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MDH COVID-19 Vaccine Update

Senate HHS Committee

12/17/20

MINNESOTA

Phased Approach to Vaccination

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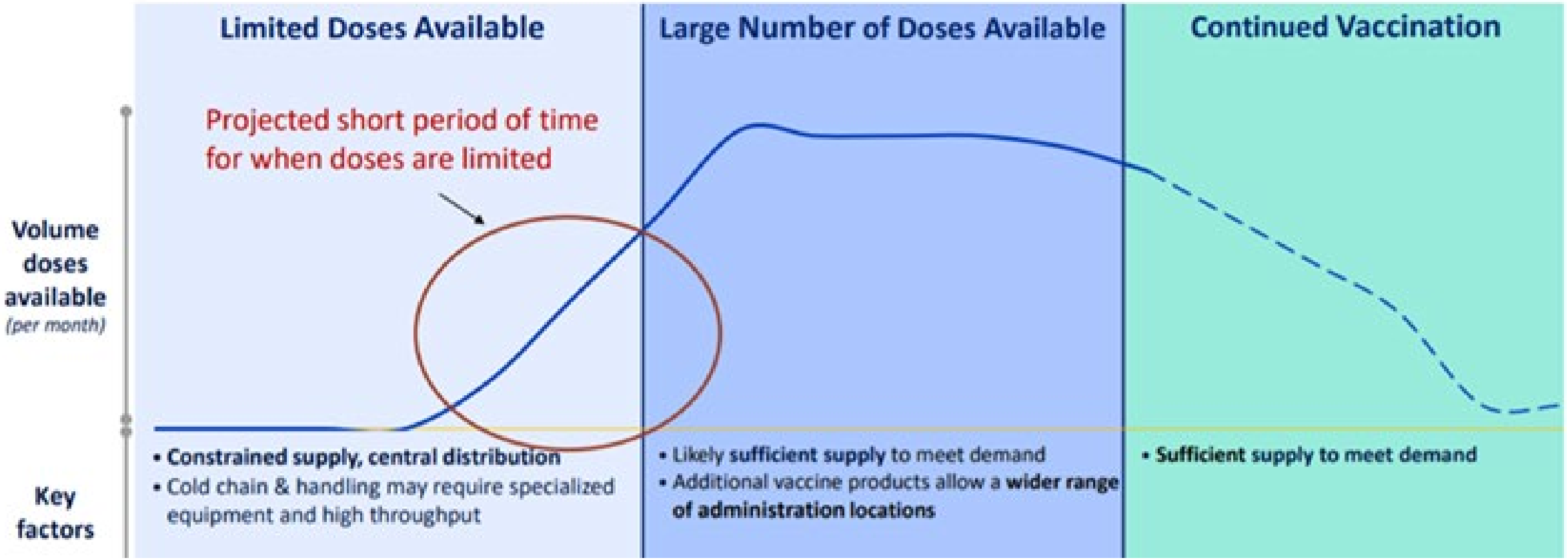
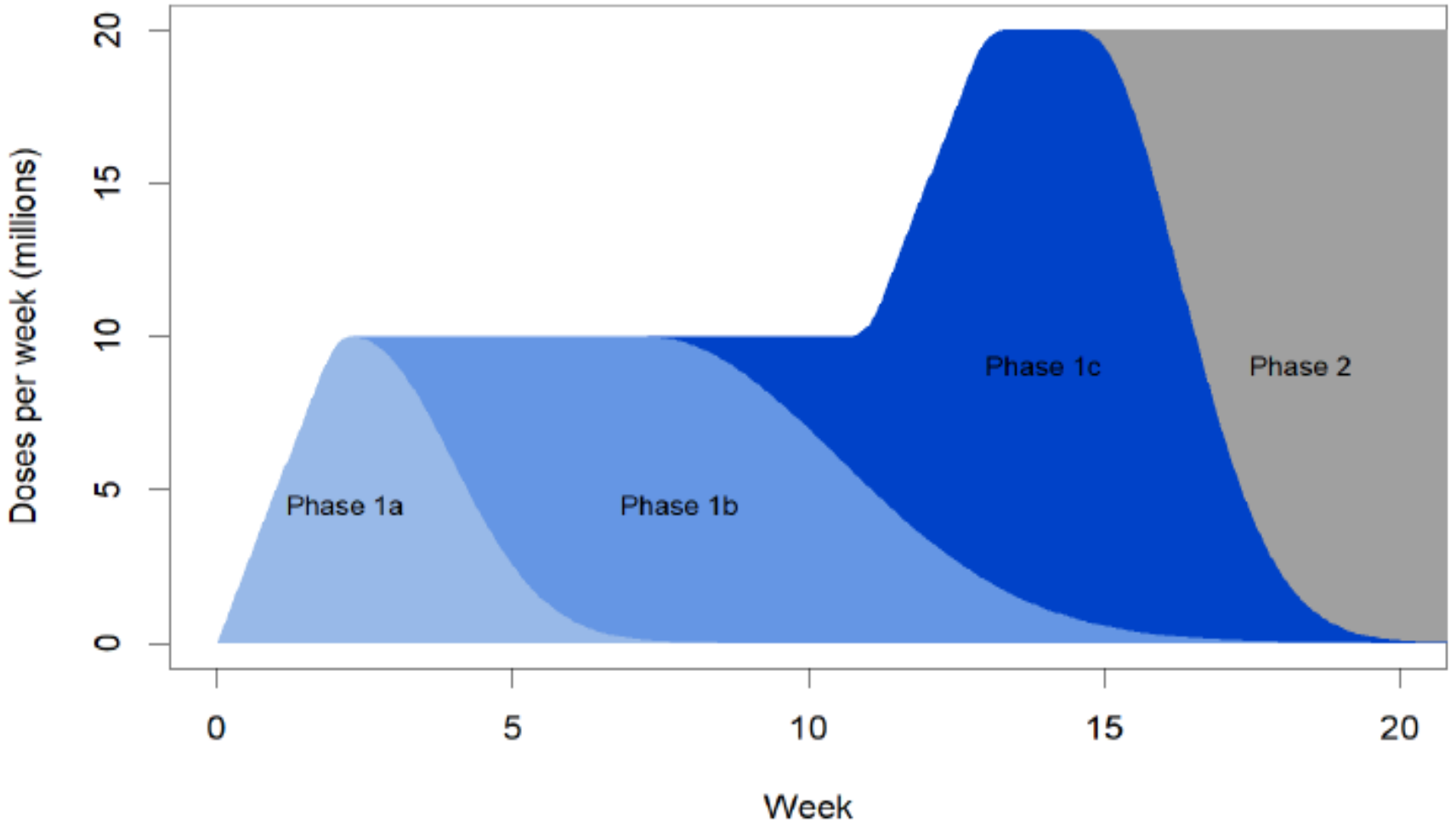


