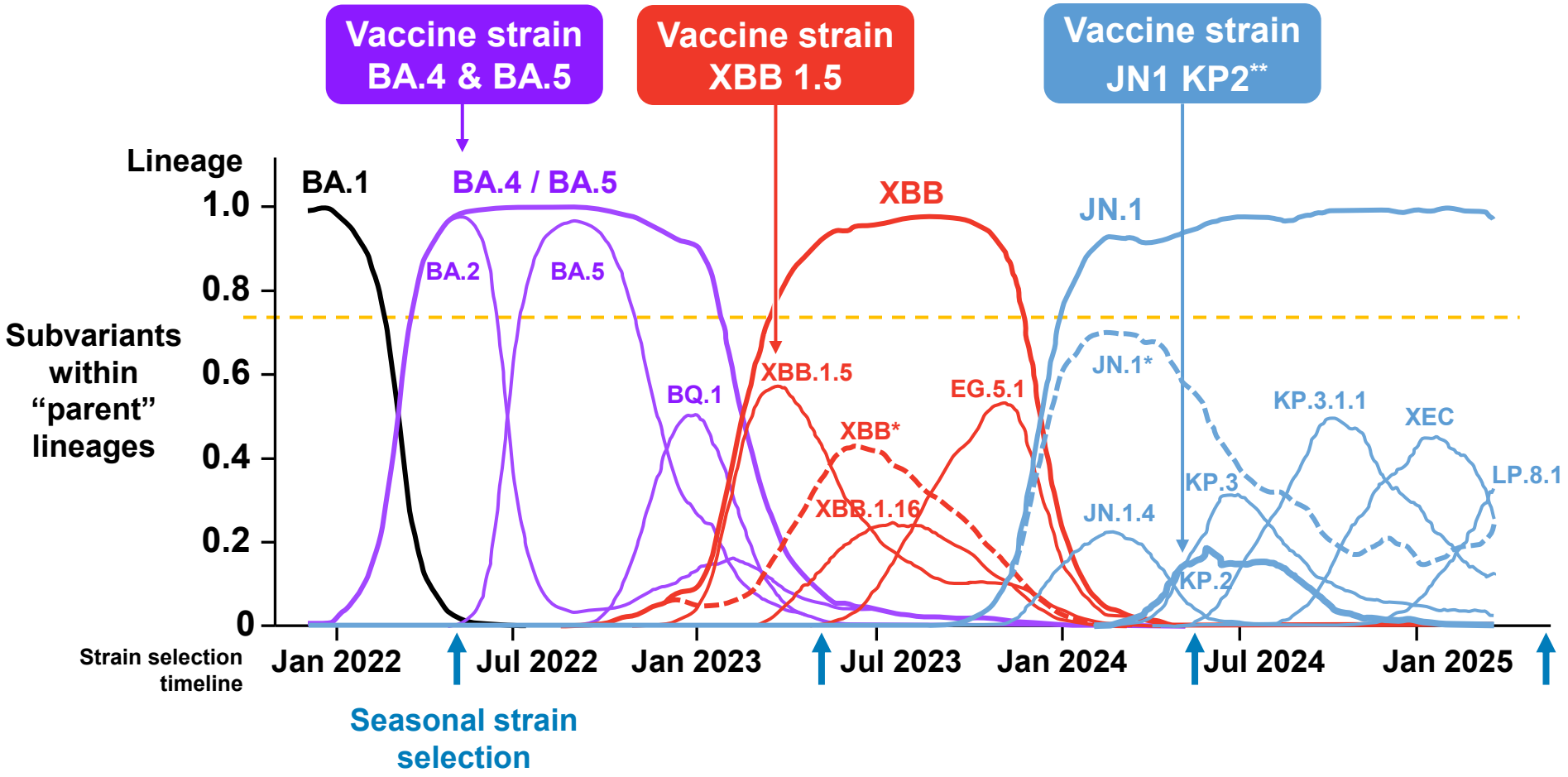


Nowcast Estimates in US
4/27-5/10/2025

WHO label	Lineage #	%Total	95%PI
Omicron	LP.8.1	70%	64–75%
	XFC	9%	4–19%
	XEC	6%	4–8%
	LF.7.7.2	3%	0–16%
	LF.7	2%	1–3%
	MC.10.1	2%	1–3%
	LB.1.3.1	2%	1–3%
	KP.3.1.1	1%	1–2%
	XEC.4	1%	1–2%
	PA.1	1%	0–3%
	LF.7.7.1	1%	1–2%
	XEQ	0%	0–1%
	LF.7.2.1	0%	0–1%
	KP.3	0%	0–1%
	XEK	0%	0–1%
	MC.1	0%	NA
	JN.1.16	0%	NA
	MC.19	0%	NA
	JN.1	0%	NA

USCDC Nowcast estimates, https://covid.cdc.gov/covid-data-tracker/#variant-proportions

JN.1 Lineage Has Persisted for 18+ Months Yet One COVID Strain Is Only Prevalent for ~14 Weeks*



- All variants of concern are within the JN.1 lineage
- LP.8.1 is unlikely to remain the predominant strain by fall 2025

