HHSC: Task Force on Infectious Disease Preparedness and Response, October 19th, 2020

The Task Force on Infectious Disease Preparedness and Response provides expert, evidence-based assessments, protocols, and recommendations related to state responses to infectious diseases and serves as a reliable and transparent source of information and education for Texas leadership and citizens. For a list of committee members, please follow this link.

1. Call to Order & Welcome Remarks. DSHS Commissioner John Hellerstedt, M.D. convened the meeting.

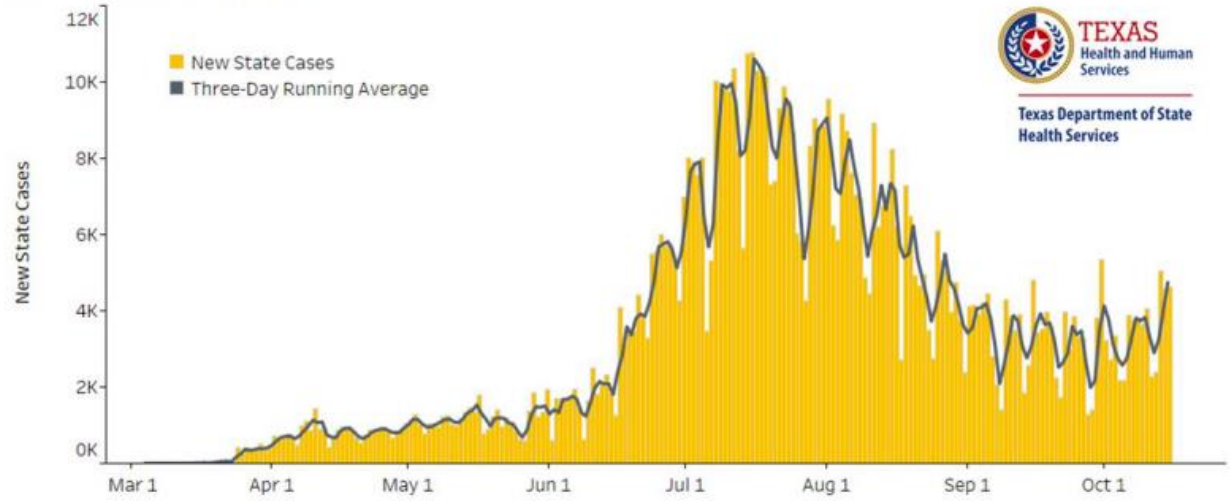
2. Approval of Meeting Minutes from February 4, 2020. The minutes were approved as written.

3. Open Meetings Act Overview - Barbara Klein. The Open Meetings Act was presented to the group. Please follow the link for detailed information on the Open Meetings Act requirements.

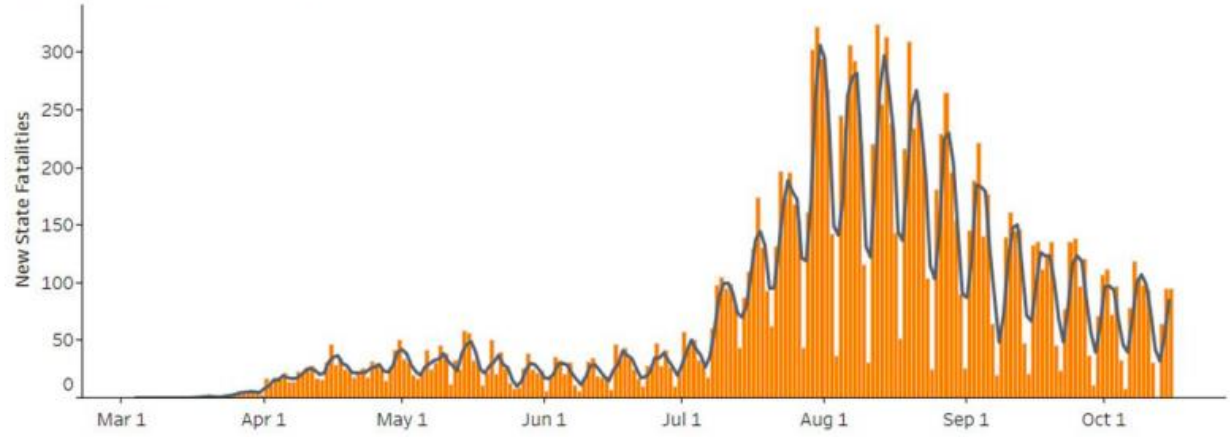
4. COVID-19 Situation Update - Dr. Hellerstedt