Phase 1 sequence based on doses available



Phase 1 vaccination

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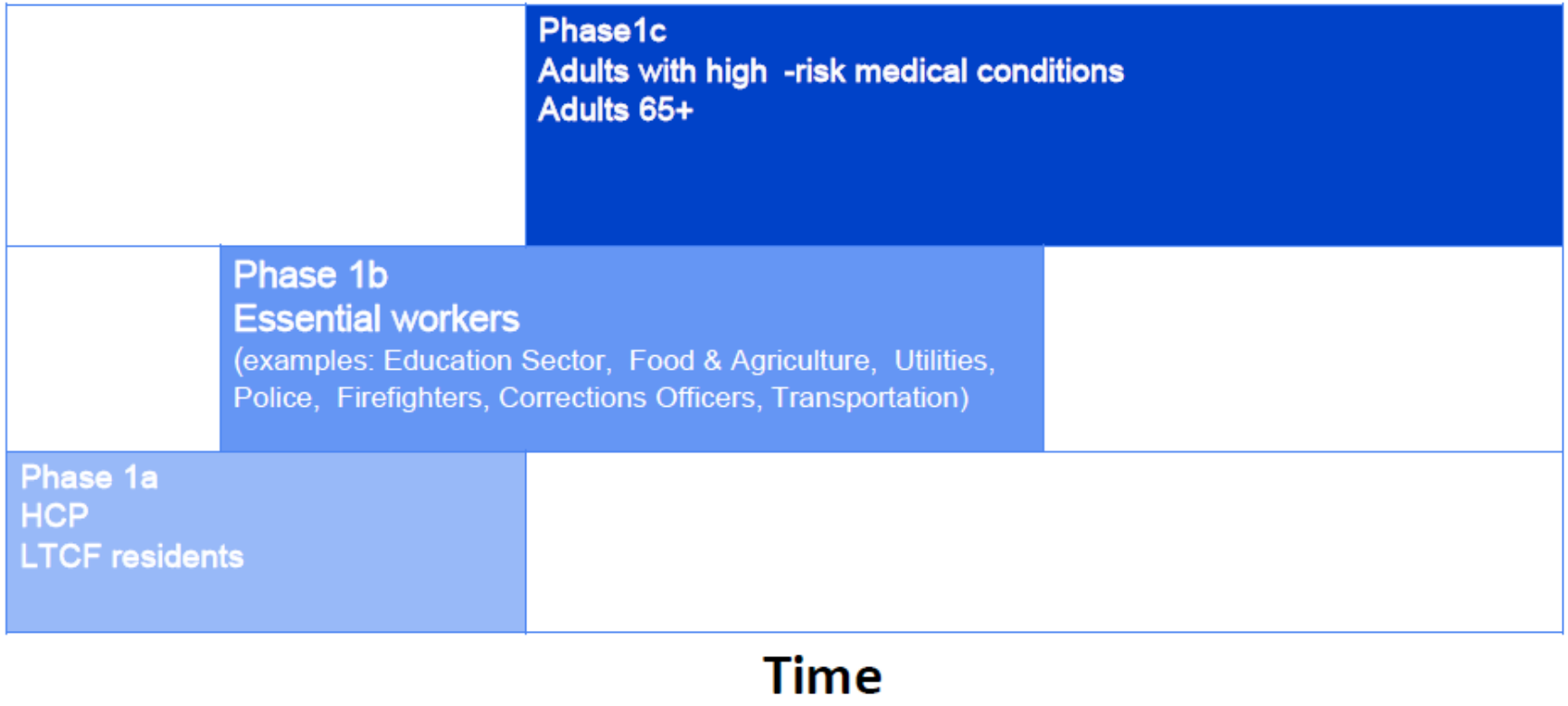
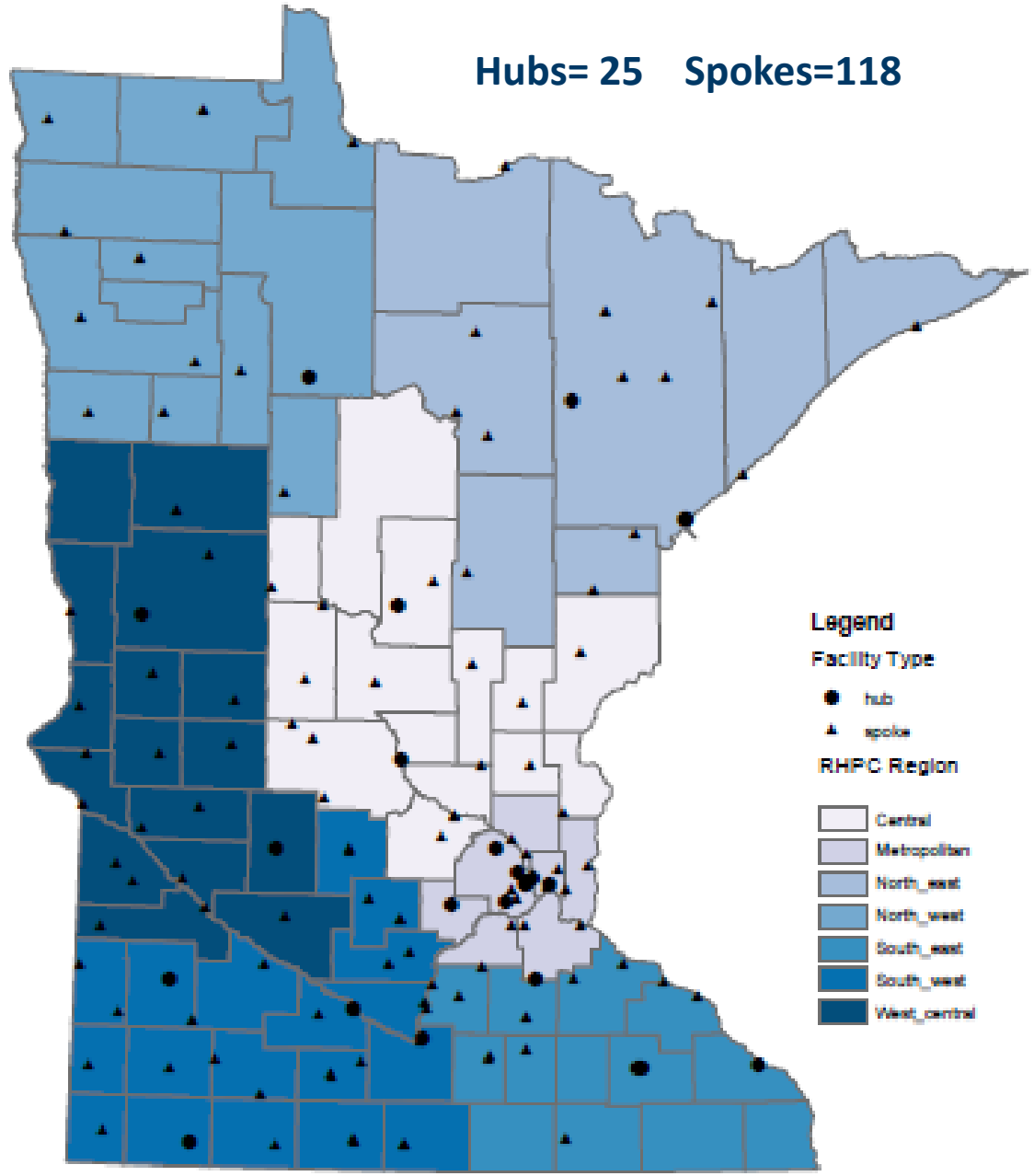
Proposed Interim Phase 1 Sequence



MN Hub and Spoke Map

- Northeast: 3 hubs, all 3 with ULC storage
- Metro: 10 hubs, 8 of 10 with ULC storage
- Southwest: 5 hubs, all 5 with ULC storage
- Southeast: 3 hubs, all 3 with ULC storage
- Central: 2 hubs, 1 of 2 with ULC storage
- Northwest: 1 hub, has ULC storage
- West Central: 1 hub, has ULC storage



