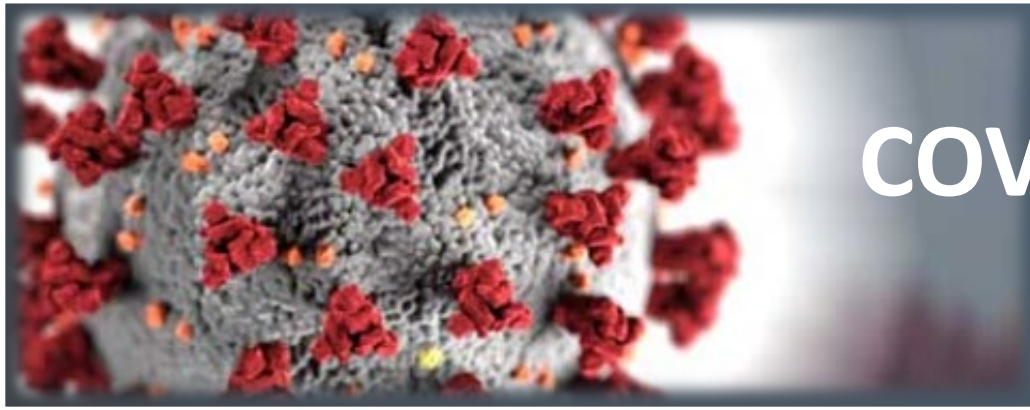
TEXAS
Health and Human Services

Texas Department of State Health Services



COVID-19 Pandemic Response and Vaccine Update

March 10, 2021

John W. Hellerstedt, MD, Commissioner

Imelda M. Garcia, Associate Commissioner

Texas Department of State Health Services

Overview

- COVID-19 Timeline & Statistics
- Pandemic Response
- Vaccine Rollout
- Vaccine Communication
- Therapeutics Research

COVID-19 Timeline & Statistics

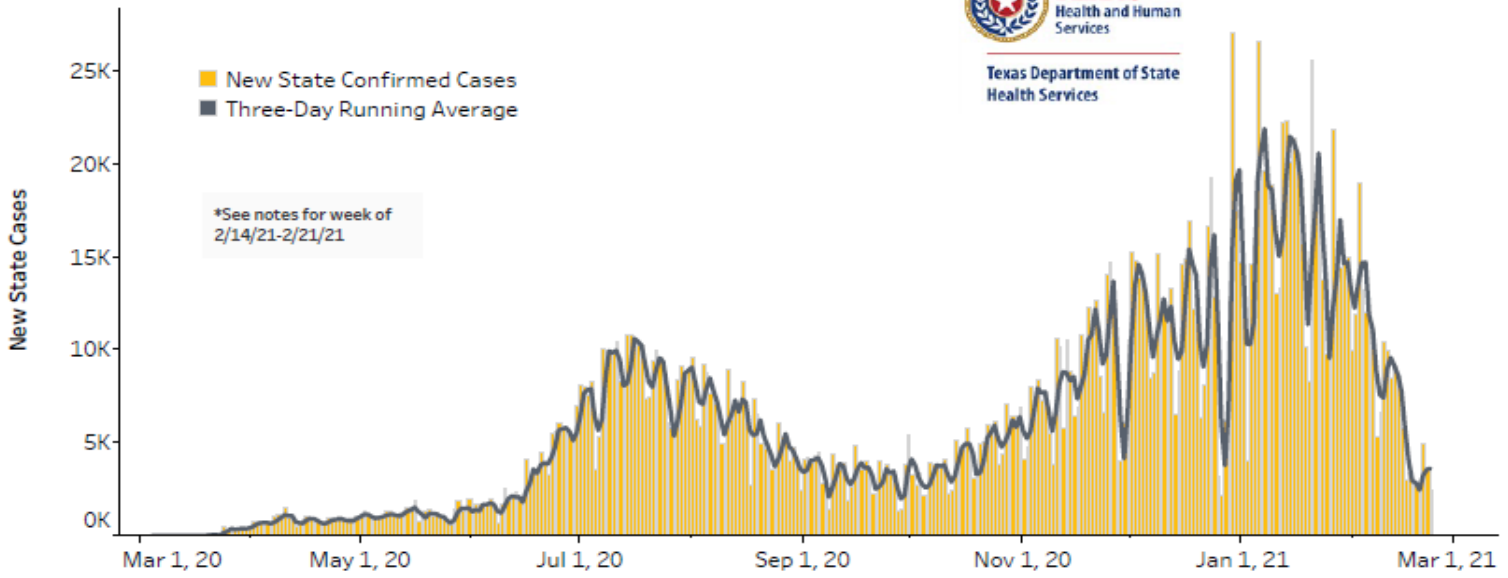
COVID-19 Timeline

- **December 31, 2019**: Municipal Health Commission reported cases of pneumonia with an unknown cause in Wuhan City, Hubei Province, China
- **January 7, 2020**: 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 dshs.texas.gov/coronavirus/ website and prepared #TexasDSHS social media campaigns
- **January 31**: DSHS activated the State Medical Operations Center (SMOC)