*Ranging from 2-28 weeks

**KP2 selected in US, with EU having JN1

Data in graph from https://gisaid.org/publish/

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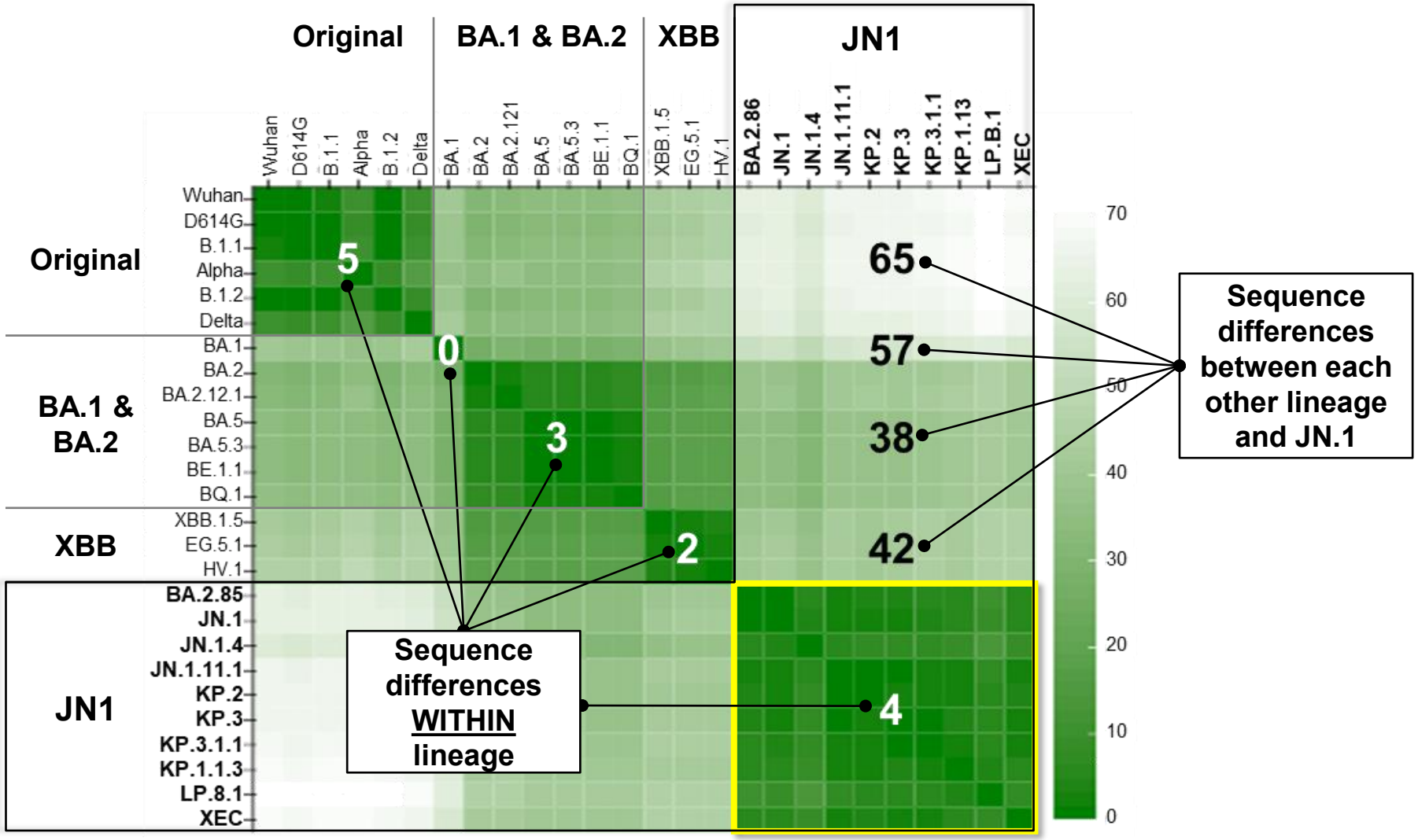
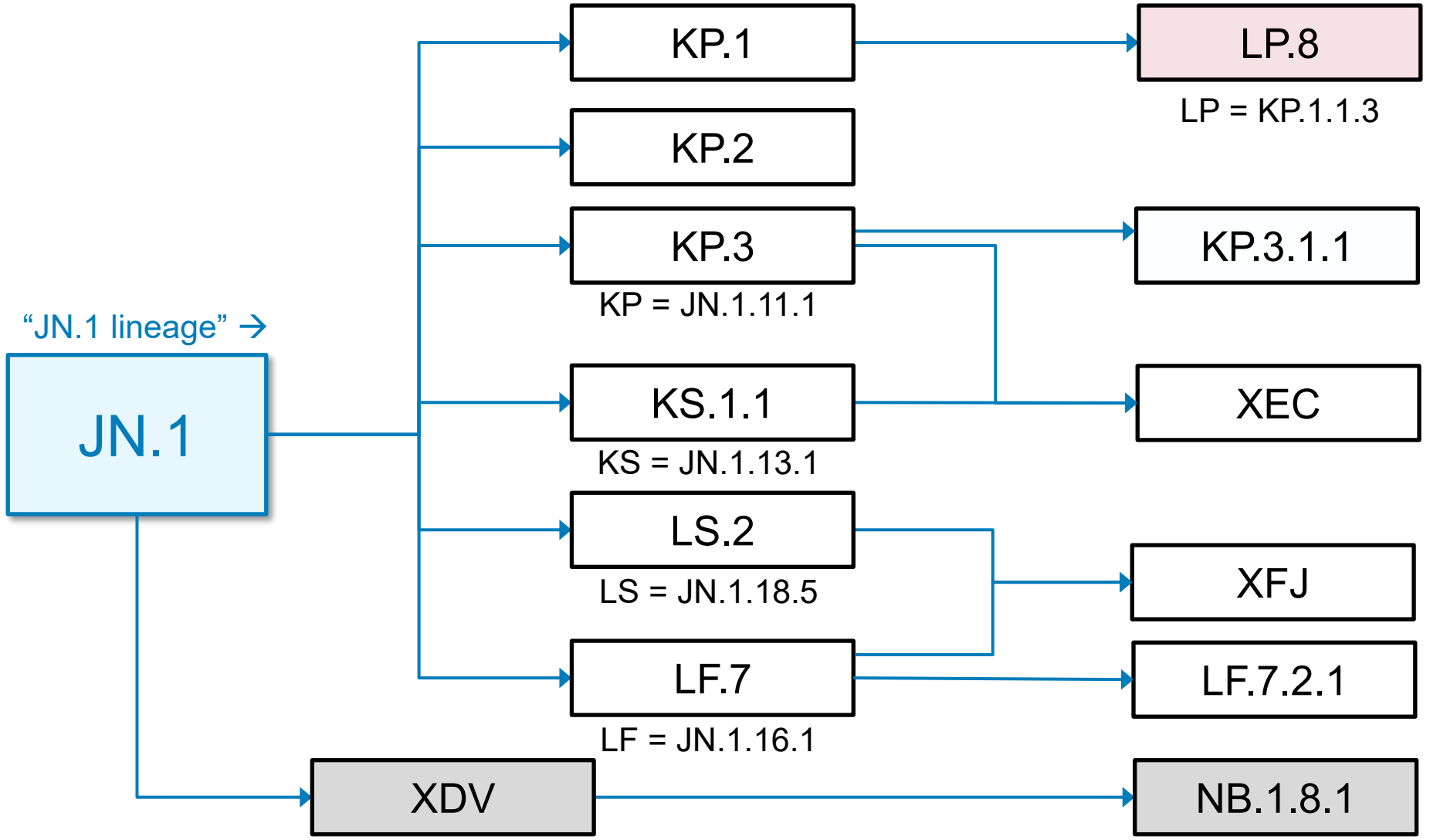
Strains Within a Lineage Have Few Sequence Differences in Spike Protein