- **January 7:** Chinese authorities identified a new (novel) type of coronavirus
- **January 21:** Centers for Disease Control and Prevention (CDC) confirmed first case of novel coronavirus in the U.S. in Washington state
- **January 23:** DSHS launched the www.dshs.texas.gov/coronavirus/ website and prepared to launch #TexasDSHS social media campaigns
- **January 30:** Task Force on Infectious Disease Preparedness and Response Rapid Assessment Subcommittee met to discuss novel coronavirus issues
- **January 31:** DSHS activated the State Medical Operations Center (SMOC)
- **February 4:** Full Task Force on Infectious Disease Preparedness and Response met to discuss novel coronavirus
- **February 11:** International Committee on Taxonomy of Viruses named the novel coronavirus "severe acute respiratory syndrome coronavirus 2" (SARS-CoV-2) and the associated disease "COVID-19"
- **March 4:** DSHS announced the first positive test result for COVID-19 in Texas
- **March 13:** Governor Greg Abbott declared a State of Disaster for all Texas counties
    - Began issuing Executive Orders and Waivers to mitigate the crisis
    - Schools, businesses, other entities and activities shut down
- **March 17:** DSHS announced the first death of a person with lab confirmed COVID-19
- **March 19:** DSHS Commissioner Hellerstedt declared a Public Health Disaster for Texas
- **March 26:** State Operations Center (SOC) integrated the SMOC and other state agencies into its Unified Command structure
- **March – May:** Task Force on Infectious Disease Preparedness and Response Rapid Assessment Subcommittee met to work on COVID-19 issues
- **October 15:** 809,808 confirmed COVID-19 cases reported in 252 counties of Texas with 16,812 fatalities

