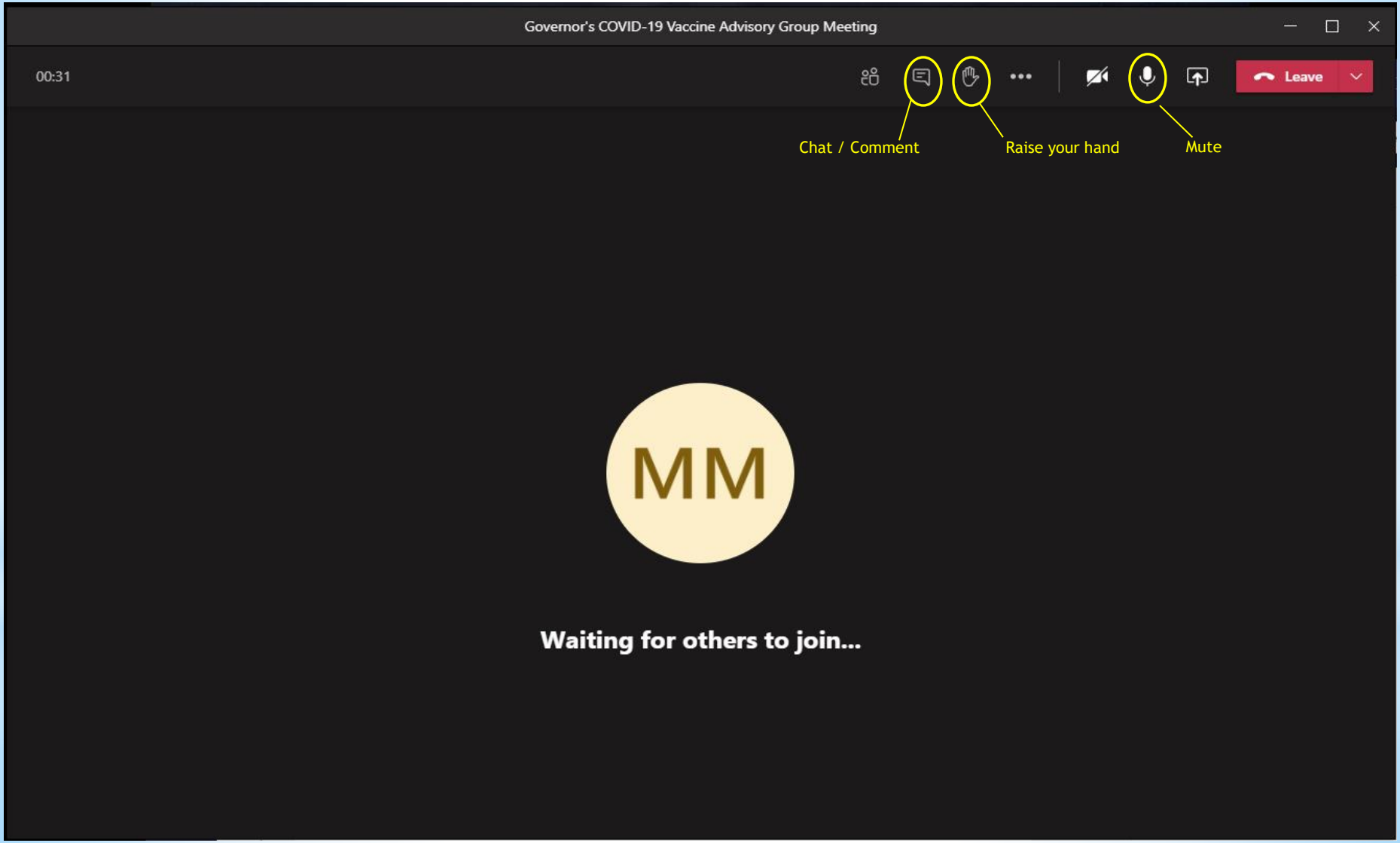
Governor's COVID-19 Vaccine Advisory Group

Thursday, November 19, 2020

Before We Begin

* Please remain muted
* Raise Hand
* Feel free to use Comments section
* Parking Lot