589 Provides Enrolled to Vaccinate

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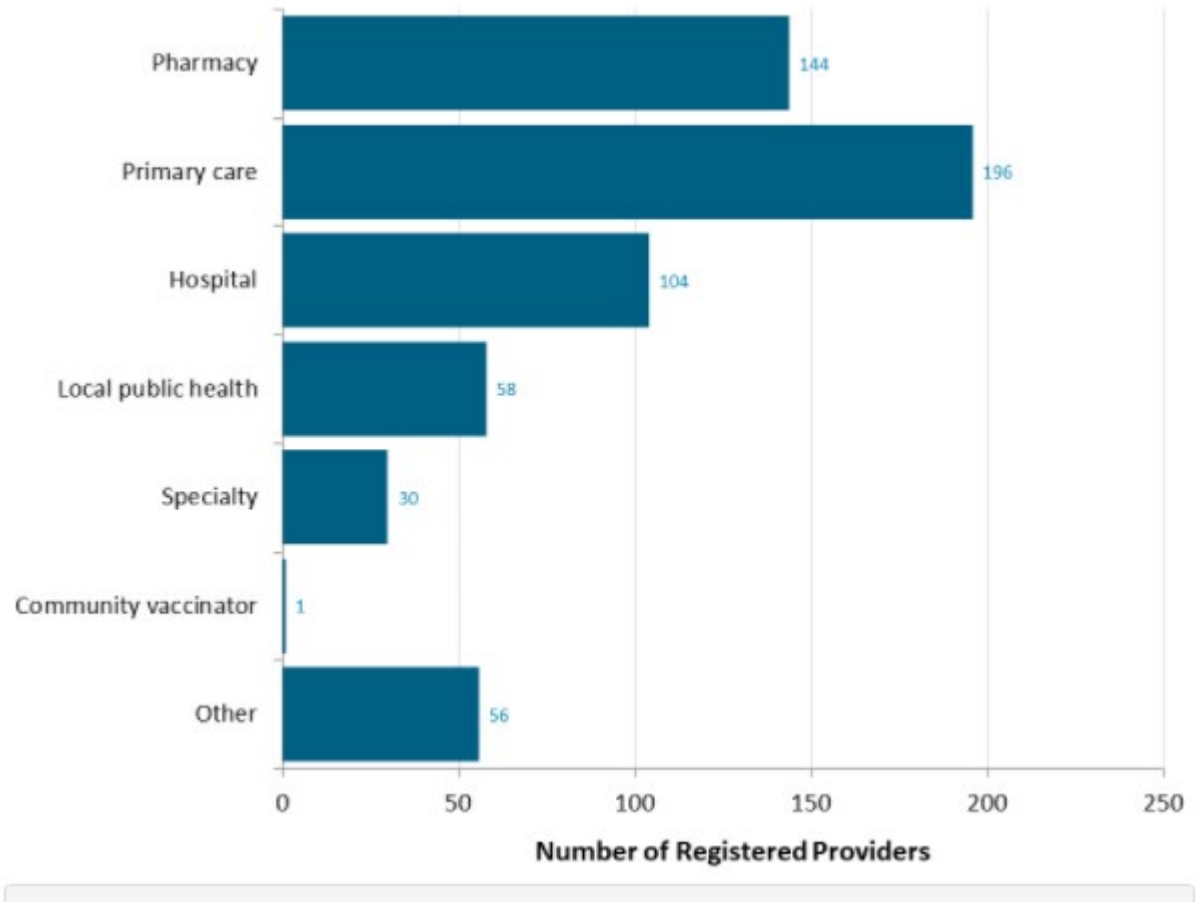
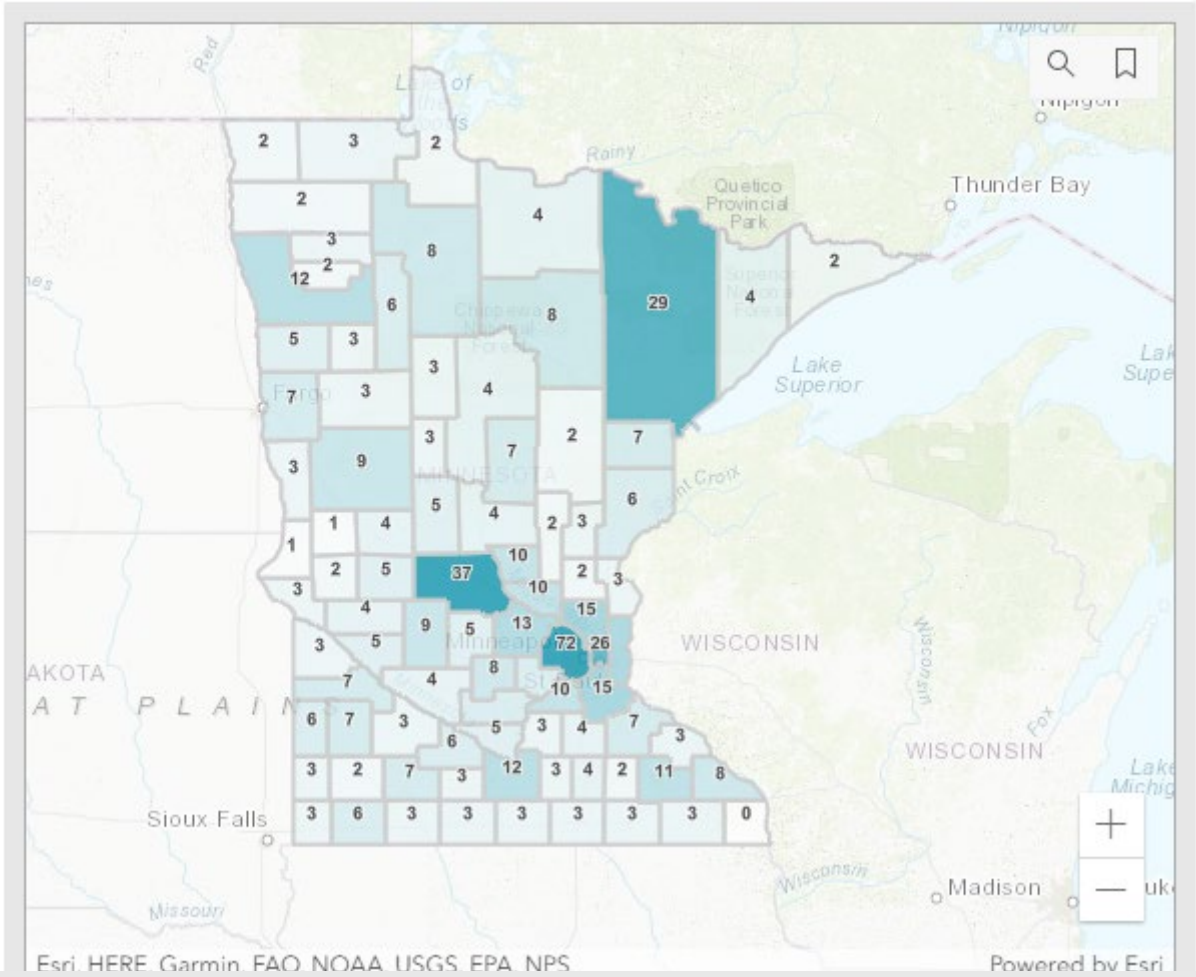
Number of providers registered by type of provider



