



# Nov. 5, 2020

## Meeting Minutes: Phase 1a

### MINNESOTA VACCINE ALLOCATION ADVISORY GROUP

**\*The following is not a word-for-word transcription of the meeting. It is an outline of the conversations had and contributions made by the Advisory Group and meeting presenters. Information and planning assumptions were based on information that was known at the time of the meeting, and assumptions may have changed.\***

### Advisors present:

Organization	Name	Title
MDH	Kris Ehresmann	Director, Infectious Disease Epidemiology, Prevention and Control Division
Minnesota Medical Association	Dr. Jill Amsberry	Pediatric specialist
LeadingAge Minnesota	Kari Everson	Director of Clinical Care & Clinical Consultant
Care Providers of Minnesota	Doug Beardsley	Vice President of Member Services
DHS Medicaid & MinnesotaCare	Dr. Nathan Chomilo	Medical Director Medicaid & MinnesotaCare
Minnesota Hospital Association	Abigail Stoffel	Quality and process improvement specialist
ICSI Immunizations Workgroup	Lee Mork	Director of Pharmacy for Allina Health Medical Group Clinics
Minnesota Board of Pharmacy	Cody Wiberg	Executive Director
MIPAC/MN Council of Health Plans	Patty Graham	Senior Quality Consultant
Tribal Health Director	Pat Butler	White Earth Tribal Health Director
Minnesota COVID Ethics Collaborative	Dr. Debra DeBruin	Interim Director, Associate Professor, Director of Graduate Studies, Center for Bioethics
MDH	Jackie Dionne	American Indian Health Director
MDH	Danushka Wanduragala	Director COVID-19 Cultural, Faith, and Disability Communities

Organization	Name	Title
Local Public Health	Christine Lees	Dakota County Disease Prevention & Emergency Preparedness Supervisor
Local Public Health	Kristie Rathmanner	Wright County Public Health Nurse
Health Equity Advisory and Leadership Council	Therese Genis	Health East Community Health & Wellbeing Strategist
Disability Representative	Karen Herman	Executive Director of Udac inc.
Mayo Clinic	Dr. Melanie Swift	Medical Director, Mayo Clinic Physician Health Center. Assistant Professor of Medicine

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## Advisory Group Welcome - Kris Ehresmann

1. The COVID situation in MN is unprecedented:
  - a. We continue to hit new milestones: Nearly 4000 new cases today; 930 people hospitalized, with 227 patients in intensive care.
  - b. Professionals trying to tackle this in all hard hit sectors (e.g., schools, corrections, long term care, health care, etc.) are feeling overwhelmed.
2. This is why the work of this Advisory Group is so important. You are the light at the end of the tunnel. The work done here will help us achieve herd immunity through vaccination as opposed to natural disease progression.
3. A heartfelt thanks to everyone on this team for doing such important work in such a dark time.

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## Agenda Review and Roll Call - Facilitator

### COVID Updates

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## Anticipated Timeline for Federal Process for COVID - 19 Vaccine Allocation - Lynn Bahta, RN, MPH, CPH, Immunization Clinical Consultant

Slide 2: Goals of the COVID-19 Vaccine Program

- Ensure safety and effectiveness of COVID-19 vaccines
  - The number one goal for ACIP is to assure that the scientific evidence shows that it is a safe and effective vaccine.
  - To that end, ACIP established the Vaccine Safety Technical Subgroup to independently review the clinical data before ACIP makes any policy recommendations.
- Reduce transmission, morbidity and mortality of COVID-19 disease

- Help minimize disruption to society and economy, including maintaining healthcare capacity
- Ensure equity in vaccine allocation and distribution

Slide 3: Vaccine Update

- Within USA, as of October 30, 2020:
  - Four vaccines in active Phase three clinical trials
  - Five vaccines in active Phase one/two clinical trials