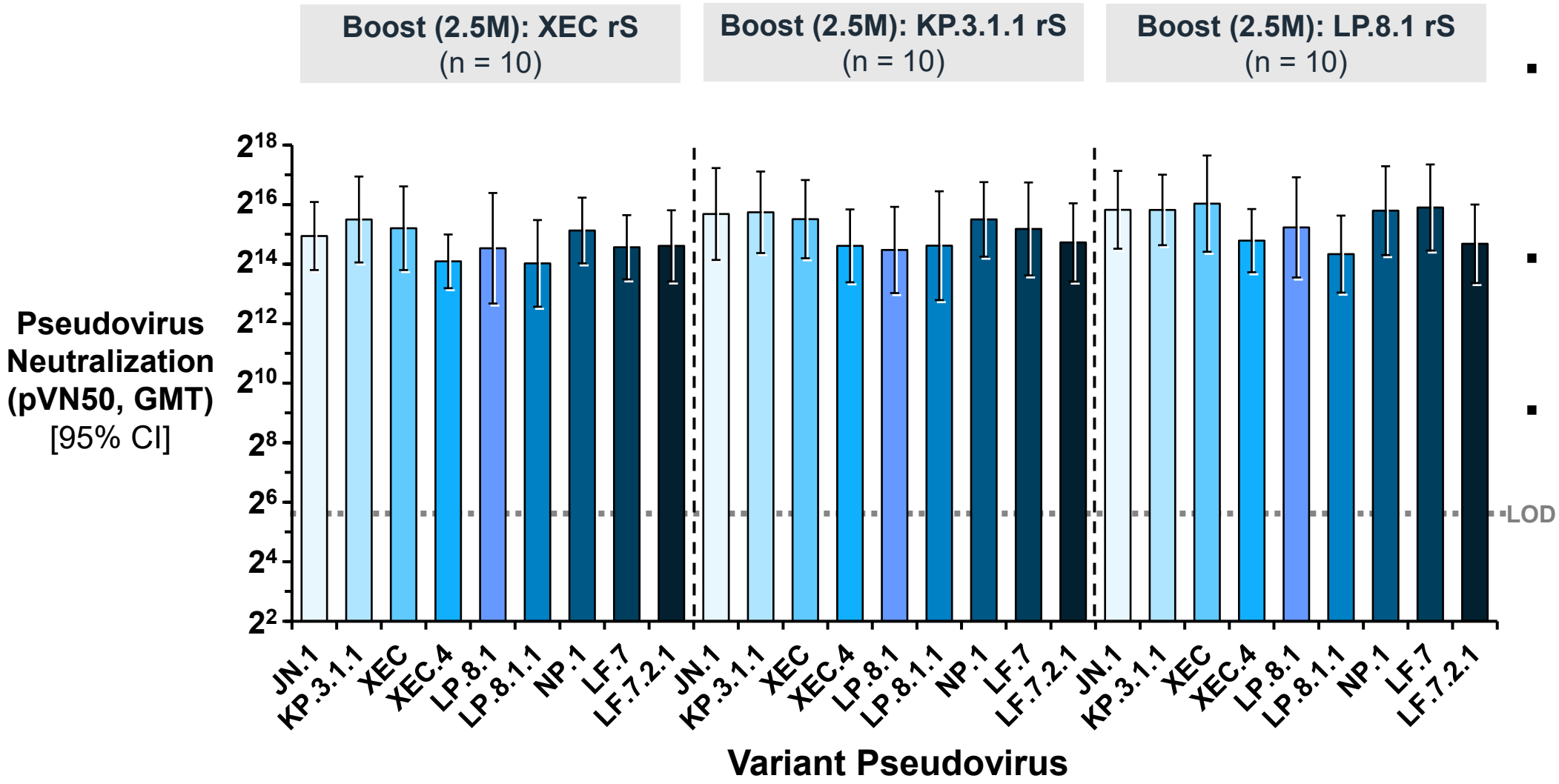


Strains selected if strain + descendants circulated > 20%
Note that size of clusters is not representative