Number of providers registered by county



MN Vaccine Allocation Advisory Workgroup

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Karen Herman, Disability Representative

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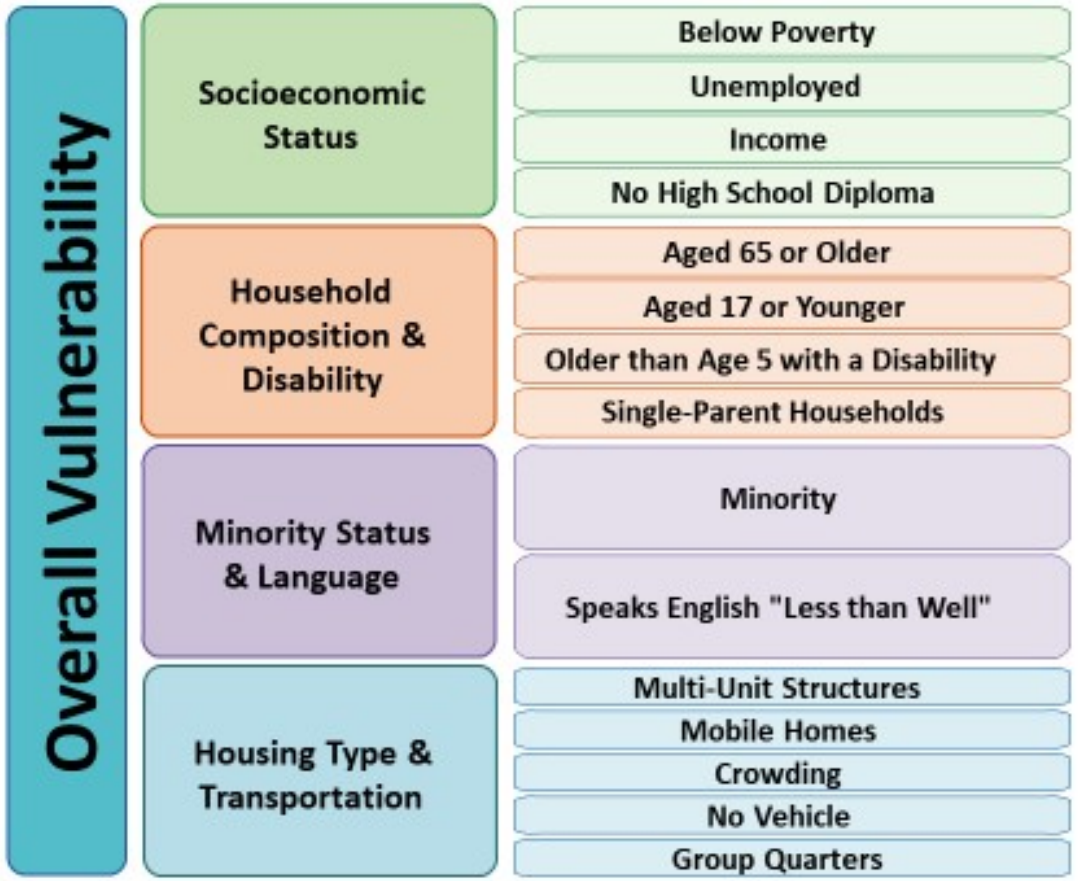
Social Vulnerability Index