Slide 4: Vaccine Update

- Two vaccines most likely to receive initial approval for Emergency Use Authorization (EUA).
- BNT162b2 vaccine (Pfizer/BioNtech)
  - 42,133 participants enrolled as of 10/26/2020
  - 35,771 participants have received their second vaccination
  - 30% of U.S. participants enrolled have “diverse backgrounds”
- mRNA-1273 vaccine (Moderna): Enrollment Complete
  - 30,000 participants enrolled as of 10/22/2020
  - 25,654 participants have received their second vaccination
  - 37% of study participant enrolled have “diverse backgrounds”
- Participants receive 8 weeks monitoring for adverse events - Ongoing
- “Diverse backgrounds” includes age, race/ethnicity, and pre-existing comorbidities

Slide 5: Vaccine Updates

- Two additional vaccine candidates on hold due to a potential adverse event, but now resuming Phase three trials
  - AZD1222 vaccine (AstraZeneca) FDA hold removed 10/23, resuming Phase three trials
  - Ad26.COVS vaccine (Janssen) safety pause lifted 10/23, resuming Phase three trials

Slide 6: Vaccine Updates

- Initially vaccines will mostly be made available under an EUA.
- EUA criteria includes:
  - Efficacy data showing protection against SARS-CoV-2 infection or disease with a point estimate of least 50% vs. placebo comparator
  - At least half of Phase three study subjects followed for both safety and efficacy for at least two months following vaccination regimen
    - Must include well over 3,000 Phase three vaccine recipients

- Must evaluate reactogenicity, serious Adverse Events, and Adverse Events of special interest
- Sufficient cases of severe COVID-19 to assess for signals of enhanced disease within the vaccinated cohort (adverse event of special interest) to ensure the vaccine does not increase severity of disease

Details: [Emergency Use Authorization for Vaccines to Prevent COVID-19 \(October 2020\)](https://www.fda.gov/media/142749/download)  
([www.fda.gov/media/142749/download](https://www.fda.gov/media/142749/download))

Slide 7: Vaccine Update - timeline in rough estimates

- Pfizer collecting efficacy and safety data post dose two
- When data is sufficient, submission to FDA for Emergency Use Authorization likely, earliest timeline: end of November
- At least two-week turn around for data review and deliberation: mid-December
- If authorized, ACIP will review data and make recommendations for use and priority populations: last part of December

## Q&A

**Advisor 5:** Heard a rumor that the drug companies may seek “expanded access” approval as an alternative to EUA. Is this likely to happen and what would that entail?

**Lynn Bahta:**

- That is an option in addition to licensure or EUA.
- “Expanded access” is another FDA regulatory mechanism for making investigational products to address serious diseases available outside of clinical trials
  - An expanded access treatment protocol could be considered for deployment of a COVID-19 vaccine
  - Benefit/risk considerations would be similar to EUA and based on available data and proposed use (e.g., populations and numbers of individuals to be vaccinated)
  - Other considerations (including for planning and implementation) are different from EUA
  - Expanded access treatment protocol would be conducted under Investigational New Drug regulations, with requirements including (but not limited to) informed consent (more rigorous than under an EUA) for clinical investigation, institutional review board oversight, and investigator responsibilities for vaccine providers

**Advisor 17:** I know under EUA there can be no mandate so what is projected licensure timing?

**Lynn Bahta:** Full licensure requires additional tracking data beyond the eight-week window necessitated by an EUA. Around six months of data. The additional time gives us a better picture regarding such things as duration of immunity, efficacy among critical subpopulations (e.g. elderly and immunocompromised), and a more complete understanding of safety.

**Advisor 3:** What is the State's role in monitoring efficacy? This is often one of the rationales given for refusing the flu vaccine, "I heard it doesn't really work."

**Lynn Bahta:** Our public communications will need to manage expectations. The vaccine may not be perfect, but in combination with current mitigation strategies (i.e. masks, social distancing, and isolation) gives us the best chance of getting the pandemic under control. We are working with our communications experts at MDH to create messaging that is both positive and realistic. But that balance can be challenging.