New Texas Cases by Day

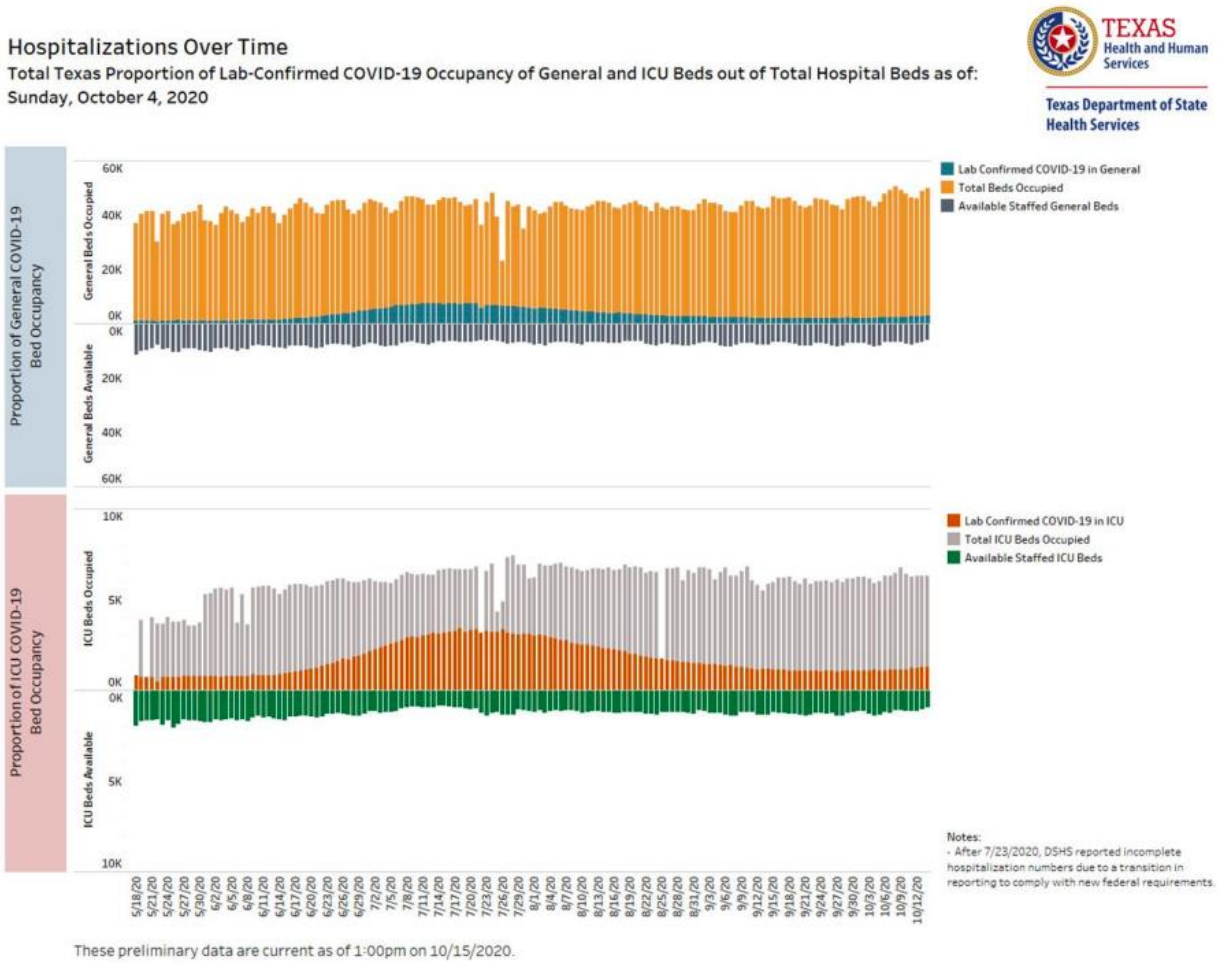


New Texas Fatalities by Day



These preliminary data are current as of 1:00pm on 10/15/2020.

Note: As of July 27, DSHS is reporting COVID-19 fatality data based on death certificates. The metric used in these charts reports total newly reported fatalities (as opposed to the date of death).



DSHS Roles during the Pandemic

- Coordination of local and state public health efforts
- Statewide management and provision of lab testing and capacity
- Data collection, analysis and reporting
- Health care system support and deployment of medical staffing to hospitals and nursing facilities
- Statewide public awareness
- Public Health guidance for individuals and businesses and consultation with local elected leaders
- Sourcing and consulting on medical supplies and personal protective equipment
- Developing the infrastructure to safely and appropriately disseminate vaccine

Coexisting with COVID-19

- COVID-19 remains a real and present danger for everyone until a vaccine and effective medicines are available

- Majority of Texans are still susceptible, situation always has potential to get worse
- Prevent virus transmission by modifying activities and incorporating new safety protocols into old routines
- Observe infection control across all sectors for as long as it takes to control virus spread
- Reopen businesses and resume activities strictly following the minimum standard protocols and Executive Orders: https://www.dshs.state.tx.us/coronavirus/opentexas.aspx
- Get vaccinated for influenza

General Prevention Messages

- Use cloth face coverings in public
- Personal hygiene: Wash hands, cover coughs, disinfect surfaces and objects
- Limit contact with others and avoid crowds in both indoor and outdoor spaces
    - Keep a physical distance of at least 6 feet apart
- Stay home as much as possible
    - Always stay home when sick
- People older than 65 and those with underlying health conditions such as diabetes and high blood pressure are at especially high risk

5. Year-to-Date Rapid Assessment Subcommittee Recap - Dr. Hellerstedt

Rapid Assessment Subcommittee Membership

- John Hellerstedt, M.D.
- Peter Hotez, M.D., Ph.D.
- Nim Kidd
- David Lakey, M.D.
- James LeDuc, Ph.D.
- Dorothy Overman, M.D.
- Gerald Parker, D.V.M., Ph.D.
- Cecile Young

They met January 30th and other dates. The group looked at PPE and other issues and distribution strategies. They discussed the criteria to be used to reduce the need for social distancing. They met to decide how Remdesivir would be distributed.