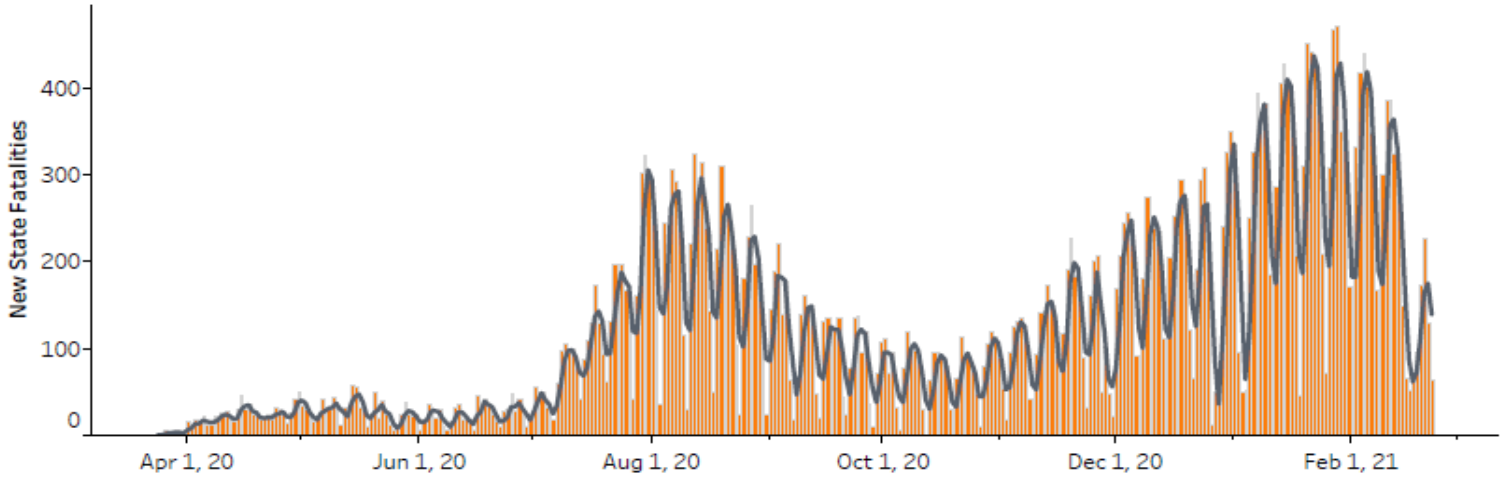
COVID-19 Timeline

- **March 4**: DSHS announced the first positive test result for COVID-19
- **March 17**: DSHS announced the first lab-confirmed COVID-19 death
- **March 19**: DSHS Commissioner Hellerstedt declared a Public Health Disaster for Texas
- **October:** DSHS assembled the Expert Vaccine Allocation Panel (EVAP)
- **November 10:** DSHS launched a COVID-19 Vaccine Information Website
- **December 14:** DSHS distributed the first COVID-19 vaccine doses
- **February 12, 2021:** 1 million people fully vaccinated in Texas
- **March 9, 2021:** 2,326,885 confirmed COVID-19 cases reported in all 254 Texas counties with 44,650 fatalities

New Confirmed Texas Cases by Day



New Texas Fatalities by Day



These preliminary data are current as of 1:00pm on 2/22/2021.

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).

Note: During the week of Feb. 14-Feb. 21, 2021, case and fatality reporting was significantly impacted across the majority of Texas counties due to weather-related issues.

Hospitalizations Over Time
Total Texas Proportion of Lab-Confirmed COVID-19 Occupancy of General and ICU Beds out of Total Hospital Beds as of:

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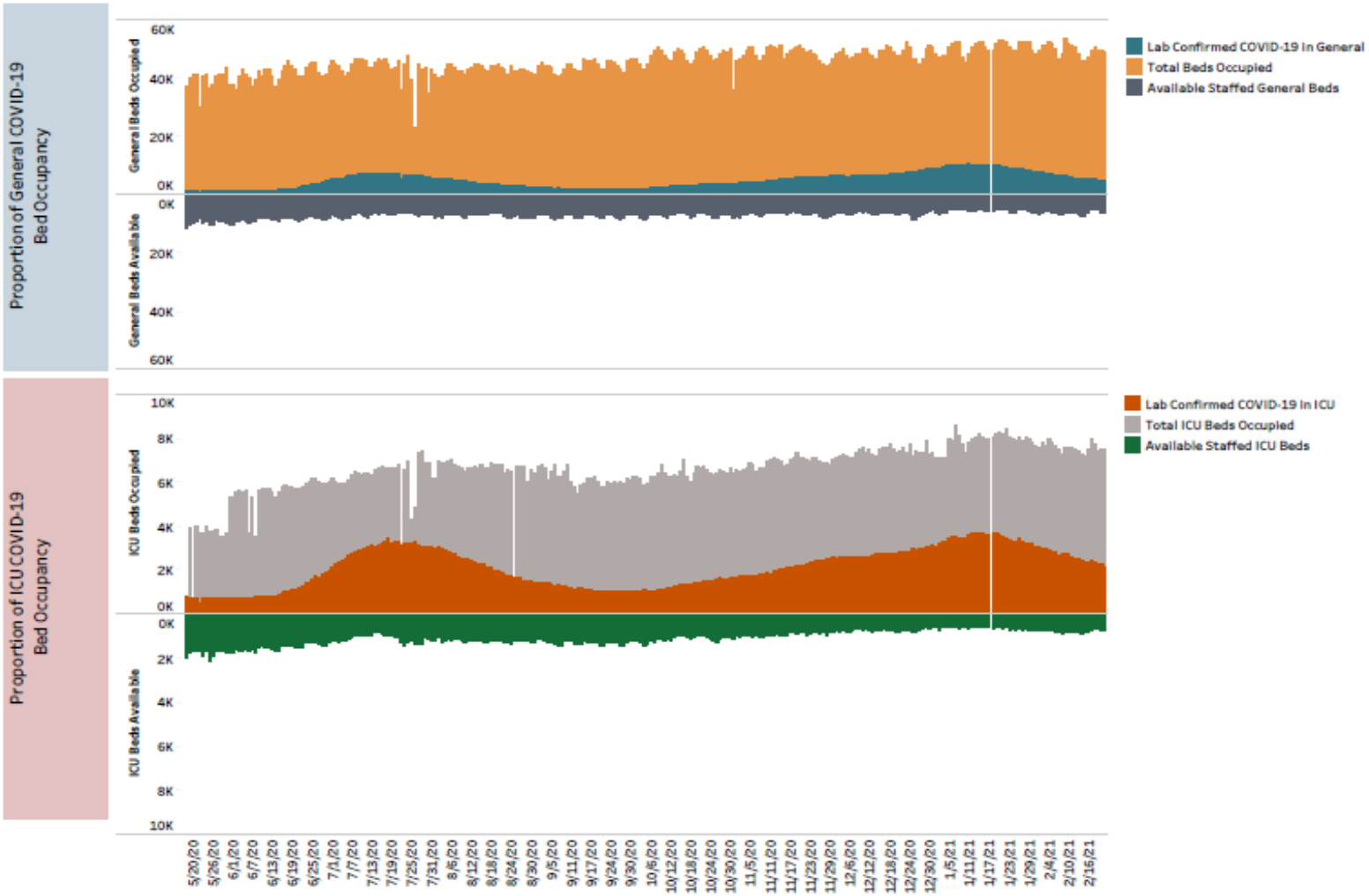
Sunday, February 21, 2021 Totals	
Lab Confirmed COVID-19 in General	4,762
Lab Confirmed COVID-19 in ICU	2,114
Total Lab Confirmed COVID-19 Gen + ICU	6,876

Notes:
- The most recent hospital data is reported for the day prior.
- After 7/23/2020, DSHS reported incomplete hospitalization numbers due to a transition in reporting to comply with new federal requirements.