Navigating Teams



Welcome

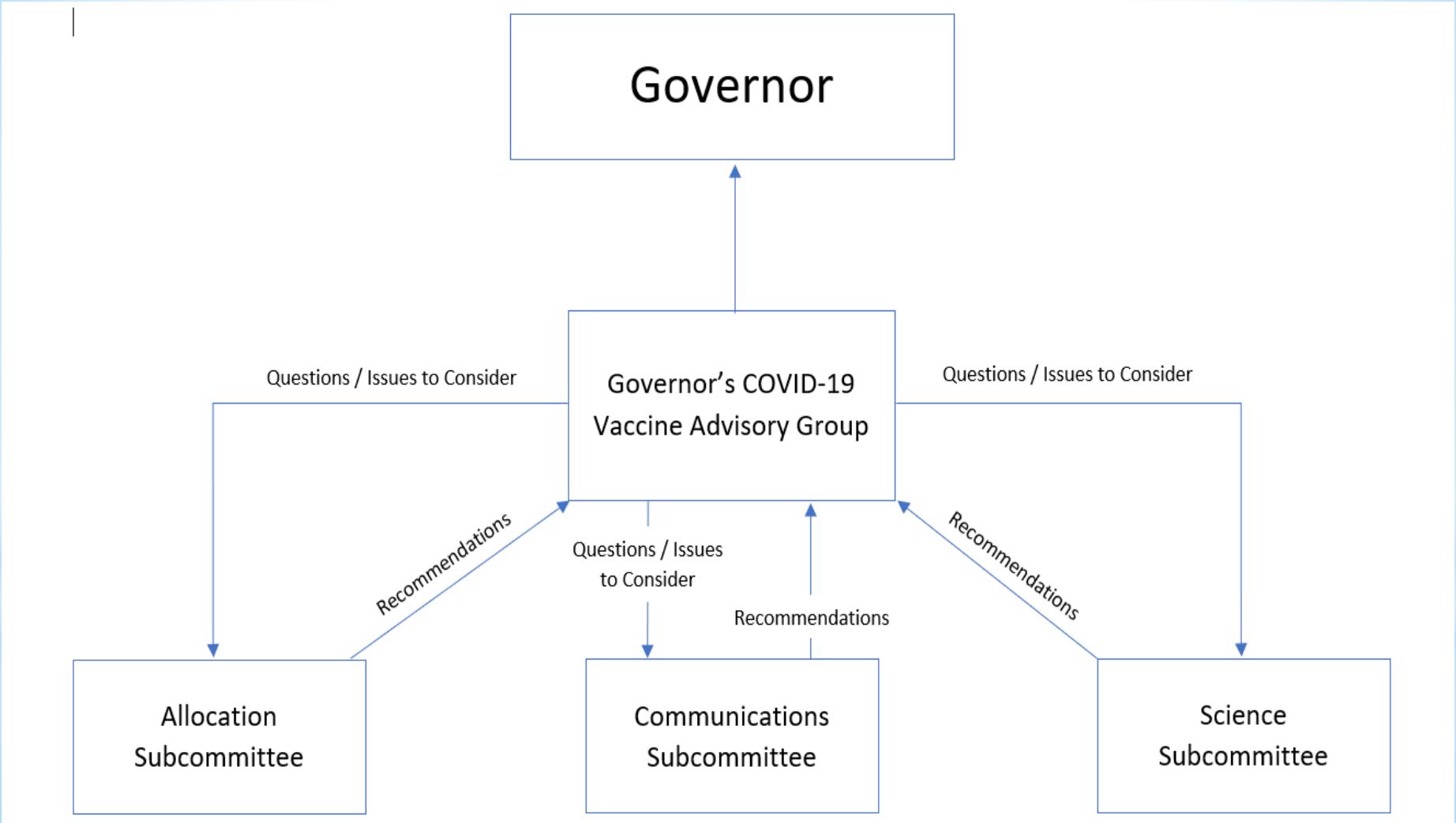
Commissioner Deidre Gifford, MD

Reginald Eadie, MD

Agenda

1. Welcome and Roll Call	Commissioner Gifford Dr. Eadie
2. Vaccine Update a. Vaccine Availability b. Vaccine Transportation and Storage i. Ultra-cold capacity	Kathy Kudish
3. Subcommittee Reports a. Science b. Allocation c. Communications	Jason Schwartz Nichelle Mullins Sen. Somers
4. Open Discussion	Advisory Group members
5. New Steps for Subcommittee Discussion	Advisory Group members
6. Next Advisory Group Meeting a. Thursday, December 17, 2020, 6:00-7:30 PM (proposed)	Mike Mozzer
7. Wrap-Up	Mike Mozzer
8. Adjourn	

Advisory Group Structure



Subcommittee Co-Chairs

* Allocation – Nichelle Mullins, Zita Lazzarini
* Science – Jason Schwartz, David Banach, MD
* Communications – Sen. Heather Somers, Joseph Quaranta, MD

Vaccine Storage and Handling: Pfizer

* Must be stored at ultra cold temperatures, at -80° to -60°C (-112° to -76°F).
* If the vaccine is thawed and stored in a refrigerator, it must be used within 5 days; once it is reconstituted with the diluent, it must be used within 5 hours. Temperatures must be monitored continuously where vaccine is stored using a data logger.
* Because of the storage requirements, Pfizer will be distributing this vaccine, shipping it directly from their facilities.
* Requires 2 doses at least 21 days apart. The minimum order amount is 975 doses.
* Reconstitution with diluent is required after thawing.