6. COVID-19 Vaccination Plan - Dr. Hellerstedt, Imelda Garcia

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Key Assumptions for COVID-19 Vaccine

Limited doses may be available by early November 2020, but **supply will increase substantially** in 2021

Initial supply will either be **approved as a licensed vaccine** or **authorized for use under an EUA** issued by the FDA

Cold chain storage and handling requirements are likely to vary from **refrigerated** to **ultra-cold frozen**

Two doses, separated by ≥21 or 28 days, will be **needed for immunity** for most COVID-19 vaccines

COVID-19 Vaccine Candidates

Manufacturer	Platform	Age Group	Doses needed[2]	Timing	Storage/Handling
Moderna[1]	mRNA	≥18 years	2	0, 28 days	Frozen ~ 7 days refrigerated
Pfizer/BioNTech[1]	mRNA	≥ 16 years	2	0, 21 days	Ultra Cold Frozen ~ 5 days refrigerated
AstraZeneca/Oxford[1*]	Non-replicating Viral Vector	TBD	2	4 weeks apart	TBD
Janssen/Johnson & Johnson[1*]	Non-replicating Viral Vector	≥18 years	1	N/A	Frozen ~ 3 months refrigerated
Novavax	Recombinant Protein Subunit	≥18 years	2	0, 21 days	Refrigerated
Sanofi/GSK	Recombinant Protein Subunit	TBD	2	TBD	Refrigerated

1. Phase 3 1*: On hold 2: Intramuscular injection Slide 6

The brands are not interchangeable and so each vaccine used must be tracked for each person who receives it. The earliest a vaccine could be available would be the end of November 2020.

Phased Approach to Vaccination (Specific dates are subject to change)

Phase 0 (October 2020): Provider recruitment and registration into ImmTrac2 and new web- based portal.

Phase 1 (November 2020 – December 2020): Limited supply of COVID-19 vaccine doses available.

- McKesson will direct ship vaccines to registered providers serving healthcare workers and other select populations based upon the DSHS Commissioner's approval in accordance with CDC and ACIP recommendations.
- Occupational healthcare settings, existing vaccinators serving closed settings will be the primary administrators of vaccines.
- Some large chains enrolled directly by CDC to serve some targeted populations (long-term care facilities).
- Continue ongoing provider recruitment and registration to ensure access to vaccination.

Phase 2 (January 2021-July 2021): Increased number of vaccine doses available.

- Emphasis on ensuring access to vaccine for members of Phase 1 critical populations who were not yet vaccinated as well as for the additional populations; expand provider network.
- Texas will use specialized vaccine teams, as needed, to vaccinate identified critical groups lacking access to the vaccine (e.g., Long-term care facilities, rural communities, etc.).

Phase 3 (July 2021 -October 2021): Sufficient supply of vaccine dose for entire population.

- DSHS will focus on ensuring equitable vaccination access across the entire population. Monitor vaccine uptake and coverage; reassess strategy to increase uptake in populations or communities with low coverage.
- May consider extending the use of vaccine teams depending on the uptake and coverage received so far, especially to ensure second doses are administered from the end of Phase 2.

Phase 4 (October 2021 and forward): Sufficient supply of vaccine with a decreased need due to most of the population being vaccinated previously.

- May include boosters or annual vaccines if required.
- Vaccine availability open throughout private providers. Population able to visit provider of choice.

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CDC Critical Populations for COVID-19

Groups and individuals may fall into multiple categories. Prioritization recommendations among and within groups are in development.	
Category	**Includes:**
Essentisal Workers	• Healthcare personnel (i.e. EMS, hospital staff, vaccinators, pharmacy and long-term care staff) • Other essential workers (i.e. first responders, education, others with critical roles who cannot easily socially distance)
People at increased risk for severe COVID-19 illness	• People 65 years of age and older • LTCF residents (i.e., nursing home, assisted living, others) • People with underlying medical conditions that are risk factors for severe COVID-19 illness
People at increased risk of acquiring or transmitting COVID-19	• People from racial and ethnic minority groups • People from tribal communities • People who are incarcerated/detained in correctional facilities • People experiencing homelessness/living in shelters • People attending colleges/universities • People living in other congregate settings
People with limited access to routine vaccination services	• People living in rural communities • People with disabilities • People who are under- or un-insured

Lessons learned include:

- Decisions about how to prioritize groups for vaccine allocation may have negatively impacted vaccine uptake (the long-term goal)
- Changes in priority groups were confusing to the public and healthcare providers, and communication was challenging
- Some products had contraindications among priority groups (i.e. could not be given safely to that group)
- Feelings of alienation in early phases may have contributed later to low uptake among some groups of people
- Many patients and health care providers expressed safety concerns
- Clear risk communication is important
- Logistical limitations such as minimum order sizes were a barrier to access for some smaller localities

Principles for Allocation:

Ethical Principles

- Maximum benefit encompasses the obligation to protect and promote the public's health and socioeconomic well-being in the short and long term.
- Equal concern requires that every person be considered and treated as having equal dignity, worth, and value.