- Counties with greater social vulnerability were more likely to become areas with rapidly increasing COVID-19 incidence (hotspot counties).[1]
- Social vulnerability is associated with higher COVID-19 case fatality.[2]

[1] https://www.cdc.gov/mmwr/volumes/69/wr/mm6942a3.htm
[2] https://www.medrxiv.org/content/10.1101/2020.04.10.20060962v2.full.pdf

ACIP Phase 1a Populations

- **Health Care Personnel:** Any paid or unpaid persons serving in health care settings who have the potential for direct or indirect exposure to patients or infectious materials.
- **LTCF Residents:** Adults who reside in facilities that provide a variety of services, including medical and personal care, to persons who are unable to live independently.

Minnesota Phase 1a sub-prioritization

Sub-prioritization guided by these risk criteria:

- Risk of infection
- Risk of severe morbidity and mortality
- Risk of transmitting to others (at work and at home)
- Risk of negative societal impact

Minnesota Phase 1a first priority group

Health care personnel (HCP)	Long-term care (LTC) residents
Hospitals: All personnel working in dedicated COVID-19 units, ICU, emergency departments, designated COVID-19 urgent care clinics. **LTCF (skilled nursing facilities and nursing homes)**: All personnel working in these facilities. **Emergency Medical Services Personnel** **COVID testers:** Personnel providing testing at large community testing centers. **COVID community vaccinators:** Public health vaccinators and those administering COVID-19 vaccine in Phase 1a.	**Residents living in skilled nursing facilities and nursing homes** (including veterans homes).

Minnesota Phase 1a second priority group

Health care personnel (HCP)	Long-term care (LTC) residents
Hospitals: All personnel providing direct patient services or handling infectious materials and not included in the first priority group. **LTCF (assisted living facilities/housing with services with an arranged Home Care Provider)**: All personnel working in these facilities. **Urgent care settings:** All personnel providing direct patient services or handling infectious materials and not included in first priority group. **Dialysis centers**: All personnel providing direct patient services or handling infectious materials.	**Residents living in Housing with services with an arranged Home Care Provider**, otherwise known as Assisted Living (including veterans homes).

Minnesota Phase 1a third priority group

Health care personnel (HCP)	Long-term care (LTC) residents
All remaining HCP not included in the first and second priority groups that are unable to telework.	Adult residents living in Intermediate Care Facilities for Individuals with Intellectual Disabilities and other adult residents living in residential care facilities licensed in MN

FDA Approves Pfizer Vaccine

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- FDA VRBPAC met to decide:
  - Based on the scientific evidence available the Pfizer-BioNTech COVID-19 Vaccine may be effective in preventing COVID-19 in individuals 16 years of age and older, and
  - The known and potential benefits of the Pfizer-BioNTech COVID-19 Vaccine outweigh its known and potential risks for use in individuals 16 years of age and older
- FDA VRBPAC voted 17 to 4 (1 abst) to recommend approval of Pfizer's vaccine.

ACIP Voted to Approve the Vaccine

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- The ACIP voted Saturday to recommend the Pfizer COVID-19 vaccine for use in persons 16 years of age and over.
- CDC approved this recommendation on Sunday, December 13, 2020