* ~20-30 million doses expected to be available in the US by end of December.
* Estimated efficacy 95%, no serious side effects

Vaccine Storage and Handling: Moderna

* Must be stored frozen at -25° to -15°C (-13° to 5°F). Standard freezers can usually reach these temperatures.
* If the vaccine is thawed and stored in a refrigerator, it must be used within 30 days. Temperatures must be monitored continuously where vaccine is stored using a data logger.
* Vaccine will be shipped by a central distributor under a Federal Government contract, the same one used to distribute vaccines under the Federal Vaccines for Children Program in CT.
* Does not require reconstitution. Two doses are required, at least 28 days apart. The minimum order amount for this vaccine is 100 doses.
* ~15 million doses expected to be available in the US by end of December
* Estimated efficacy 94.5%, no serious side effects

Science Subcommittee Update

Jason L. Schwartz

Yale School of Public Health

Science Subcommittee Members

Jason Schwartz* – Co-Chair, Yale School of Public Health
David Banach – Co-Chair, UConn Health

Jessica Abrantes-Figueiredo* – Trinity Health
Keith Grant* – Hartford HealthCare
Jim Hadler – Yale School of Medicine
Danyal Ibrahim – Trinity Health
Albert Ko – Yale School of Public Health
Roxy Kozyckyj – Healthcare Distribution Alliance
Richard Martinello* – Yale Medicine / Yale New Haven Health
William Petit* – Connecticut State House of Representatives
Jack Ross – Connecticut Infectious Diseases Society
Jody Terranova – American Academy of Pediatrics