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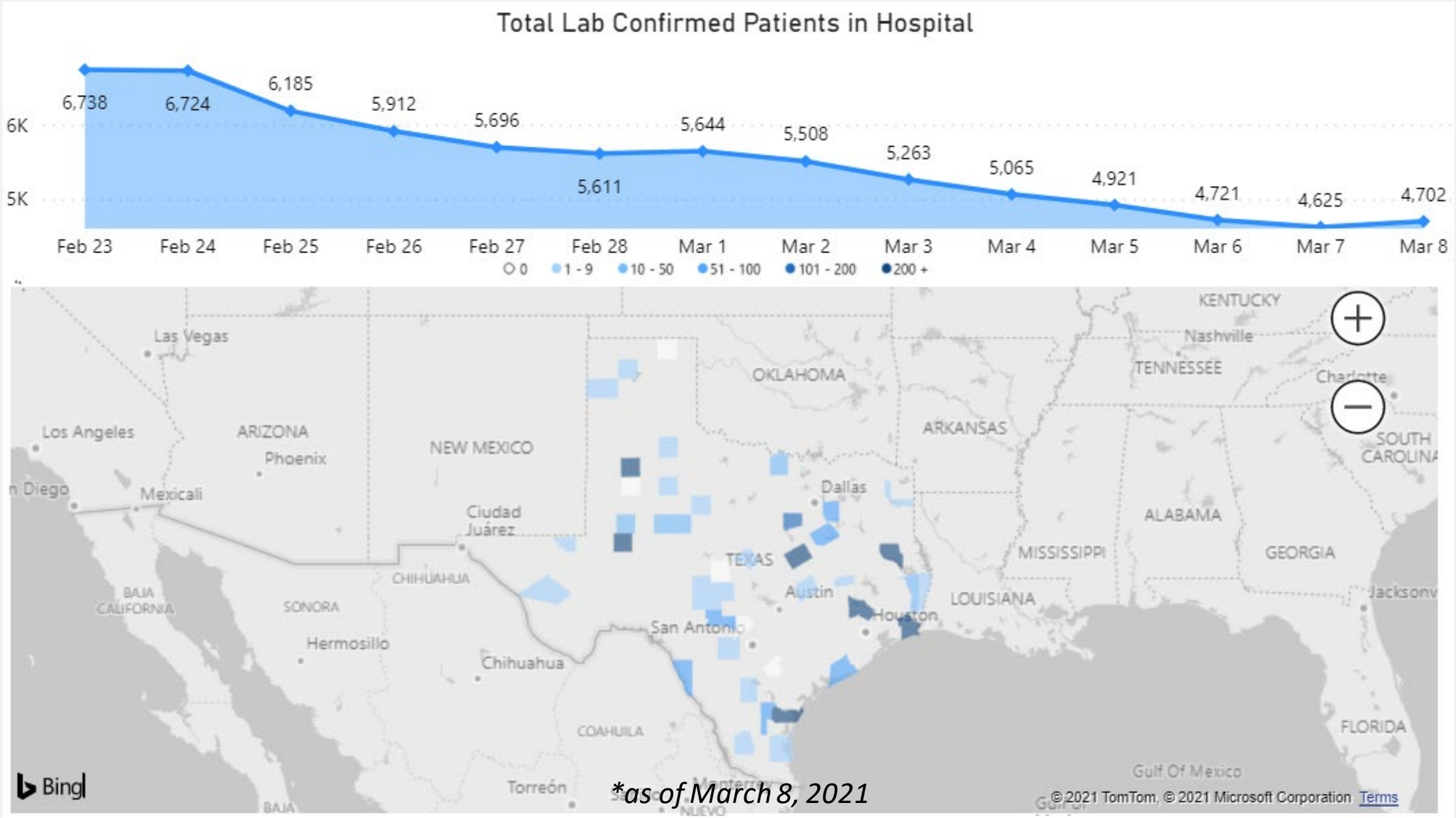
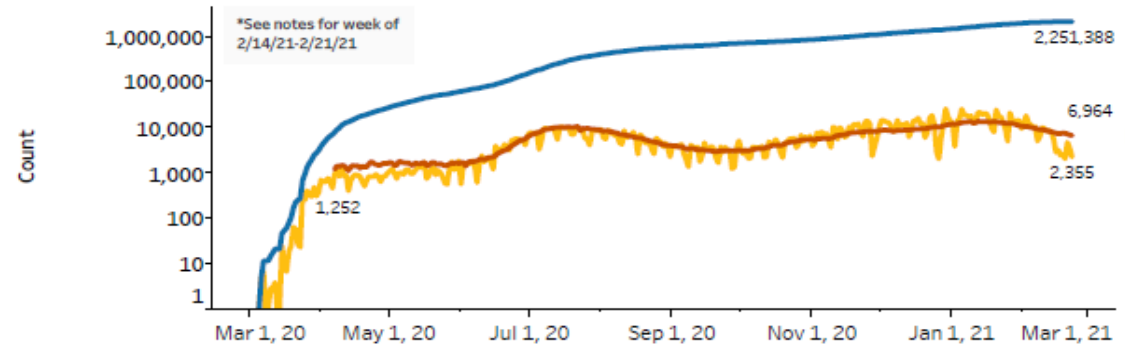


*as of March 8, 2021

Texas COVID-19 Trends: A Full Picture

Total Texas Covid-19 Confirmed Cases, Confirmed New Cases, and Current Confirmed Hospitalizations



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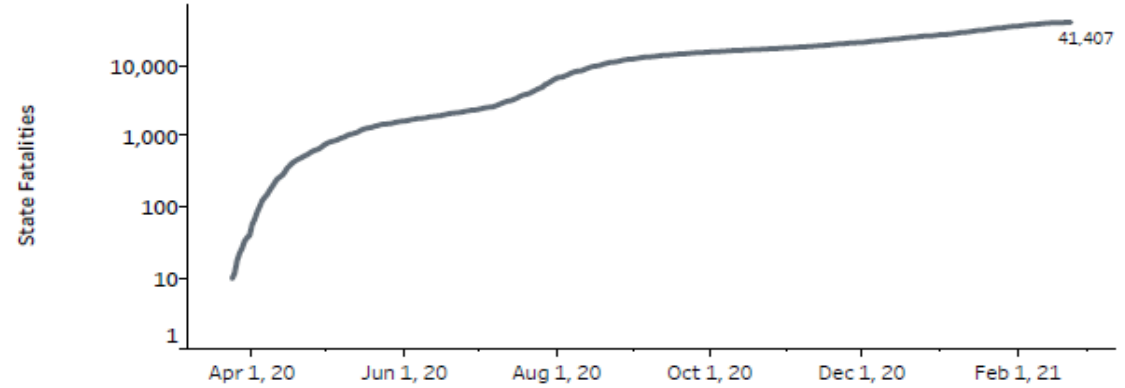
Legend
- State Cases
- New State Confirmed Cases
- Currently Hospitalized

These preliminary data are current as of 1:00pm on 2/22/2021.

Notes:

- After 7/23/2020, DSHS reported incomplete hospitalization numbers due to a transition in reporting to comply with new federal requirements. As of 8/19/2020, 91% of hospitals were reporting.