New Variants Emerge Non-Linearly



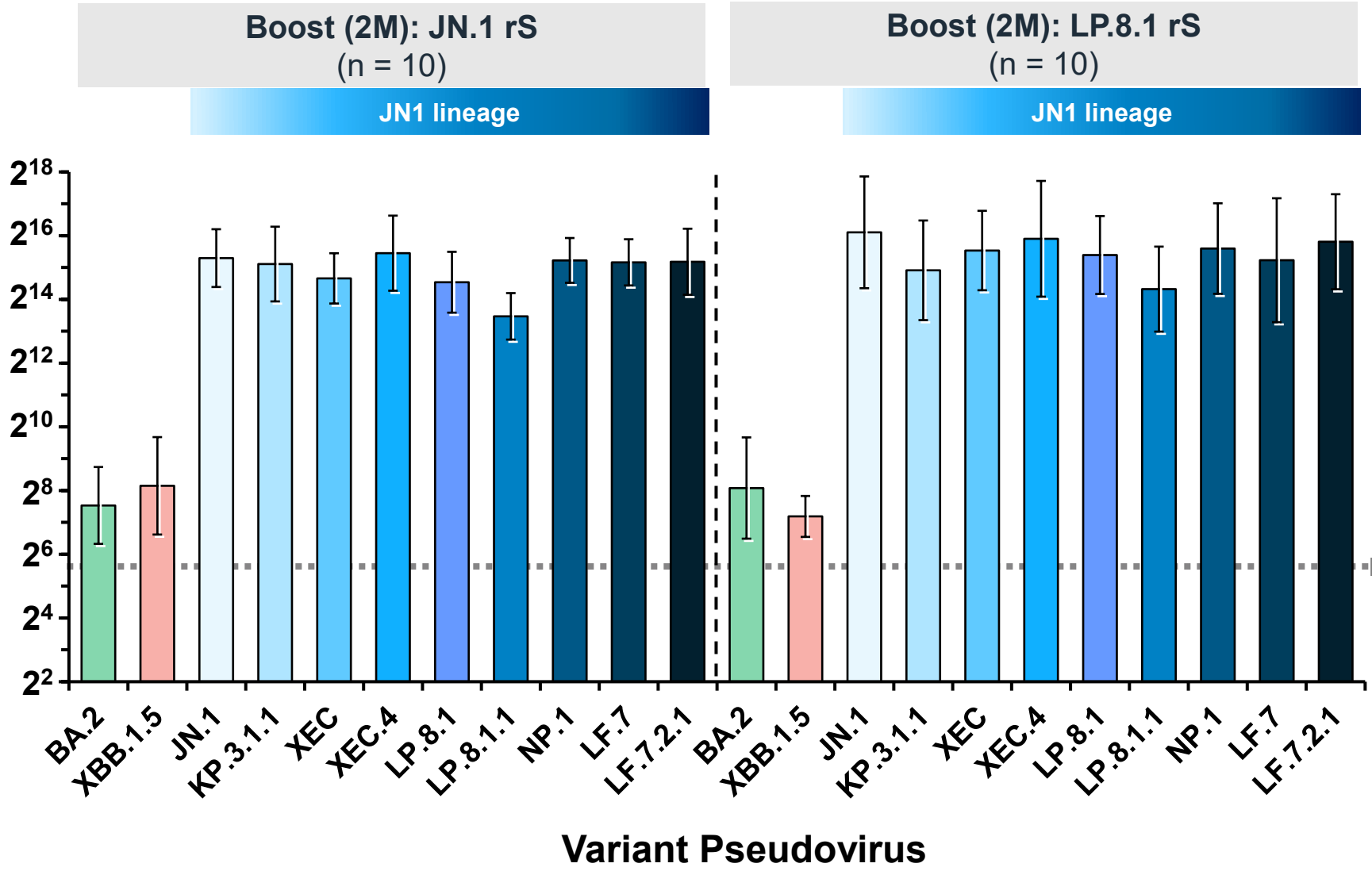
Substantial Cross Reactivity Within JN.1 Lineage Prime + Boost Mouse Model