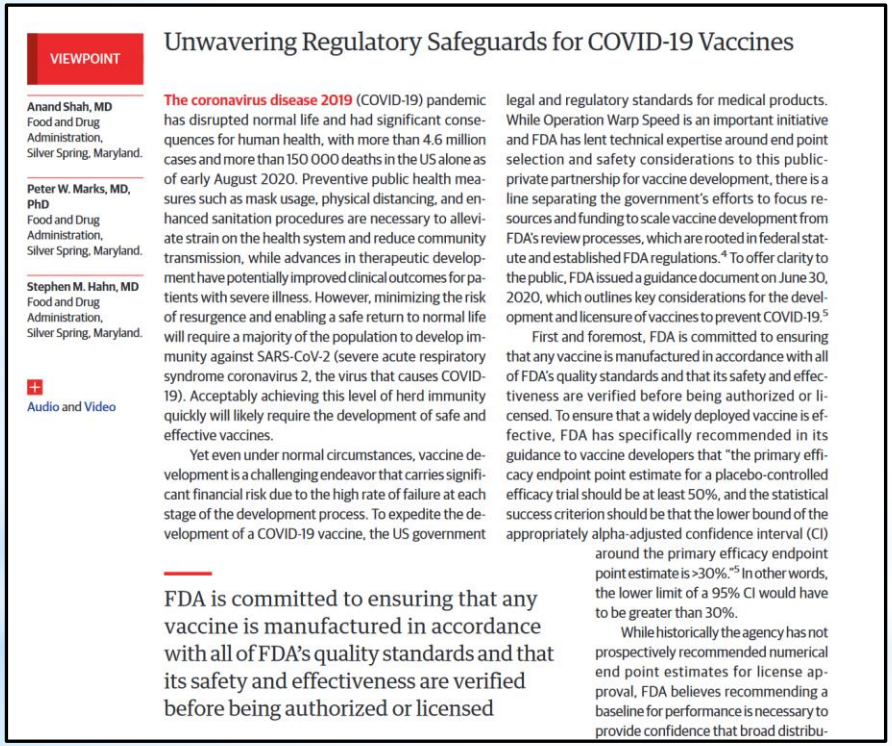
Subcommittee Charge & Approach

* Charge: “Confirm the integrity of the approval process”
  * “Approved”: Biologics License Application (BLA)
  * “Authorized”: Emergency Use Authorization (EUA)

* Approach:
  * Review of regulatory submissions, presentations, reports, statements, and other public materials from COVID-19 vaccine manufacturers and the Food and Drug Administration (FDA)
  * Scrutiny of FDA advisory committee proceedings and deliberations
  * Solicitation of perspectives from participants in FDA decision-making activities

* Outcome: Findings and recommendations shared with the advisory group for each vaccine authorized or approved by FDA

FDA Commitments to Rigor, Independence, and Transparency in COVID-19 Vaccine Decision-Making



VIEWPOINT

Unwavering Regulatory Safeguards for COVID-19 Vaccines

Anand Shah, MD
Food and Drug Administration, Silver Spring, Maryland.

Peter W. Marks, MD, PhD
Food and Drug Administration, Silver Spring, Maryland.

Stephen M. Hahn, MD
Food and Drug Administration, Silver Spring, Maryland.

Audio and Video

The coronavirus disease 2019 (COVID-19) pandemic has disrupted normal life and had significant consequences for human health, with more than 4.6 million cases and more than 150 000 deaths in the US alone as of early August 2020. Preventive public health measures such as mask usage, physical distancing, and enhanced sanitation procedures are necessary to alleviate strain on the health system and reduce community transmission, while advances in therapeutic development have potentially improved clinical outcomes for patients with severe illness. However, minimizing the risk of resurgence and enabling a safe return to normal life will require a majority of the population to develop immunity against SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2, the virus that causes COVID-19). Acceptably achieving this level of herd immunity quickly will likely require the development of safe and effective vaccines.

Yet even under normal circumstances, vaccine development is a challenging endeavor that carries significant financial risk due to the high rate of failure at each stage of the development process. To expedite the development of a COVID-19 vaccine, the US government legal and regulatory standards for medical products. While Operation Warp Speed is an important initiative and FDA has lent technical expertise around end point selection and safety considerations to this public-private partnership for vaccine development, there is a line separating the government's efforts to focus resources and funding to scale vaccine development from FDA's review processes, which are rooted in federal statute and established FDA regulations.[4] To offer clarity to the public, FDA issued a guidance document on June 30, 2020, which outlines key considerations for the development and licensure of vaccines to prevent COVID-19.[5]

First and foremost, FDA is committed to ensuring that any vaccine is manufactured in accordance with all of FDA's quality standards and that its safety and effectiveness are verified before being authorized or licensed. To ensure that a widely deployed vaccine is effective, FDA has specifically recommended in its guidance to vaccine developers that "the primary efficacy endpoint point estimate for a placebo-controlled efficacy trial should be at least 50%, and the statistical success criterion should be that the lower bound of the appropriately alpha-adjusted confidence interval (CI) around the primary efficacy endpoint point estimate is >30%."[5] In other words, the lower limit of a 95% CI would have to be greater than 30%.