Total Texas Covid-19 Fatalities



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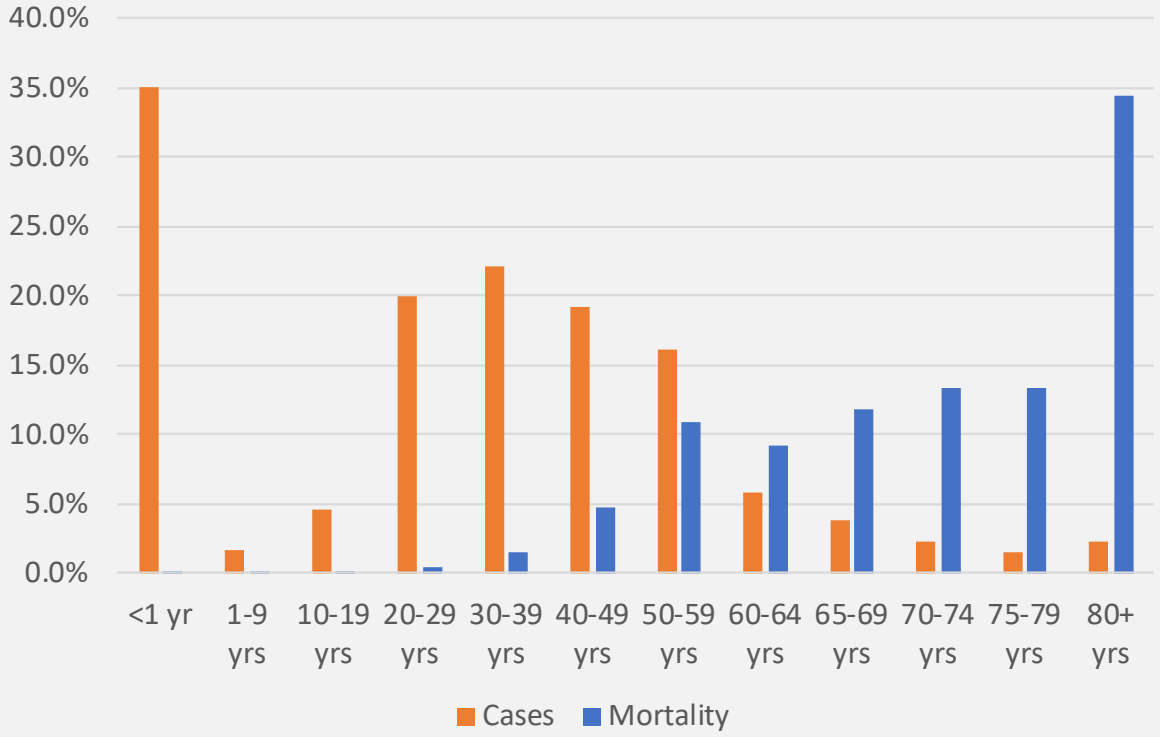
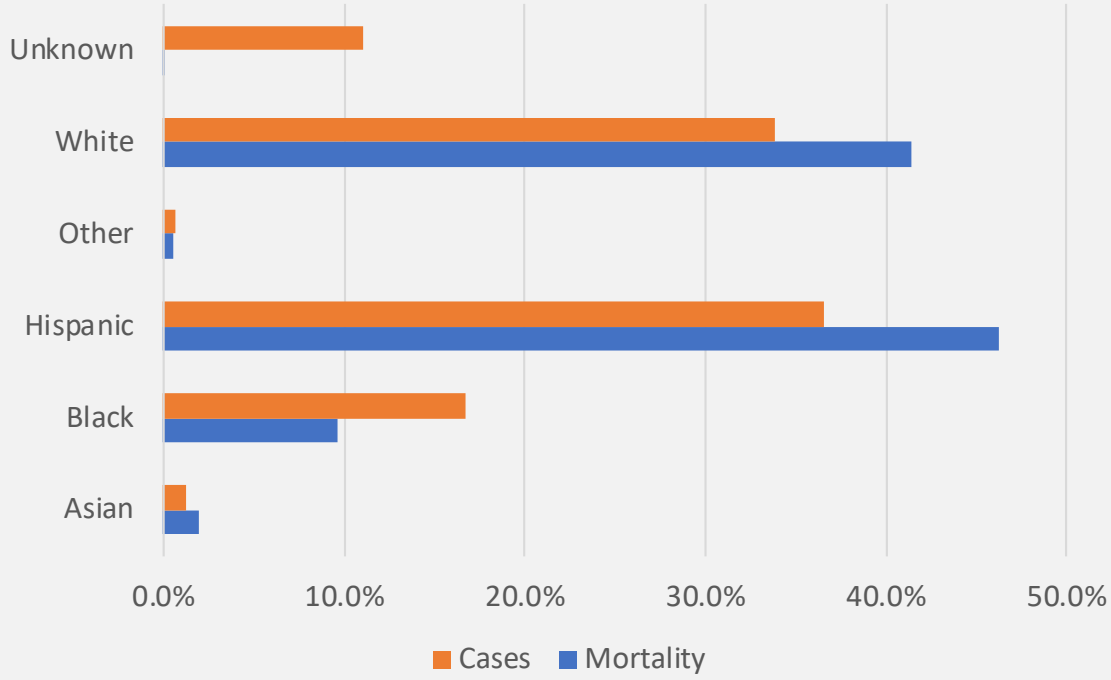
Note: During the week of Feb. 14-Feb. 21, 2021, case and fatality reporting was significantly impacted across the majority of Texas counties due to weather-related issues.

Demographics

Cases & Mortality by Age



Cases & Mortality by Race/Ethnicity



**as of March 7, 2021*

Pandemic Response

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 education and awareness
- Public health guidance for individuals and businesses, and consultation with local elected leaders
- Sourcing and allocating therapeutics and medications, medical supplies, and personal protective equipment
- Utilizing the established infrastructure and expanding it further to safely and appropriately disseminate vaccine