- XEC or KP.3.1.1 or LP.8.1 vaccine used for boost in JN.1 primed mice
- Neutralization across JN.1 lineage pseudoviruses
- Assay done post-boost (2.5 M)

Data are from one experiment

No Substantial Cross Reactivity Across Lineages Prime + Boost Mouse Model

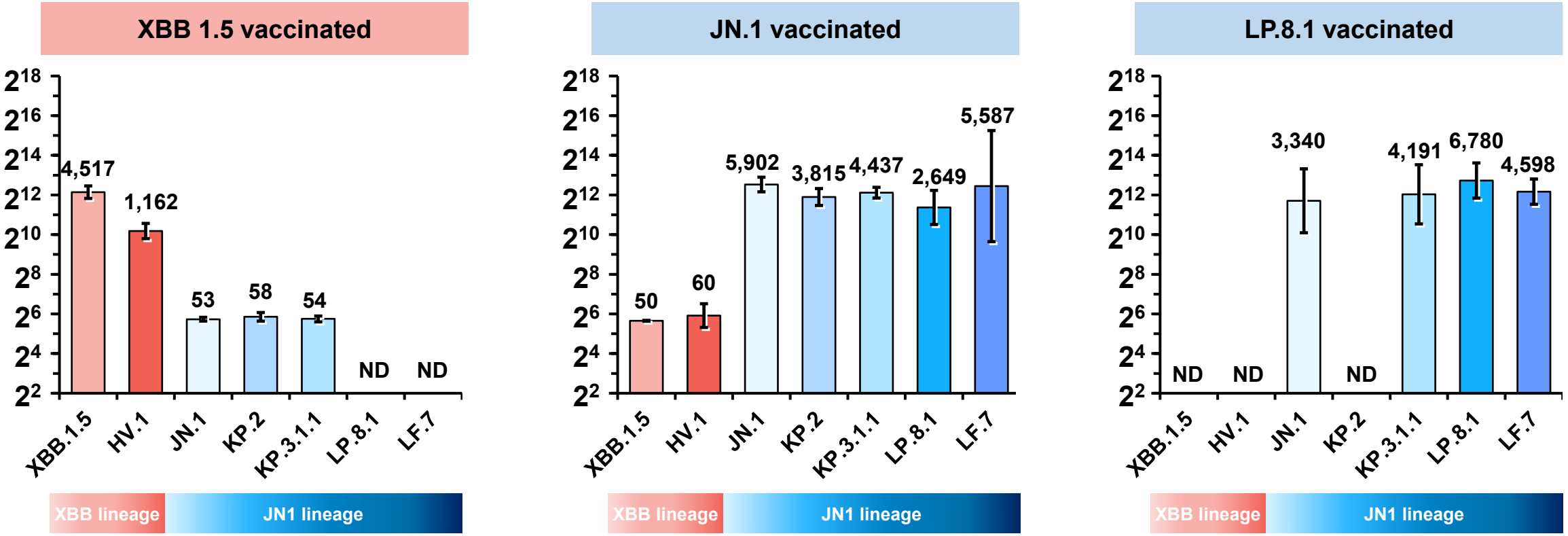


- JN.1 or LP.8.1 vaccine used for boost in JN.1 primed mice
- Neutralization using pseudoviruses across JN.1 lineage, with single representative from BA.2 and XBB1.5 lineage
- Assay done post-boost (2M)

Data are from one experiment

Substantial Cross Reactivity Between Strains Within a Lineage, But Not Across Lineages