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## COVID Vaccine Allocation Assumptions - Jessica Munroe, VMI Unit Supervisor, Vaccine Preventable Disease Section

Slide 2: Agenda: This presentation will cover:

- Background
- Known tenets of vaccine distribution
- Allocation principles to consider specific to COVID-19 vaccination
- Evaluation of impact on distribution

Slide 3: Background on Ongoing Planning:

- Eight Health Care Coalition (HCC) Regions that do emergency preparedness planning
  - Each emergency preparedness region operates with a multi-disciplinary team
  - Defined geographic regions will provide framework for distribution in all phases
  - Early phase planning is ongoing to coordinate reaching priority populations with ultralow cold (ULC) vaccine product
  - Regions will be used as the geographic unit within following allocation scenarios. Regions are a partnership between LPH, hospitals, and emergency preparedness partners.

Slide 4: Known Tenets of Distribution:

- These are tenets learned from H1N1 and are used in allocating the seasonal flu vaccine
  - Geography
  - Each HCC or county will receive at least some vaccine initially
- Similar to federal allocations to states
  - Pro Rata:
    - Each HCC or county will receive a pro rata allocation

- The pro rata distribution could be based on many different reference points: e.g. pro rata based on overall population, or health care workers or other critical infrastructure or chronic health conditions
- Vaccine would be allocated to enrolled providers within the region. This size of the allocation would depend on the size of the priority population they serve
- Randomization:
  - If not enough vaccine for all sites serving priority populations, we will need to randomize sites.

Slide 5: Allocation Principles to Consider:

- Should the Social Vulnerability Index (SVI) be included?
  - Should the allocation be weighted to account for areas with higher social vulnerability? Areas with higher SVI ratings would receive additional doses
  - Vaccine would still be administered to prioritized populations, but assumes there are more vulnerable people in the targeted group
- Should we consider disease incidence?
  - Should the allocation be weighted to give more doses to geographies with higher COVID-19 incidence?

Slide 6: SVI Index

- Composite score of a variety of social factors by geography
- Four categories each with two to five subcategories:
  - Socioeconomic Status:
    - Below poverty
    - Unemployed
    - Income
    - No High School Diploma
  - Household Composition & Disability:
    - Aged 65 or Older
    - Aged 17 or Younger
    - Older than Age 5 with a Disability
    - Single-Parent Households
  - Minority Status and Language:
    - Minority
    - Speaks English “Less than Well”

- Housing Type and Transportation:
  - Multi-Unit Structures
  - Mobile Homes
  - Crowding
  - No Vehicle
- Group Quarters
- Counties with greater social vulnerability were more likely to become areas with rapidly increasing COVID-19 incidence (hotspot counties)
- Social vulnerability is associated with higher COVID-19 case fatality

Slide 8: Thought Scenarios - Assumptions

- **NOTE: All scenarios are notional to illustrate possible differences that could occur and do not represent any allocation decisions - thought experiment only**
- 100 dose package size
- 100,000 doses initially available
- Providers in each county would register and be selected to receive vaccine based on their ability to vaccinate specific priority populations
- The order of providers who receive vaccine may need to be randomized based on the number of doses available

Slide 9: Thought Scenarios - Scenario one

- Pro Rata allocation based on county level population
- Assuming 100,000 doses, this would vaccinate just under 1% of the population in each HCC region (variations in percent vaccinated are rounding errors due to minimum package size)
- This would not take into account priority populations

Slide 10: Thought Scenarios - Scenario two

- Incorporate SVI score to allocation
- 90% of statewide allocation would be distributed based on county level population
- 10% of statewide allocation would be distributed to counties in the highest SVI quartile

Slide 11: Thought Scenarios - Scenario three

- Incorporate five-week COVID-19 case incidence to allocation
- 90% of statewide allocation would be distributed based on county level population
- 10% of statewide allocation would be distributed to counties in the highest quartile based on five-week case incidence