COVID Response by the Numbers

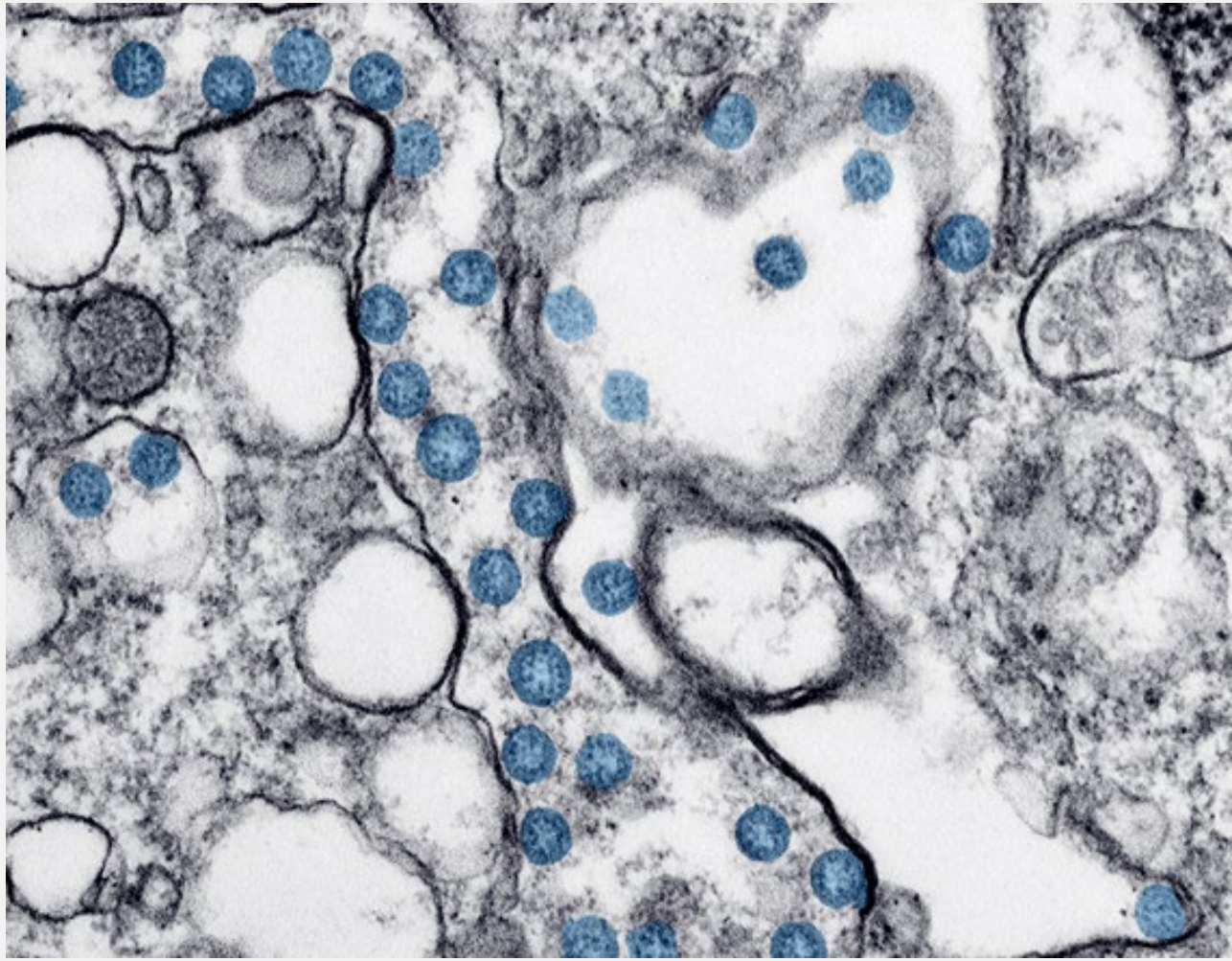
401 days of emergency response activation	**1,567** DSHS staff working on COVID response	**193,000** COVID data points collected and processed daily	**7,332** vaccinators fully registered to administer COVID vaccine
13,737 maximum medical surge staff deployed	**229** hospitals supported with medical surge staff	**82,781** calls or emails to DSHS Call Center staff	**6,970,799** doses administered
3,561 public health follow up staff supporting local health departments	**75,385** COVID tests performed by the state public health laboratory	**81,701** patient courses of monoclonal antibodies allocated to treat COVID patients	**2,463,006** persons fully vaccinated

1,340 Alternate Care Beds	**140** Isolation and Quarantine Sites	**2,965** State of Texas Assistance Request related to the pandemic

**as of March 9, 2021*

Pandemic Hurdles Addressed

- Expanding initial testing capacity & managing PPE scarcity
- Expanding and standardizing testing, hospital, and mortality reporting
- Scaling public health follow up
- Addressing COVID-19 hospitalizations
- Adapting prevention messaging as new scientific data emerges
- Scaling vaccine effort to meet statewide need and demand



Pandemic Response Overview

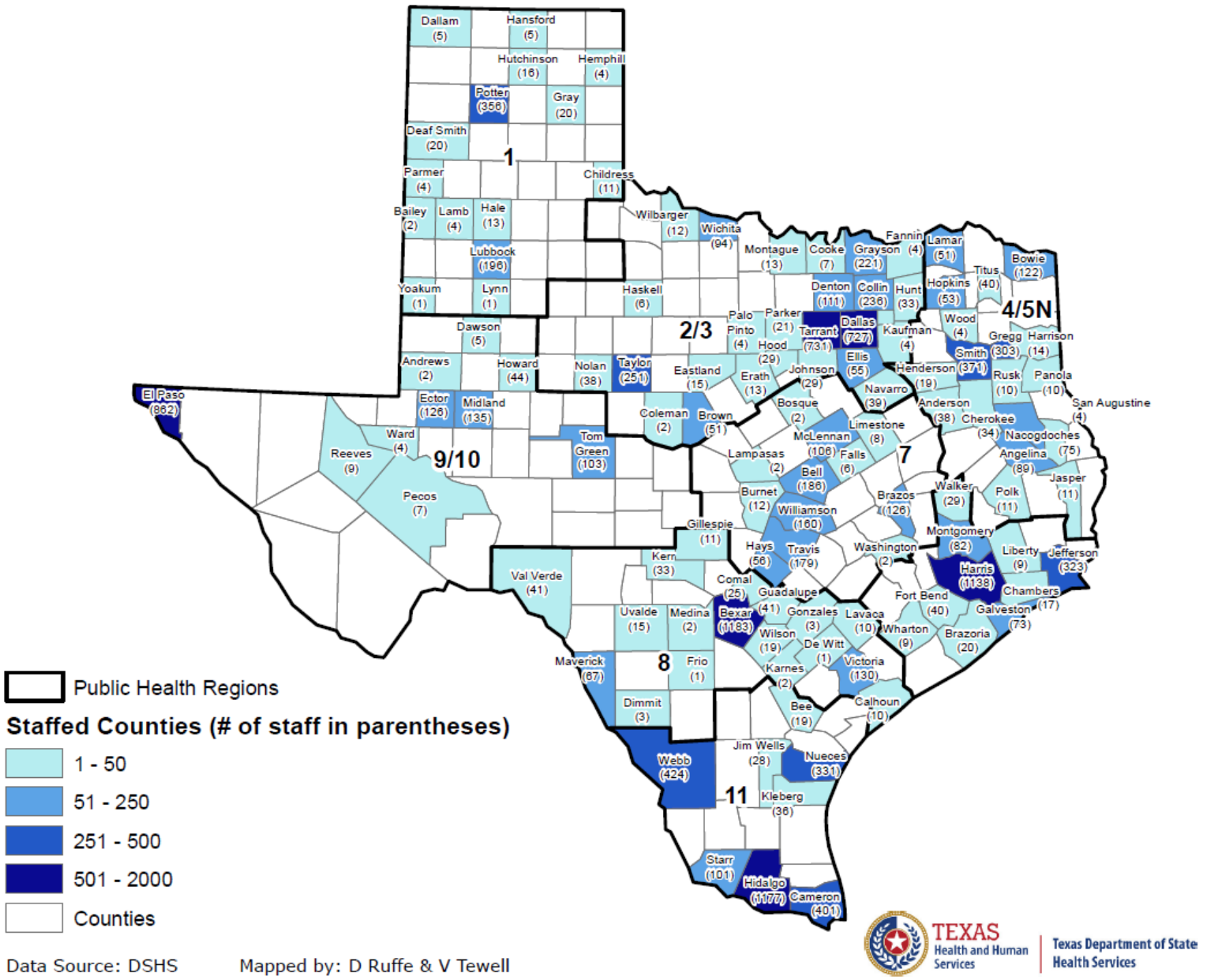
- Rapidly modernized the lab result reporting system- National Electronic Disease Surveillance System (NEDSS)
  - Increasing daily lab result ingestion by 9,990% (from 2,000 to 200,000 per day)
- Processed 89,040 hospitalizations data points from Texas healthcare facilities on daily basis
  - Over 20 million COVID-19 data points collected from hospitals to date
- Developed a functioning statewide public health follow up system in less than three weeks
  - Mature system within five months with significant participation by local health jurisdictions
  - Grew DSHS-supported public health follow up staff from 115 to 2,400
- Supported responses to more than 600 facility outbreaks
- DSHS given “A” grade from The COVID Tracking Project for data transparency
  - Based on consistent, reliable, and complete reporting including patient outcomes and demographics