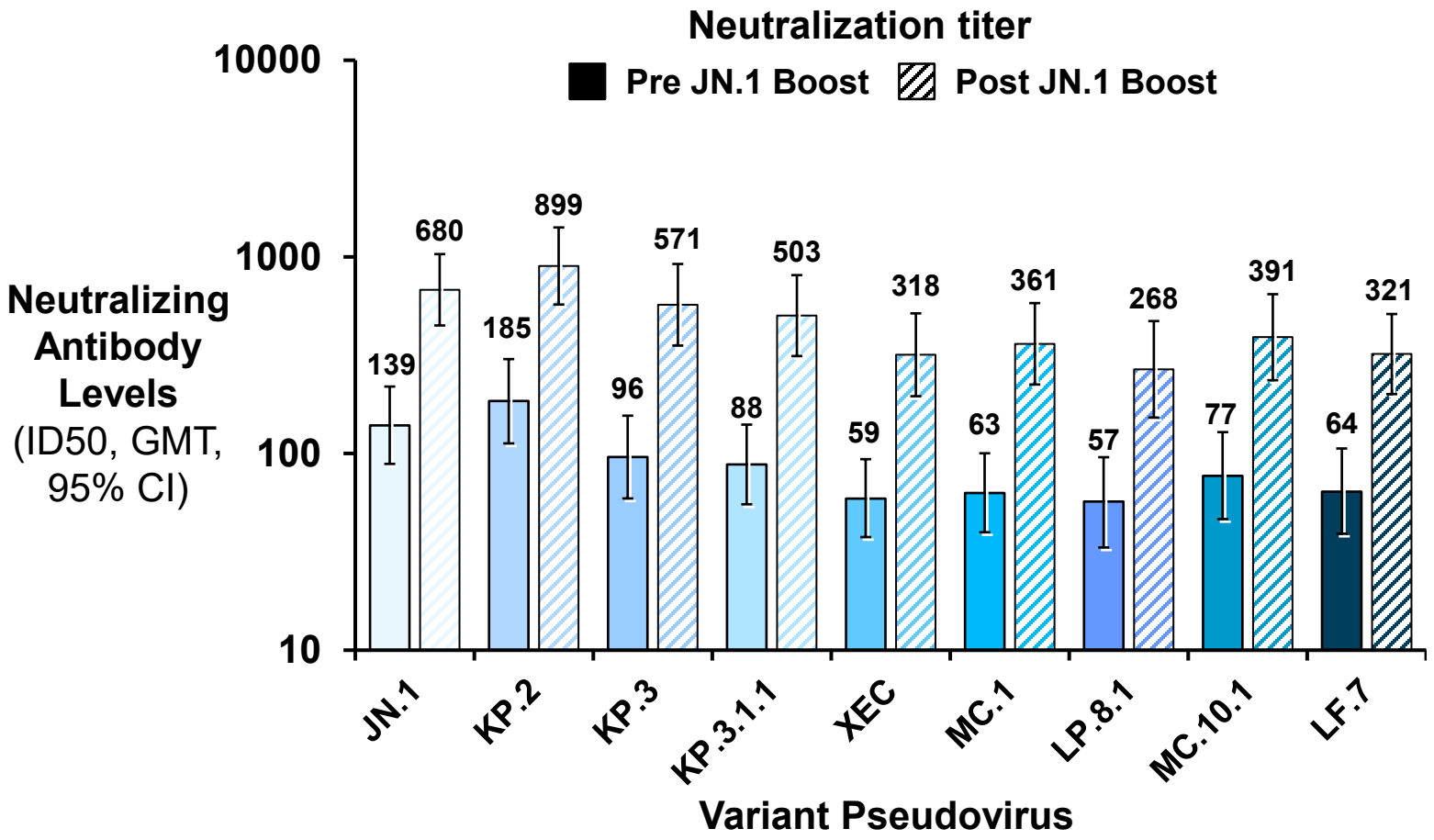
Neutralizing antibody titer 14 days post primary vaccination with JN1, XBB.1.5,or LP.8.1 in naïve mice[1]*