Slide 12: Thought Scenarios - Scenario four

- Include both SVI score and five-week case incidence to allocation
- 80% of statewide allocation would be distributed based on county level population
- 20% of statewide allocation would be distributed to counties in the highest quartile based on SVI and five-week case incidence

Slide 13: Impact to scenarios with additional doses

- Percent of population vaccinated in each regional HCC, by scenario (assuming 1 million doses)
- 1 million doses would provide enough to vaccinate roughly 9% of people in each region with a population based pro rata distribution

## Q&A

**Advisor 3:** Why only 10% withheld on these scenarios?

**Jessica Munroe:** The 10% was selected simply to demonstrate how distribution would change by region in each of the 4 scenarios. We would like your feedback on the benefits using a higher percentage of the statewide allocation for pro rata distribution based on SVI, case incidence, or some other factor.

**Advisor 1:** Did you overlay SVI and disease incidence? Since they are so related?

**Jessica Munroe:** We did the allocations separately in these scenarios. However, those indicators are correlated, so we found that the additional doses seemed to go to the same regions. If advisors are interested, we could consider the methodology and apply something a bit more nuanced.

**Advisor 11:** Will the regional allocations include tribes? Will they get access this way?

**Jessica Munroe:** Tribes have until tomorrow to decide if they want to receive their allocation federally, through IHS, or through our state allocation process.

**Advisor 15:** Out of eleven tribes in the state, six or seven have selected to receive their allocations through the state of MN.

**Advisor 15:** How would weighted allocation work between regional HCCs and the tribes that reside in those regions? Would a regional HCC get additional doses simply because they have a larger American Indian population?

**Jessica Munroe:** That is something we need to consider.

**Advisor 14:** Do we know the death reduction with using the outbreak allocation?

**Lynn Bahta:** We don't yet have efficacy data for any of the vaccine candidates. The criteria for efficacy is any symptoms of the disease. At some point we should have that data from the manufacturers, but it will take time.



**Advisor 5:** If someone is vaccinated where they work in one coalition, but reside in another coalition's geography, where are they counted in the coverage percentages?

**Jessica Munroe:** That would depend on the population targeted for pro rata allocation; general public or HCP. In the case of HCP, I'm not sure if we would record their vaccination under the region in which they lived or work. I'll need to get back to you on that.

**Advisor 2:** Is data available to suggest an equitable reduction of burden on healthcare systems with these models? (ex. regional vs metro)

**Jessica Munroe:** Also a question I will need to get back to you with an answer.

**Advisor 16:** Is there discussion about any other epidemiological measures besides five-week incidence? Could you say more about the decision to use this?

**Jessica Munroe:** We chose the five-week incidence because it's more robust at measuring trends compared to say the one-week incidence, which can fluctuate based on local testing efforts.

**Advisor 1:** We have lots of different measures we could use to assess disease burden, such as test positivity rate, incidence over time, etc. The question for the Advisory Group is, should we use some metric for disease burden in our allocation considerations?

**Deb Radi:** I think there is some confusion about geography and health care coalitions. Geography and coalitions are one in the same. However, the coalitions will only be helping with the initial logistics, but they won't be the ones making the allocation decisions.

**Advisor 3:** To add to Advisor 15's point/question: how are the regional collectives different/same? What ability do we have in the development of the framework to require the regional coalitions to distribute the vaccine to those communities that we are trying to target with SVI weighting? What enforcement does the state have in case this doesn't happen?

**Jessica Munroe:** We are currently working with local public health departments to identify their providers who can reach priority populations. Once identified, we get those providers registered with MDH as COVID vaccine providers. As to enforcement, all registered providers will sign a provider agreement that includes a commitment to comply with MDH recommendations. However, the best way to ensure that priority populations are receiving the vaccine, is to identify and register the providers who serve those communities.