COVID-19 Pandemic Expenditures (Estimated)

Category	How much we spent
Medical Surge Staffing	$4.5 Billion
Local Response	$261.3 Million
Disease Surveillance	$160.8 Million
Local Contracts	$67.3 Million
Lab Costs	$27.7 Million
Repatriation	$5.5 Million
Other Costs	$0.5 Million
Total	**$5.0 Billion**

**as of March 9, 2021*

Deployed DSHS Medical Surge Staff Support - 02/23/2021

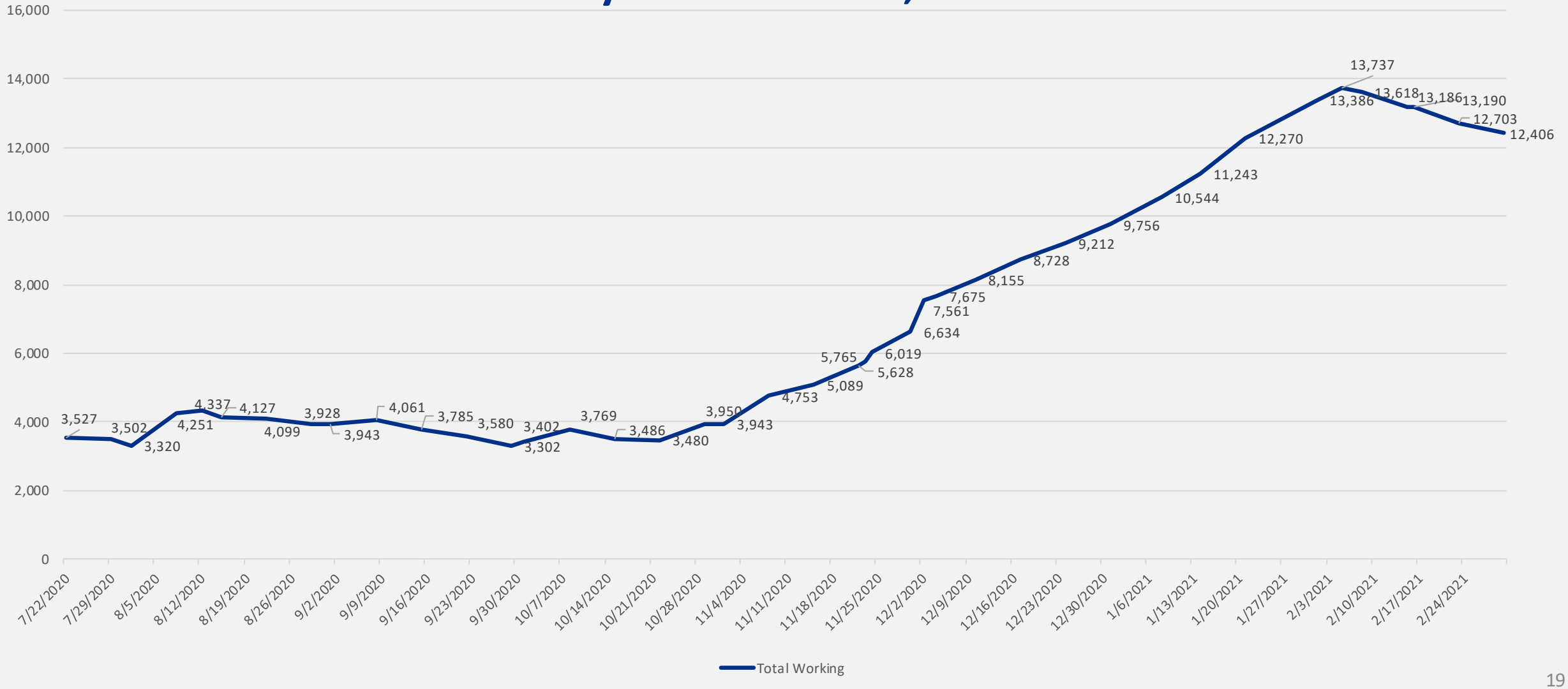


Current Staff Deployed:
11,702
(staff demobilization continues)

Maximum Staff Deployed:
13,737

Medical Surge Staff Working

July 2020-March 5, 2021



Federal Grants to Support COVID-19 Expenses

Grantor	Description	Total in Millions	Uses
FEMA	Public Assistance - FEMA Category B	$2,399.6	General disaster public assistance. The funds require a 25% state match. Additional funds can be requested.
Dept of Treasury	Coronavirus Relief Fund (CRF)- CARES Act	$2,009.5	Various uses, funds allocated to DSHS for direct care medical staffing needs.
CDC	Coronavirus Response and Relief Supplemental Appropriations Act/Epi & Lab Capacity (ELC) Enhancing Detection Expansion	$1,535.4	Develop, purchase, administer, process, and analyze COVID-19 tests, conduct surveillance, and related activities.
CDC	Paycheck Protection Program and Health Care Enhancement Act/Epi & Lab Capacity for Testing (PPPHEA-ELC)	$473.6	Develop, purchase, administer, process, and analyze COVID-19 tests, conduct surveillance, and related activities.
CDC	Coronavirus Response and Relief Supplemental Appropriations Act/Implementation and Expansion of the Vaccine Program	$227.1	Vaccine distribution and administration
CDC	Coronavirus Preparedness and Response Supplemental Appropriations (Crisis CoAg)	$55.1	Crisis response and recovery, information and surge management, surveillance
CDC	CARES Act/Epi & Lab Capacity to Reopen America. (ELC)	$39.1	Surveillance, epidemiology, lab capacity, data surveillance and analytics infrastructure, disseminating information about testing, and workforce support necessary to expand and improve COVID–19 testing.
CDC	COVID-19 Supplemental via 2020 CARES ACT Round 1	$14.4	Plan and implement COVID-19 vaccination services
CDC	PPPHEA National Center for Immunization and Respiratory Diseases	$10.1	Enhanced Influenza-COVID19 response for staffing, communication, preparedness and vaccination, with emphasis on enrolling new vaccinators. Funds may not be used to purchase vaccines.
CDC	COVID-19 Supplemental via 2020 CARES ACT Round 2	$10.1	Plan and implement COVID-19 vaccination services