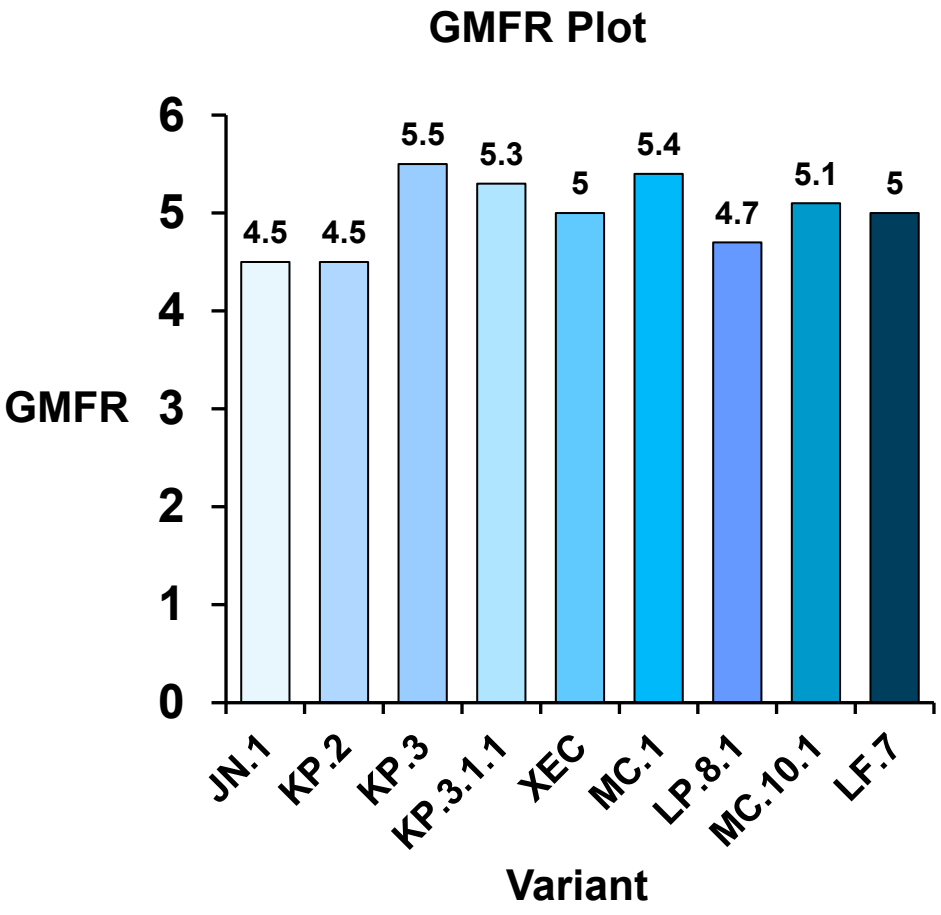


Samples sizes vary. Data are from multiple experiments.

JN.1 Vaccination in Humans Induces Comparable Neutralizing Antibody Titers Against JN.1 Lineage Strains

Prior primary COVID-19 vaccines with single Novavax JN.1 vaccination in 2024/25 season (N = 52-60)





Novavax Study 2019n-COV-315: A Strain Change Study for SARS-CoV-2rS Vaccines (COVID-19); ClinicalTrials.gov ID: NCT06409663

JN.1 Lineage Selection Facilitates Platform Diversity for Patient Choice and Timely Vaccine Access

Robust preclinical and clinical immunological evidence demonstrate that JN.1 covers emerging variants

Nonlinear emergence patterns coupled with short windows of strain prevalence make it impossible to correctly predict seasonal dominant strains

Lineage level strain selection provides consistent and robust approach to maximize public confidence by mitigating unpredictability of strain emergence

US consumer want a tolerable vaccine choice, as recently evidenced in the ACIP public comments session[1]

Totality of data support **JN.1 lineage selection without preference for any single strain** for the 2025-2026 season, enabling timely availability of protein-based COVID vaccine

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1. ACIP public submissions. >3,200 comments supportive of Novavax COVID-19 vaccine availability: https://www.regulations.gov/document/CDC-2025-0017-0001/comment?filter=novavax%202025%20comment