While historically the agency has not prospectively recommended numerical end point estimates for license approval, FDA believes recommending a baseline for performance is necessary to provide confidence that broad distribu-

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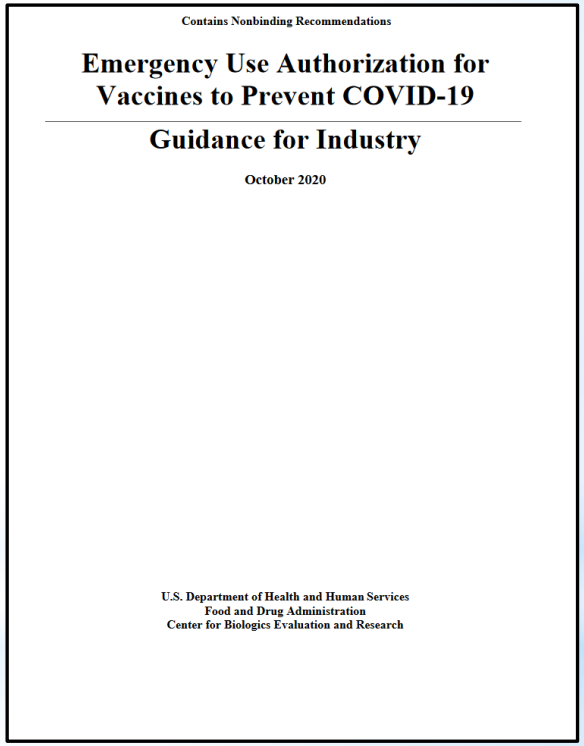

Contains Nonbinding Recommendations

Emergency Use Authorization for Vaccines to Prevent COVID-19

Guidance for Industry

October 2020

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research

Vaccines and Related Biological Products Advisory Committee (VRBPAC)

* Independent committee of outside experts that assists FDA in its review of new and existing vaccines; established in 1980
* Meetings—including meeting materials, deliberations, and votes—are public, per requirements of the Federal Advisory Committee Act
* Public commitments from senior FDA leaders to convene VRBPAC prior to any COVID-19 vaccine EUA or approval decision
* Met October 22 for *general* discussion of COVID-19 vaccine development and regulatory considerations
* Expected to meet in early December for review and recommendations related to one or more EUA requests

Subcommittee Meeting and Reporting Plans

* Scheduled monthly meetings
  * First Meeting: November 5
  * Next Meeting: November 30
* Additional meetings as developments warrant
  * Anticipated in December
* Written summaries of each meeting shared with advisory group; oral updates at advisory group meetings
* Following each vaccine authorization or approval by FDA, a statement from the subcommittee reporting its findings and recommendations

Other Potential Subcommittee Activities

* Ready to support and assist in the work of allocation and communications subcommittees, as needed.

* Ready to offer analyses and/or recommendations for any science-related issues that emerge after vaccination begins, as needed.

* Any other work requested by the advisory group

Allocation Subcommittee

Nichelle Mullins

Allocation Subcommittee Charge and Goals

Utilizing the CDC framework, this subcommittee is charged with making recommendations for vaccine allocation to critical populations for each of the three planning phases of distribution.

Members

Michael Carius
Past President, American College of Emergency Physicians

Stephen Civitelli
Director of Health, Wallingford Health Department

Tekisha Everette
Executive Director, Health Equity CT

Lori Fedewa
Director, CT Office of Rural Health

Khuram Ghumman
President, Hartford County Medical Association

Marwan Haddad
Medical Director, Center for Key Populations
Community Health Center, Inc.