mRNA Vaccines

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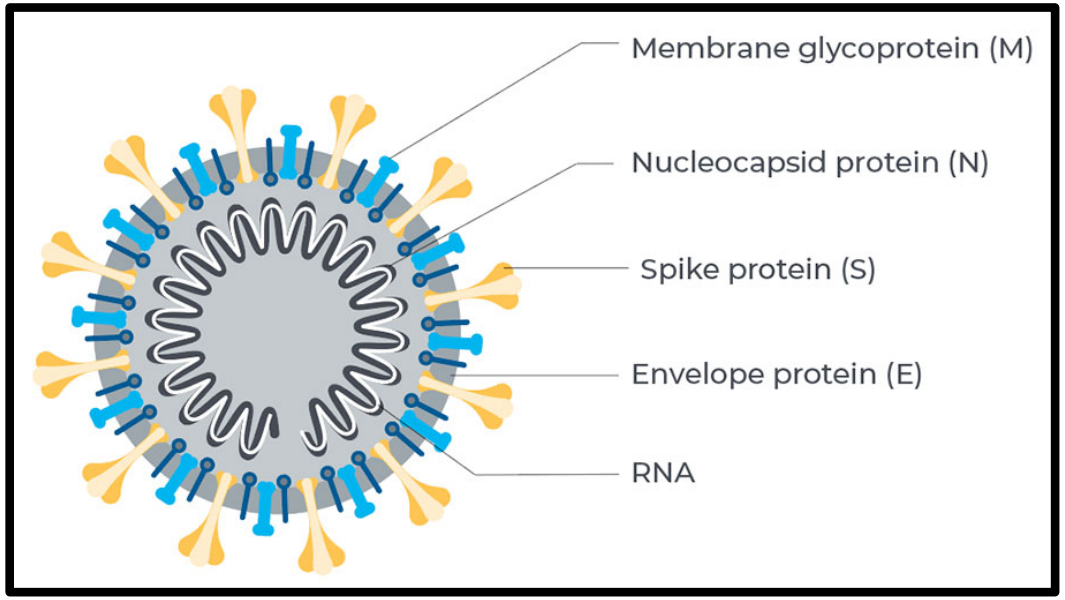
- Many vaccines put a weakened or inactivated germ into our bodies to trigger an immune response.
- COVID-19 mRNA vaccines give instructions to cells to make **a harmless piece** of what is called the “spike protein.” The spike protein is found on the surface of the virus that causes COVID-19. This protein is what will trigger an immune response.
- COVID-19 mRNA vaccines are given in the arm. Once mRNA are inside the immune cells, the cells use them to make the protein piece. After the protein piece is made, the cell breaks down the instructions and gets rid of them.
- When the cell displays the protein piece on its surface. Our immune systems recognize the protein as foreign and begin developing antibodies.
- At the end of the process, our bodies have learned how to protect against future infection.



Demographics of Clinical Trial Participants

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- The phase 2/3 clinical trial population included 49.4% females, 81.9% White, 9.8% African American, 4.4% Asian participants, and <3% from other racial groups
- 26.2% of participants were Hispanic/Latino
- 21.4% of participants were >65 years of age
- The median age was 51 years.
- Comorbidities included obesity (35.1%), diabetes (8.4%) and pulmonary disease (7.8%).
- Geographically, 76.7% of participants were from the US, 15.3% from Argentina, 6.1% from Brazil, and 2% from South Africa.

Vaccine Efficacy

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- The vaccine efficacy after 7 days post Dose 2 was 95%, (95% CI 90.3; 97.6) in participants without prior evidence of SARS-CoV-2 infection
- >94% in the group of participants with or without prior SARS-COV-2 infection
- Efficacy outcomes were consistently robust (≥93%) across demographic subgroups

Vaccine Efficacy by Age

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Age Group	Cases in Vaccine Group N=18,198	Cases in Placebo Group N=18,325	Vaccine Efficacy % (95% CI)
All Participants	8	162	95.0 (90.3, 97.6)
16 to 55 years	5	114	95.6 (89.4, 98.6)
>55 years and older	3	48	93.7 (80.6, 98.8)

*Efficacy for 65-74 years 92.9%, efficacy >75 years 100%

Asymptomatic Infection and Viral Shedding

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- Not able to assess the effect of the vaccine against asymptomatic infection
- Asymptomatic infections may not be prevented as well as symptomatic infections and may be associated with sequelae (e.g., myocarditis).
- Additional study will be needed to assess the effect of the vaccine in preventing long-term effects of COVID-19
- Additional study will be needed to assess the effect of the vaccine in preventing virus shedding and transmission, in particular in people with asymptomatic infection

Effectiveness of a single dose

- Based on the number of cases identified after Dose 1 and before Dose 2, there is some protection against COVID-19 disease after one dose
- No data for protection longer than 21 days since everyone received a second dose
- Bottom line: NEED TWO DOSES

Duration of Protection

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- As the interim and final analyses have a limited length of follow-up, it is not possible to assess sustained efficacy over a period longer than 2 months.

Pfizer Vaccine Safety Data

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- Safety data on 38,000 participants at 2 months post-vaccination did not raise any safety concerns
- The most common adverse reactions were injection site reactions (84.1%), fatigue (62.9%), headache (55.1%), muscle pain (38.3%), chills (31.9%), joint pain (23.6%), fever (14.2%);
- Severe adverse reactions occurred in 0.0% to 4.6% of participants, were more frequent after Dose 2 than after Dose 1, and were generally less frequent in participants ≥55 years of age (≤2.8%) as compared to younger participants (≤4.6%)

Pfizer Vaccine Safety Data

- The frequency of serious adverse events was low (<0.5%); no differences between vaccine and placebo groups.
- The number of subjects reporting hypersensitivity-related adverse events was numerically higher in the vaccine group compared with the placebo group (137 [0.63%] vs. 111 [0.51%]).
- There were no specific safety concerns identified by age, race, ethnicity, medical comorbidities, or prior SARS-CoV-2 infection, and occurrence of adverse events was consistent with the overall study population.