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## Breakout Groups

Advisors and Steering Committee members were split up into four breakout groups and asked to consider the following questions.

1. As you review these scenarios, what are the key elements important to helping inform how we distribute the initial allocations of the vaccine geographically?

2. What role, if any, should disease incidence in specific regions play in helping to guide geographic allocations?
3. What role, if any, should the social vulnerability index play in helping to guide geographic allocations?
4. Are there any other indicators, not included in the following scenarios, we should take into consideration?

## **Breakout Groups Debrief**

### **Facilitator's Group - Ben Christianson reporting:**

1. Disparities seen among racial/ethnic groups. SVI may cover some of those groups, however not an exact fit. Is there additional data we need to better understand and target allocation?
  - a. Need a way to compare incidence rates across groups (apples to apples comparison). Example: Native American rates are high, but gross numbers are low.
  - b. Case incidence can be misleading. High incidence does not always occur in the communities that have the most severe outcomes. Example: college towns.
2. How will framework be used in later phases? Group thinks it should be used.

### **Denise Dunn's Group - Advisor 4 reporting:**

1. Variation among regional coalitions and what does vulnerability mean in terms of impact for each region based on its unique characteristics (e.g. socioeconomic, mortality, morbidity). Do we need to weight allocations towards intended populations within regions
  - a. Note: unsure if weight should be given because a region has a higher proportion of an intended population, or if we should weigh allocation to the intended population based on regional conditions (e.g. we vaccinate more at risk people in regions with higher case incidence).
2. Vaccination in the absence of other public health interventions. How effective will it be to allot additional vaccines in regions that have little social distancing and low mask usage? Should this behavior be taken into account when weighing allotments?
3. Disease incidence and allocations. Inequality and justice need to be factored into that equation.
4. SVI may not be the best metric for identifying vulnerable populations. The index is not a one to one match for populations most vulnerable to COVID. What are some of the other tools and approaches we could use to drill down to our target populations?
5. What impact timeframe should we use? Five-week incidence rates, or impacts over the entire course of the pandemic? Call for reciprocity value; e.g. those regions/populations that have already borne the worst brunt of the pandemic may deserve additional assistance.

### **Facilitator 2's group - Danushka Wanduragala reporting:**

1. SVI may be a helpful indicator since it correlates with case incidence rates, but some concerns leading with geography. May also want to consider healthcare capacity, and who has access.

2. Don't want to chase hotspots. Would like to use longer-term less variable metrics for weighted allocation.
3. Case rates and SVI don't reflect all the needs we should be taking into account
4. How do we make sure guidelines are followed?

#### **Deb Radi's group - Advisor 5 reporting:**

1. Meta question: How does the geographic allocation effect phase 1a (HCP). Is a geographic framework appropriate for HCP, or better applied to later phases? Consensus of breakout group was that geographic based allocation was better for phase 1b and later.
2. How well are congregate settings incorporated into SVI? How do you handle turnover of HCP in congregate settings (80%). Example: Do you want to "pursue a strategy of allotting extra vaccine to facilities to vaccinate incoming new hires? Or do you want to try to blanket those communities more densely with vaccinated people in their applicant pools?"
3. Using SVI plus disease incidence is a good way to target geographies that have a high "risk of exposure, disease and poor outcomes."
  - a. However, predicted disease incidence should be used instead of chasing after peaks.
  - b. Disease incidence is still difficult to operationalize. How do you modify allotment when you're following a moving target? One recommendation was to hold back a portion of vaccines for emergency deployment to areas in crisis.
4. Should only 10% of MN's total allotment be allocated using a weighted distribution, or should that percentage be higher? How do we deal with vaccine hesitancy among those groups?
5. Logistically how well can the regional distributor reach the target populations? How should that requirement be addressed in the provider agreement?
6. Can we improve upon SVI with more targeted metrics? Examples: could we pad allotments to regions with higher rates of comorbidities like diabetes and obesity? Can we strip out younger regions from the index and target additional allotments to regions with older populations?
7. Request for more modeling of assumptions. What are the effects of dedicating a larger percentage of MN allotment to weighted distribution? What are the effects of using different proxy measurements for disease incidence?
8. Liked the idea of a reserve holdback to target at emergencies; e.g. outbreak in a nursing home.
  - a. NOTE: HHS has made an agreement with CVS and Walgreens to vaccinate nursing homes. We need to take into consideration this federal arrangement when deciding how much vaccine to allocate to nursing homes.
9. Nursing homes are required to sign up for allotments via CVS and Walgreens. Deadline for signing up was November 6.