- Mitigation of health inequities includes the obligation to explicitly address the higher burden of COVID-19 experienced by the populations affected most heavily, given their exposure and health inequities.

Procedural Principles

- Fairness requires engagement with the public, particularly those most affected by the pandemic, and impartial decision-making about and evenhanded application of allocation criteria.
- Transparency includes the obligation to communicate with the public openly, clearly, accurately, and straightforwardly about the allocation framework as it is being developed, deployed, and modified.
- Evidence-based expresses the requirement to base the allocation framework on the best available and constantly updated scientific information and data.

Expert Vaccination Allocation Panel (EVAP):

- Made of external and internal subject matter experts
- Make recommendations to the Commissioner
    - Establish prioritization of critical populations for Phase 1 and Phase 2 distribution
    - Weekly review of the data to guide allocation recommendations

CDC Requirements for COVID-19 Vaccination Providers

- Must have an active NPI/TPI number.
- Must follow ACIP requirements and recommendations.
- Must comply CDC requirements for COVID-19 vaccine management and maintain adequate storage capacities to maintain integrity of the vaccine cold-chain requirements
- Must report dose usage within 24 hours to the state immunization registry, ImmTrac2.
- Must report of all doses received including those administered, lost, wasted, etc.
- Must report of any adverse event related to receiving the vaccine.

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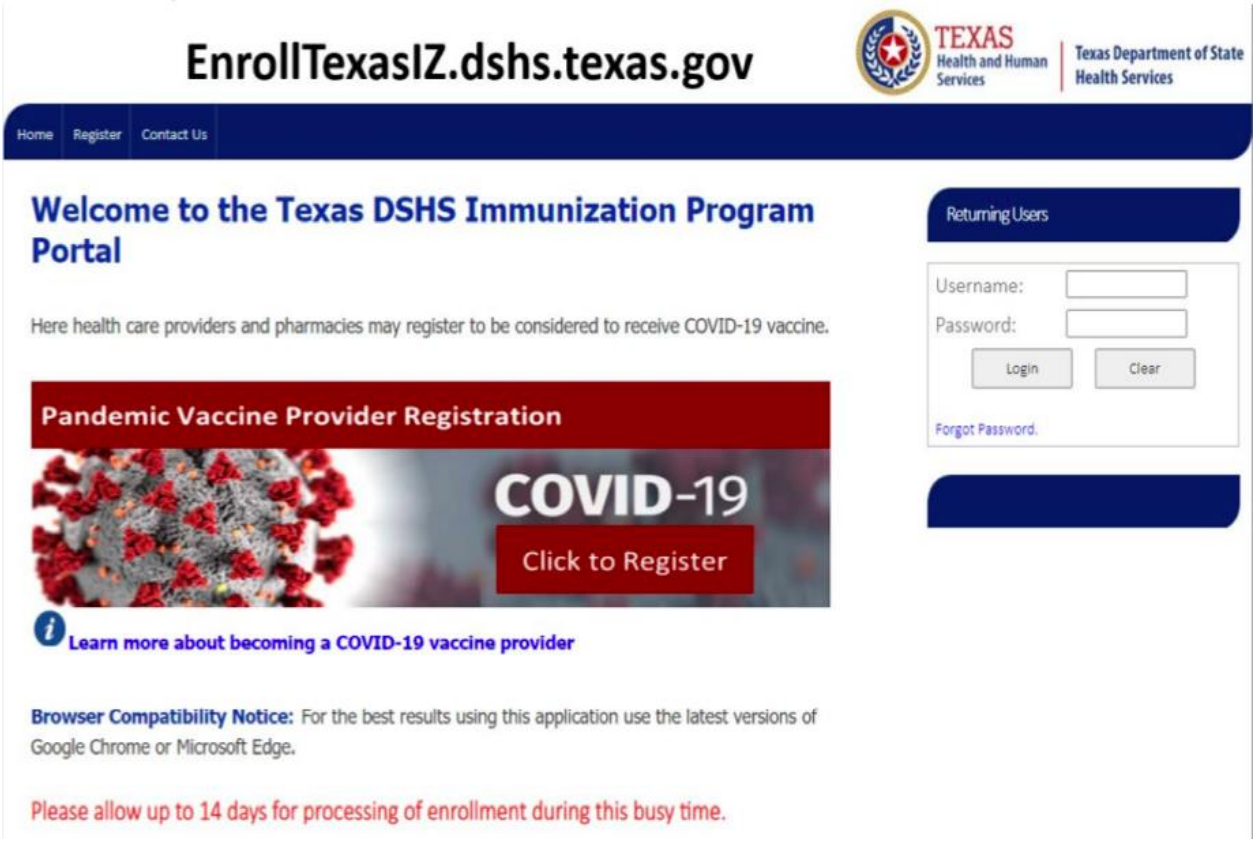
Provider Registration Portal