Nicole Hawley
Emergency Management Program Specialist,
UConn Office of Emergency Management

Tim Klufas
Contact Tracer and Contact Tracing Mentor, DPH

Suzanne Lagarde
CEO, Fair Haven Community Health Center

Zita Lazzarini – Co-chair
Associate Professor, UConn Health

Andrew Mais
Commissioner, Connecticut Insurance Department

Leslie Miller
President, Fairfield County Medical Association

Nichelle Mullins – Co-chair
President and CEO, Charter Oak Health Center

Neil O'Leary
Mayor, City of Waterbury

Sara Parker McKernan
Legislative/Policy Advocate, New Haven Legal Assistance

Regina Rush-Kittle
Deputy Commissioner, DESPP / DEMHS

Marlene Schwartz
Professor and Director, UConn Rudd Center for Food Policy and Obesity

Michelle Seagull
Commissioner, Consumer Protection

Raymond Sullivan
Director of Health, Brookfield Health Department

CDC Phase 1A Recommendations

* Paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials and are unable to work from home.

Recommended Groups for Focus during Phase 1A

* ICU/ER staff
* Staff assigned to COVID units
* LTC and Assisted-living facilities
* Nursing homes
* Dentists, dental hygienists
* Community health center staff
* Active EMS
* Home health aides

Recommended Groups for Focus during Phase 1A

* Staff performing COVID testing
* Urgent Care facilities
* Visiting nurses, school nurses, pharmacists, health districts (if they are going to vaccinate)
* Respiratory therapists
* Maintenance/facilities staff, medical support staff, hospital food staff (if not already included in one of the above categories)

Populations for Consideration

* Health care workers who may be more at risk either because of individual risk factors or because of who they serve
* Individuals that care for family members in multifamily homes
* Congregate living facilities

Key Considerations

- Potential method to distribute within any signal group:
  - High risk groups by personal characteristics (i.e., age, co-morbidities)
  - High risk by exposure (i.e., type of practice/setting)
  - Highest risk of transmission due to number of patients seen
  - Random methodology (i.e., last name, year of birth, etc.)
- Allocate equal amount of doses to each county for distribution
- Allocate to health care institutions for distribution

Key Questions

* How many doses can we expect for Phase 1A?
* Should community spread (hot spots) be considered for initial allocation?
* How should we account for individuals who work in CT but live in another state?

Suggestions/Feedback

* Feedback or recommendations for the allocation subcommittee

Communications Subcommittee

Senator Heather Somers, Co-Chair

Joseph Quaranta, MD, Co-Chair

Initial Meeting

* Committee held initial meeting November 12
* Thirty participants
* Representing diverse organizations:
  * State and Municipal Government
  * Faith-based organizations
  * Unions
  * Community-based Organizations
  * Business
  * Healthcare
* Active participation/contribution

Subcommittee Goals

* Communicate the who, when, where, why and how relative to COVID-19 Vaccination
* Will need to engage members of the community who
  * Are not able to receive messages through “traditional” channels
  * Have vaccine hesitancy
* Questions to answer:
  * Who are stakeholders?
  * How messages should be disseminated (e.g. PSA, video, town halls”
  * Consistency of message

Challenges

* Different vaccines/manufacturers
* Delivery system may vary between vaccines
* Still many unknowns
* Communicating priority groups/why some get initial vaccine and others won't

Communications Considerations

Simple, consistent communications applicable to different vaccines	Digital messaging more nimble than advertising
One trusted source/accessible website	Use member orgs to push messages to stakeholders
Culturally appropriate/non-English speaking populations	Tailor messages to meet needs of stakeholders
Leverage CDC materials/campaign	Social Media toolkits/Infographics
“We’re all in this together” theme	Digital not for everyone (e.g. large print
Identify spokespersons trusted in their community	Some community leaders hesitant to get vaccine

Next Steps

* Convene weekly meetings (Doodle Poll)
* Idea Table - Identify:
  * Stakeholders
  * Targeted audience
  * Message
  * Message Medium
* Coordinate with other subcommittees
* Questions/Ideas/Discussion

Open Discussion

Administrative Updates

- Proposed next meeting (6:00 – 7:30 PM):
  - Thursday, December 17th
- https://portal.ct.gov/DPH/Communications/Disease-Preparedness/COVID-19-Vaccine-Advisory-Group
  - Agendas, meeting recordings, meeting summaries
- Parking Lot

Questions?

Thank you for your participation