Ongoing Vaccine Safety Monitoring

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- As is the case with all approved vaccines, post-approval monitoring of the vaccine will be ongoing.
- Multiple national systems in place that identify signals and evaluate whether the signal is related to vaccination or just coincidence.
- Vaccine safety monitoring systems are designed to rapidly detect even the slightest signal, so detecting signals means the system is working.
- Systems have been in place for more than 30 years and they are used to detect potential problems with every vaccine that is recommended for the American public

Ongoing Vaccine Safety Monitoring

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- V-SAFE: smart phone based app to check in with vaccine recipients for health problems post-vaccines.
- VAERS: national system that collects reports from healthcare professionals, vaccine manufacturers, and the public of adverse events after vaccination
- Vaccine Safety Datalink: network of 9 healthcare organizations that conducts active surveillance and research related to VAERS
- CISA: 7 medical research centers that provide expert consulation

Vaccinating LTC

- LTC facilities had the option to participate in the federal Pharmacy Partnership for LTC Program (PPP) or go through another pharmacy of their choice or local public health
- In Minnesota, 210 of 364 SNF facilities chose to participate in PPP

Vaccinating Skilled Nursing Facilities(SNFs)

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- Finalizing the plan for vaccinating SNFs using first allocation of Moderna vaccine, expected to be available for distribution 12/21.
- We “pushed the button” for the Pharmacy for LTC Partnership Program for SNFs with Moderna vaccine (we had to guarantee 50% of need with our MN allotment)
- CVS/Walgreens/Thrifty White will be vaccinating in SNFs starting the week of 12/28
- Partners that are vaccinating SNFs that opted out of the PPP will begin vaccinating with state allocation the week of 12/28 if not before

Training Plan for Week of December 14

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- We released 20-page provider guide and on demand video trainings (4 modules) Tuesday. Based on EUA and ACIP guidance.
- Live MN provider guide training by MDH staff over noon hour on W through F
- Pfizer is conducting storage and handling training twice daily all week
- Provider hotline has been staffed up
- Individual providers are required to attest they have completed the training prior to vaccinating
- Once attested, provider is greenlit to vaccinate

Vaccine Arrival Timeline from CDC

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- Pfizer began processing the first orders for COVID-19 vaccines Saturday evening (December 12).
- Seven pre-position sites received vaccine M-T (7,000 of 46,800 doses)
- Remaining hub sites will receive their vaccine on Thursday/Friday.
- Distribution to spokes when ready to vaccinate (given the 5 day time frame)

How do we track the doses given?

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- We have a system to track how many doses MN has received and where they have been shipped
- Providers are required to provide doses administered data to Minnesota Immunization Information Connection (MIIC) within 24 hours
- MIIC can track when second doses are needed. Recommend scheduling the second dose at the time of the first. PrepMod also does reminders.
- The patient will receive a vaccination card. We are also encouraging the patient to take a photo of the record card as back up documentation.

Overarching Final Messages

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- Hope: vaccine is here!
- Patience: there will not be enough vaccine for everyone who wants it initially, this will take time
- Immunize for Impact: focusing on staff in health care, LTC most vulnerable

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Thank you!

DEPARTMENT OF HEALTH

Vaccine Efficacy by Comorbidities

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Co-Morbidity	Cases in Vaccine Group	Cases in Placebo Group	Vaccine Efficacy (95% CI)
Overall	8	162	95.0 (90.0-97.9)
No Comorbidity	4	76	94.7 (85.9-98.6)
Any Comorbidity	4	86	95.3 (87.7-98.8)
Any Malignancy	1	4	75.7 (-145.8, 99.5)
Cardiovascular	0	5	100.0 (-0.8, 100.0)
Chronic Pulmonary Disease	1	14	93.0 (54.1-99.8)
Hypertension	2	44	95.4 (82.6-99.5)
Diabetes	1	19	94.7 (66.8-99.9)
Obese (BMI >= 30 kg/m^2	3	67	95.4 (86.0-99.1)

Vaccine Efficacy point estimates were uniformly high across the comorbidities examined, though for some interpretation of the results is limited by small numbers of participants and/or cases.

Vaccine Efficacy by Race/Ethnicity

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Race/Ethnicity	Cases in Vaccine Group	Cases in Placebo Group	Vaccine Efficacy (95% CI)
Ethnicity			
Hispanic/Latino	3	55	94.5 (83.2-98.9)
Non-Hispanic/Latino	6	114	94.7 (88.1-98.1)
Race			
AI/AN	0	1	100.0 (-3511.0, 100.0)
Asian	1	4	74.4 (-158.7, 99.5)
Black/African American	0	7	100 (30.4-100.0)
White	7	153	95.4 (90.3-98.2)
Multiracial	1	1	10.4 (-6934.9, 98.9)