Communication, Outreach, Engagement (COE) Plan.

Provider

- Recruitment
- Vaccine Administration logistics/guidance

Public

- Statewide media campaign (TV, radio, digital, out-of-home)
- General information
- Vaccine availability
- Vaccine's safety/importance

Stakeholders

- Outreach to providers and public
- Source of feedback

COE Plan – Timeline (Specific dates are subject to change)

Phase 0 (Sept. 2020 – Oct. 2020): Presentations to stakeholders; mass emailing (GovDelivery); media briefings (Ex. provider portal); creation of supporting panels

Phase 1 (Nov. 2020 – Dec. 2020): Statewide media campaign's message: what to expect, why vaccine is important; continued provider outreach (targeted and aided by stakeholder mobilization)

Phase 2 (Jan. 2021 – July 2021): Statewide media campaign's message: vaccine safety, dose requirements and provider locations

Phase 3 (July 2021 – Oct. 2021): Statewide media campaign's message: Vaccine safety, dose reminder

Vaccine Reporting Requirements

CDC Requirements

- Dose level accountability, connecting the Lot ID to the patient
- Providers must report dose usage within 24 hours

Texas DSHS reporting from providers

- Doses Allocated by County
- Doses Shipped by County
- Doses Administered by County
- Doses Wasted by County

Reporting to Texas Immunization Registry for Disasters and Emergencies

Health and Safety Code §161.00705— Recording Administration of Immunization and Medication for Disasters and Emergencies, any antiviral medication distributed by the state in response to a declared disaster or public health emergency must be entered into the Texas Immunization Registry, known as ImmTrac2.

Texas Administration Code §100.7— The immunization registry shall contain information regarding individuals who receive an immunization, antiviral, or other medication administered.

Existing Safety Monitoring Systems

Vaccine Adverse Event Reporting System (VAERS)— The national system that collects reports from healthcare professionals, vaccine manufacturers, and the public of adverse events that happen after vaccination; reports of adverse events that are unexpected, appear to happen more often than expected, or have unusual patterns are followed up with specific studies.

Vaccine Safety Datalink (VSD)— A network of 9 integrated healthcare organizations across the United States that conducts active surveillance and research; the system is also used to help determine whether possible side effects identified using VAERS are actually related to vaccination.

Biologics Effectiveness and Safety System (BEST)— A system of electronic health record, administrative, and claims-based data for active surveillance and research.

Other systems using electronic data from Medicare, Medicaid, VA

The following systems build upon the existing safety monitoring to evaluate COVID-19 vaccine in real time and provide additional surveillance.

CDC V-SAFE A new smartphone-based, after-vaccination health checker for people who receive COVID-19 vaccines.

- V-SAFE will use text messaging and web surveys to check in with vaccine recipients for health problems following COVID-19 vaccination.
- The system also will provide telephone follow-up to anyone who reports medically significant (important) adverse events.

CDC National Healthcare Safety Network (NHSN)

- An acute care and long-term care facility monitoring system with reporting to the Vaccine Adverse Event Reporting System or VAERS.

FDA Other large insurer/payer database

- A system of administrative and claims-based data for surveillance and research.