Federal Grants to Support COVID-19 Expenses

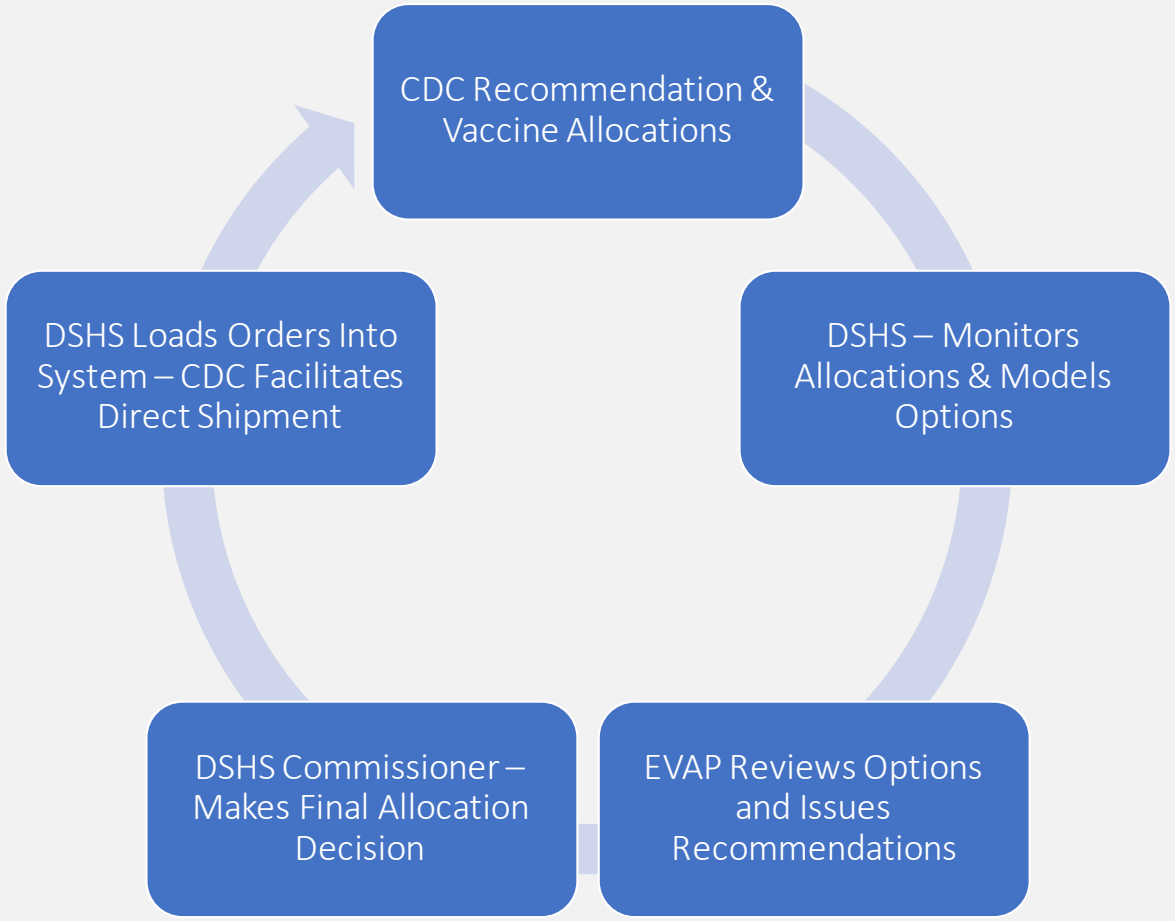
Grantor	Description	Total in Millions	Uses
ASPR	CARES Act - Hospital Preparedness Program Supplemental Award for COVID-19 (CARES HPP)	$8.7	Urgent preparedness and response needs of hospitals, health systems, and health care workers on the front lines.
CDC	Paycheck Protection Program and Health Care Enhancement Act Epi & Lab Capacity	$5.4	focus on genetic testing lab preparedness; and ensuring safe travel through optimized data sharing and communication with international travelers
CDC	ELC /Healthcare-associated Infections/ Antimicrobial Resistance Program (ELC-HAI)	$3.7	Funds support Project Firstline, a CDC training collaborative for health care infection prevention and control.
HRSA	CARES Act - Ryan White HIVAIDS	$1.5	Infrastructure and practice improvement needed to prevent, prepare, and respond to COVID-19 for Texans living with HIV.
HUD	CARES Act - Housing Opportunities for Persons With AIDS COVID-19 Supplemental (CARES HOPWA)	$0.7	Allowable activities authorized by the AIDS Housing Opportunity Act to maintain housing for low-income persons living with HIV (PLWH) and their households.
ASPR	Paycheck Protection Program and Health Care Enhancement Act (PPPHEA) (PPP HPP Ebola)	$0.4	Funds dedicated for Special Pathogen Hospital to increase the capability of health care systems to safely manage individuals with suspected and confirmed COVID-19.
ASPR	CARES Act - Hospital Preparedness Program Ebola (CARES HPP Ebola)	$0.3	Funds dedicated for Special Pathogen Hospital to increase the capability of health care systems to safely manage individuals with suspected and confirmed COVID-19.
CDC	Rape Prevention & Education: Using the Best Available Evidence for Sexual Violence Prevention - COVID-19	$0.3	The OAG will interagency cooperation contracts with Texas Association Against Sexual Violence and Texas A&M University Health Science Center to enhance existing activities that address the most pressing COVID-19 related violence issues including Intimate Partner Violence
HHS	ATSDR's Partnership to Promote Local Efforts to Reduce Environmental Exposure – COVID-19	$0.2	Development of a training and educational module on safe ways to disinfect for COVID-19 at home-based child care facilities.
USDA	Cooperative State Meat and Poultry Inspection – COVID-19	$0.01	COVID-19 specific prevention and safety activities.