#### **Breakout Group Discussion**

**Facilitator:** Returning to Advisor 5's meta question. How does geography affect phase allocation?

**Margo Roddy:** We're looking to develop guiding principles for how to achieve equitable allocation on a geographic basis. Phase 1a is HCP and we are already conducting regional planning to address that group, much of which is already baked in. We are waiting on ACIP guidance to better understand prioritization of target populations in Phase 1b. When we start sending out allocations for phase 1b vaccinations (regardless of target population) we need to decide if we should weight geographic allocations and on what basis. How should we decide how much to allocate to the southeast region, northwest region, or metro, for instance.

**Advisor 15:** So Margo, this discussion is for later in the plan - sometime late next year?

**Margo Roddy:** The high level guiding principles for geographic distribution will be applied in all phases of vaccine distribution.

**Advisor 15:** Thank you

**Facilitator:** [Reviewing issues raised by Advisors regarding geographic pro rata allocations]

- Advisors would like to see a pro rata allocation based on some measure of risk for COVID mortality and morbidity.
  - Does SVI adequately capture COVID vulnerability?
  - Do we need to drill down to find additional factors for targeting initial allocations?
- Advisors would like to see a pro rata allocation based on risk of infection (disease incidence).
  - Is five-week disease incidence the best metric to capture infection risk?
- What is the appropriate proportion of the statewide allotment that should be set aside for pro rata allocation to areas of higher risk?
  - 10% did not seem adequate to Advisors.
- Is there a way to model the effects of increasing the percentage directed at either SVI, disease incidence, or a combination of both?
- Should we set aside a proportion of the statewide allocation to address specific crises or high-risk environments? Examples:
  - 10% set aside for local hotspots.
  - 10% set aside for congregate living facilities.

**Advisor 1:** Incidence rates are not always a one for one measure of transmission risk. For example, a county could have high disease incidence due to an outbreak in a correctional facility, but the transmission risk is not as high because staff at that facility are the only vectors for community spread. Also bear in mind that we don't know if the vaccine will prevent infectiousness.

**Advisor 14:** We don't want to chase our tail on outbreaks. Rather look for the metrics that are associated with outbreaks and act proactively.

**Advisor 1:** We have trend data that could be used in a more proactive manner. We could share that with the group.

**Advisor 5:** On a related note. It may be a good idea for the state to withhold a portion of the total allotment for distribution at their discretion, so we can respond in a more targeted fashion once we know more about the vaccine. For example, is it better at preventing transmission or mortality/morbidity? How well does it work in target populations such as seniors?

**Advisor 1:** Agreed. But keep in mind that we may not have that level of detail available to inform the development of our initial framework.

**Advisor 3:** One other point from our group: if our goal is greater equity we discussed that the weighted allocation should be flipped, 90% by SVI and 10% pro rata, or even 100% by SVI

**Advisor 15:** Also, for American Indian older adults, very few of them are in nursing homes, in fact nursing homes race demographics have very few POC and AI. Do we need another approach to those populations when we are thinking about nursing homes as well?

**Margo Roddy:** Regarding AI older adults, we are collecting info on how local plans (tribal and local public health plans) are including vaccination of these individuals. Knowing where they seek health care to make sure that we have that information to factor into our distribution plans is important.