Website for Providers: https://dshs.texas.gov/immunize/providers.shtm

Vaccine Provider hotline: (877) 835-7750, 8 a.m. to 5 p.m., Monday through Friday or Email: COVID19VacEnroll@dshs.texas.gov

Website to enroll as a COVID-19 provider: EnrollTexasIZ.dshs.texas.gov

General Questions: Email: COVIDvaccineQs@dshs.texas.gov

Dr. Hellerstedt named the expert vaccine allocation panel:

- Emelda Garcia, Chair
- Senator Kolkhorst
- Senator Lucio
- Representative Klick
- Representative Senfronia Thompson
- Vice Chancellor David Lakey
- Gerald Parker MD
- Vice Chancellor John Zerwas
- Mr. Kidd, Emergency Management

- Steven Williams, Houston Department of Health
- Casey Stratton, Amarillo Public Health
- Paul McGaha
- Dane Gruber
- Amanda Hall, MD
- Steven Pont
- Jennifer Shupert, MD
- Dr. Van Ramshorst

The information presented today is based on CDC's recent guidance and MAY change.

Questions/Answers/Comments
CDC says 30-35% of deaths in minority communities are under the age of 65, and we might want to change the high-risk calculation for the vaccine. We also do not know why the two vaccines are on pause.

Comment on what was happening in practice and in communities. There are two definitions of "close contact". TEA has a different definition from DSHS and CDC. This creates a lot of problems. Dr. Hellerstedt stated that the different environments play a role in the different definitions. We hope there is convergence over time. Students also play football with no masks on. There is a need for more to be done on this.

On agenda number 5— 223,000 dead nationally and hospitals have had problems with accessing equipment. The rapid response subcommittee report commented on the national stockpile and regional advisory committees with unknown stockpiles in those regions. What is the preparedness at the RACs? Dr. Hellerstedt stated that he did not have additional notes from the meeting. There was a worldwide crunch regarding PPE. We are pretty flush with PPE now. He has heard in the field that there were not problems any longer.

7. Public Comment.
The Committee received written comments that were read aloud and are summarized below. Duplicate comments were not repeated.

- What percentage of providers have registered to receive COVID-19 vaccine?
- Will field hospitals be used to administer vaccines?
- What is the plan for urban vs rural areas of the state?
- Will there be an open RFP?
- (Dr. Hellerstedt and staff stated that there are 1,044 completed provider applications. They are largely at urban centers. Thermal freezers are required to store the vaccine—100 doses is the minimum order without the cold storage, and 1,000 for those with the cold storage.)
- If a vaccine has an egg component, will there be vaccine for pregnant and elderly?

- Why are we to take a vaccine for something that has never been isolated and based on inflated numbers?
- Is there any information if a specific vaccine is targeted for a different population?
- Are there any vaccines made available for athletes?
- How do providers enroll?
- (HHSC had some responses to the questions but it will be dependent on circumstances).
- In the past two weeks, El Paso has reported several new cases and hospital capacity is decreasing, making El Paso a "hot spot". El Paso is disproportionately impacted by COVID-19.
- (HHSC stated that it is clear that there is complexity in getting the vaccine out where it has to be. Quantities will be limited at first.)

Oral Public Comment.

Brian Masel, MD, asked a few questions. There was some concern about overwhelming providers offices with patients and if vaccine will be a billable service. He inquired about vaccine mobile sites. The efficacy of the vaccine is still up in the air, and will there be any follow-up testing following vaccine administration?

DSHS stated that if a provider is offering the vaccine, they still get to set the ground rules. There are reporting requirements as well as storage requirements. Nothing is off the table regarding mobile sites. We are focusing on the providers we have typically had. Sites must be safe and employing best practices for vaccine administration. There will be patients followed at least during the trials, ensuring efficacy. At this point, there are no recommendations to do antibody testing.

Representative from the Texas Hospital Association rapidly read from her written testimony. THA stands ready to administer the vaccine. Texas hospitals play an important role in vaccination. They stated their appreciation for flexibility in how they address patients during this pandemic.

Dr. John Carlo, Texas Medical Association, dated their involvement in vaccinations back to the days of polio. There are a lot of unknowns. They offer the following:

- Make sure IMMTRAC 2 is capable of tracking
- Data should be shared
- Continued leverage of partnerships like TMA
- Work to promote confidence in the vaccine and trust in communities

8. Planning and Discussion of Future Meeting Topics

- Follow-up on the agenda items above
- Vaccines and therapeutics in general

- Update on research programs related to antibodies
- For the foreseeable future, we will have to focus on COVID
- If we have vaccines by the end of November, it might be worth scheduling a meeting in December or early January

9. Adjourn. There being no further business, the meeting was adjourned.

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