**Advisor 17:** Just a comment about minority populations and their growing distrust of the HC system--a significant percentage of the workforce in congregate care settings are from communities of color so until there is more efficacy information shared I am concerned about the voluntary take up rate.

**Advisor 3:** Mistrust is actually better defined as having experienced historical trauma at the hands of the healthcare system. This is why it is key to have the providers offering the vaccine be those the community does trust – i.e. not enforced by their employer or only through the state. That said, I do not believe that should weigh into the allocation guideline recommendations. We shouldn't punish communities for having a reasonable reaction to the trauma they have endured at the hands of the healthcare system.

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## MDH Health Care Worker COVID-19 Exposure Data: Ashley Fell, Epidemiologist, COVID-19 Health Care Worker Monitoring Team Co-Lead

Slide 2: CDC Morbidity and Mortality Weekly Report (MMWR) data published 10/29/2020

- As of 7/11/2020, over 5,300 Minnesota HC workers have had close prolonged contact with someone with COVID-19 while not wearing appropriate PPE.
  - One in three of these exposures occurred outside of patient care (according to data collected between March and early July)
  - HC workers post exposure are expected to:

- Quarantine for 14 days post exposure (exceptions are made for staffing shortages)
- Complete daily symptom survey for 14 days post exposure
- If they display symptoms, do they test positive

Slide 3: MMWR Key Points

- Many higher risk exposures occur outside of direct patient care
- Health care workers with higher-risk exposures in congregate living and long-term care settings
  - More likely to test positive in the 14 days following exposure than workers in acute care or outpatient settings
  - Less likely to be wearing masks and eye protection
    - Note: Access to PPE in congregate care settings has improved since this data was collected

Slide 4: Updates Since July

- 62% of all higher-risk exposures in September occurred outside of work
- The number of higher-risk exposures occurring within health care facilities has decreased
- 1824 in April compared to 407 in September
- Health care workers in congregate living and long-term care settings with higher-risk exposures continue to be at higher risk of infection

Slice 5: Updates Since July

	Acute Care	Long-Term Care	Assisted Living	Group Home	Outpatient	Other Settings	Household/Social Exposures
<b>Number of HCWs with higher risk exposures</b>	2,458	1,687	897	578	343	548	3,939
<b>HCWs tested positive for COVID-19 during monitoring</b>	2.0%	6.9%	7.0%	13.7%	1.5%	5.7%	11.6%

Slide 6: Race/Ethnicity of Healthcare Workers with Higher-risk Exposures by Facility Type (see table)

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## Ethical Considerations - Lynn Bahta, RN, MPH, CPH, Immunization Clinical Consultant

### Slide 9: ACIP Ethical Principles

- Proposed ethical principles from October ACIP meeting
  - Maximize benefits and minimize harms
  - Mitigate health inequities
  - Promote justice - promoting fairness was folded into the justice principle
  - Promote transparency
- Developed key questions stratified by ethical principles that can be used to develop allocation plans. We are hoping to post this guidance in the near future.
- Guidance coming so that local jurisdictions can tailor their plans

### Slide 10: Maximize benefits and minimize harms - Does the allocation plan address?

- What populations are at highest risk of infection, hospitalization, and death from COVID-19?
- What populations are essential to the COVID-19 response?
- What populations are essential to maintaining critical functions of society?
- What are the key characteristics of these populations, e.g., size or geographic distribution, that may inform the magnitude of benefit based on the amount of vaccine available or its characteristics?

### Slide 11: Mitigate health inequities

- Does the plan identify and address any population groups who are disproportionately affected by COVID-19?
- Does the plan contribute to a reduction in health disparities in COVID19 disease and death?
- What health inequities may inadvertently result from the allocation plan, and what interventions could remove or reduce them?

### Slide 12: Promote justice (and fairness)

- Does the plan include input from groups who are disproportionately affected by COVID-19 or economically/socially marginalized?
- Does the plan result in fair and equitable access of the vaccine for all people?
- Does the plan identify and address barriers to vaccination among groups who are disproportionately affected by COVID-19 or economically/socially marginalized?
- How do characteristics of the vaccine and logistical considerations impact equitable access for all people?

Slide 13: Promote transparency

- How does the plan include diverse input, and if possible, public engagement?
- Is the plan and its evidence-based method publicly available?
- Is the plan clear about the knowns, unknowns, and certainty of evidence?
- What is the process for revision of allocation plans based on new information?

## Discussion

**Facilitator:** What are some key areas of inquiry that we need to consider or that needs further clarification?

**Advisor 14:** How do we get doses to long-term care facilities and the HCP who work there? They are not signing up to regional compacts to receive vaccines. How do we get a hold of them?

**Advisor 3:** Group homes, assisted living, and long-term care settings stand out as the facilities that should be prioritized early. I'd also like us to give guidance regarding which HCP roles should be prioritized in these settings. Prioritizing the lower-wage positions, such as nursing admin and environmental services, would also have the benefit of addressing racial/ethnic health disparities since workers in these roles are disproportionately Black.

**Advisor 5:** Follow up to Advisor 3's comment. I think it's important to articulate the reasons these groups, and others, need to be prioritized. Two critical sources of "high risk" that have to be balanced; individual risk of occupational infection and collective risk due to loss of HCP critical to COVID response. We also need to be very clear in how we communicate "high risk" and the reasoning behind our prioritization. There's a lot of confusion among the public as to what a "high-risk" HCP is. We mean occupational risk of exposure and essential role in COVID response. However, many people hear "high risk" and think any health care worker with a pre-existing condition.

**Advisor 17:** There is also a transmission risk that needs to be taken into account. Staff are bringing COVID into these congregate care settings from the community. Many HCP who work in these settings pick up shifts at multiple facilities. So these workers are an important vector of asymptomatic transmission to populations at higher-risk of COVID mortality and morbidity (both residents and fellow HCP coworkers).

**Advisor 2:** I want to emphasize the importance of protecting personnel critical to the COVID response. ICU staff are very difficult to replace. You can't train another HCP into those positions at a moment's notice. Critical staff need to be prioritized.

**Advisor 11:** Two ethical factors that may help frame how we talk about risk. Instrumentality; how important is this work to the overall effort? And reciprocity; what do we owe this worker because they take on risk on behalf of the rest of us?

**Advisor 3:** There is also the external environment that can change the risk calculus. For example: if we start having PPE shortages again, then infection risk for ICU personnel sky rockets. As we try to develop



these recommendations we need to build in some flexibility to make modifications based on changing risk environments.

### Comments and questions from the chat that didn't make it into the discussion:

**Advisor 1:** Keep in mind access to PPE was a problem earlier in the pandemic for our LTC settings.

**Advisor 11:** I strongly agree with Advisor 5. Need to think of the underlying principles for prioritizing people. Risk of exposure. Risk of poor outcomes. Essential nature of their role. Maybe — if this can be determined or is relevant with the vaccine — risk of transmission. And all team members should be open to consideration — even volunteers.

**Advisor 1:** And we have experienced real staffing crises in our LTC ongoing.

**Advisor 1:** A challenge is that acute care is prioritized for PPE above LTC.

**Advisor 3:** Exactly Advisor 1

**Advisor 11:** I really agree with what Advisor 3 just said about ongoing assessment given varying supplies of PPE.

**Advisor 14:** Agree on the definition of high-risk need clarity in the context of priority. In vaccine we use high risk for a patients disease - for HCP it is the high risk for exposure is the risk.

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## Timeline and Next Steps - Facilitator

### Timeline

- FDA review of EUA applications by mid-December
- ACIP vaccine allocation final recommendations by end of December
- The Advisory Group may need to have a meeting between Christmas and New Years

Next Steps: We will be in touch soon with any materials requested during our discussion, as well as the synthesis from our breakout sessions.



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