Vaccine Rollout

Phased Approach

Phase 0 (Oct.-Nov. 2020)	• Planning and provider reruitment
Phase 1 (Dec. 2020-Present)	• Limited supply of COVID-19 vaccine doses available
Phase 2 (Mar.-July 2021)	• Increased number of vaccine doses available
Phase 3 (July - Oct. 2021)	• Sufficient supply of vaccine doses for entire population
Phase 4 (Oct. 2021 forward)	• Sufficient supply of vaccine with decresed need due to most of population being vaccinated previously

Vaccine Distribution Process



COVID-19 Expert Vaccination Allocation Panel (EVAP)

- Texas has convened a team of appointed external and internal subject-matter experts into the COVID-19 Expert Vaccine Allocation Panel to develop vaccine allocation strategies as recommendations to the Texas Commissioner of Health.
- The panel has developed guiding principles and utilizes in their recommendations.
- The recommendations from the Expert Vaccine Allocation Panel will be sent to the Texas Commissioner of Health for final approval.
- EVAP voting members https://www.dshs.texas.gov/coronavirus/immunize/evap.aspx

Texas Vaccine Allocation Guiding Principles

Texas will allocate COVID-19 vaccines that are in limited supply based on:

- **Protecting healthcare workers** who fill a critical role in caring for and preserving the lives of COVID-19 patients and maintaining the healthcare infrastructure for all who need it.
- **Protecting front -line workers** who are at greater risk of contracting COVID-19 due to the nature of their work providing critical services and preserving the economy.
- **Protecting vulnerable populations** who are at greater risk of severe disease and death if they contract COVID-19.
- **Mitigating heath inequities** due to factors such as demographics, poverty, insurance status, and geography.
- **Data-driven allocations** using the best available scientific evidence and epidemiology at the time, allowing for flexibility for local conditions.
- **Geographic diversity** through a balanced approach that considers access in urban and rural communities and in affected ZIP codes.
- **Transparency** through sharing allocations with the public and seeking public feedback.

Texas Phase 1A and 1B Definitions

Phase 1A, Tier 1	Phase 1A, Tier 2	Phase 1B
• Paid & unpaid workers in hospital settings working directly with patients who are positive or at high risk for COVID-19 • Long-term care staff working directly with vulnerable residents • EMS providers who engage in 911 emergency services like pre-hospital care and transport • Home health care workers, including hospice care, who directly interface with vulnerable and high-risk patients • Residents of long-term care facilities	• Staff in outpatient care settings who interact with symptomatic patients • Direct care staff in freestanding emergency medical care facilities and urgent care clinics • Community pharmacy staff who may provide direct services to clients, including vaccination or testing for individual who may have COVID-19 • Public health and emergency response staff directly involved in administration of COVID-19 testing and vaccinations • Last responders who provide mortuary or death services to decedents with COVID-19 • School nurses who provide health care to students and teachers	• People 65 years of age and older • People 16 years of age and older with at least one chronic medical condition that puts them at increased risk for severe illness from the virus that causes COVID-19

~ 13.5 million Texans in Phase 1A and 1B

Federal Directive: School/Daycare Settings

- **Tuesday, March 5th:** DSHS notified by US Health and Human Services that all COVID-19 providers should include school and daycare staff on list of people eligible to be vaccinated
- **Includes:**
  - "those who work in pre-primary, primary, and secondary schools, as well as Head Start and Early Head Start programs (including teachers, staff, and bus drivers)" and
  - "those who work as or for licensed child care providers, including center based and family care providers."
- **Effect in Texas:** Texas 1A & 1B populations, and persons meeting school/daycare staff criteria outlined above are eligible to receive vaccine

COVID-19 Vaccine: Texas Milestones

- **December 14, 2020: First doses of COVID-19 Vaccine arrive** in Texas
- **December 21, 2020: DSHS announces Phase 1B** population definition
- **December 23, 2020: DSHS announced vaccinating Phase 1A & 1B** population.

1 month

- **January 14, 2021: 1 Million doses of COVID-19 vaccine administered in Texas**
  - 1M Dose administered reported in ImmTrac2 retrospectively by January 9, 2021

14 Days

- **January 28, 2021: 2 Million doses of COVID-19 vaccine administered in Texas**
  - 2M Dose administered reported in ImmTrac2 retrospectively by January 24, 2021

9 Days

- **February 6, 2021: 3 Million doses of COVID-19 vaccine administered in Texas**
  - 3M Dose administered reported in ImmTrac2 retrospectively by February 5, 2021

9 weeks

- **February 12, 2021: 1 Million Texans fully vaccinated**
  - 1M fully vaccinated reported in ImmTrac2 retrospectively by February 11, 2021

7 Days

- **February 13, 2021: 4 Million doses of COVID-19 vaccine administered in Texas**
  - 4M Dose administered reported in ImmTrac2 retrospectively by February 11, 2021

13 Days

- **February 26, 2021: 5 Million doses of COVID-19 vaccine administered in Texas**
  - 5M Doses administered reported in ImmTrac2 retrospectively by February 25, 2021

18 days

- **March 3, 2021: 2 Million Texans fully vaccinated**
  - 2M fully vaccinated reported in ImmTrac2 retrospectively by February 27, 2021

6 Days

- **March 4, 2021: 6 Million doses of COVID-19 vaccine administered in Texas**
  - 6M Doses administered reported in ImmTrac2 retrospectively by March 2, 2021

Vaccine Distribution – Provider Enrollment

- All interested providers required to register with DSHS
- Must meet ordering, handling, administration, and reporting requirements
- Common registered COVID -19 provider types:
  - Hospitals
  - Health departments
  - Federally qualified health centers (FQHCs)
  - Rural health clinics
  - Long term care facilities
  - Fire departments
  - Medical practices
- Fully-enrolled providers: 7,332

Vaccine Distribution Strategies - State

Community Based Providers	Vaccine Hubs	Other State Programs	DSHS Regions	Other State Initiatives
• Ensure that rural communities and underserved areas have access to vaccine • Register with individual provider	• Mass efforts to quickly vaccinate 1,000s of Phase 1A and 1B individuals each week • Must use all doses and report doses administered to DSHS and Texas Division of Emergency Management • Register online or by phone	• Mobile Vaccine Pilot Program: Vaccination Texas National Guard deployed to certain rural counties • Save Our Seniors: Texas National Guard deployed to vaccinate homebound seniors	• DSHS Region offices hold local clinics • Facilitate open enrollment for providers to serve in hard-to-reach areas	• Federal Qualified Health Centers to reach medically underserved • Long Term Care/Intellectual or Developmental Disability - partnering with pharmacies not served by Federal Long Term Care program

Getting Vaccines to all Texans

Vaccine Distribution Strategies - Federal

Pharmacy Program for Long-Term Care Facilities

- Federal program to vaccinate staff and residents of nursing homes and long-term care
- Partnership with DSHS, HHS, Walgreens and CVS

Federal Retail Pharmacy Program

- Vaccines sent to pharmacies nationwide
- Doses shipped directly to Texas pharmacies will not be deducted from Texas allocations

Federal Emergency Management Agency (FEMA)

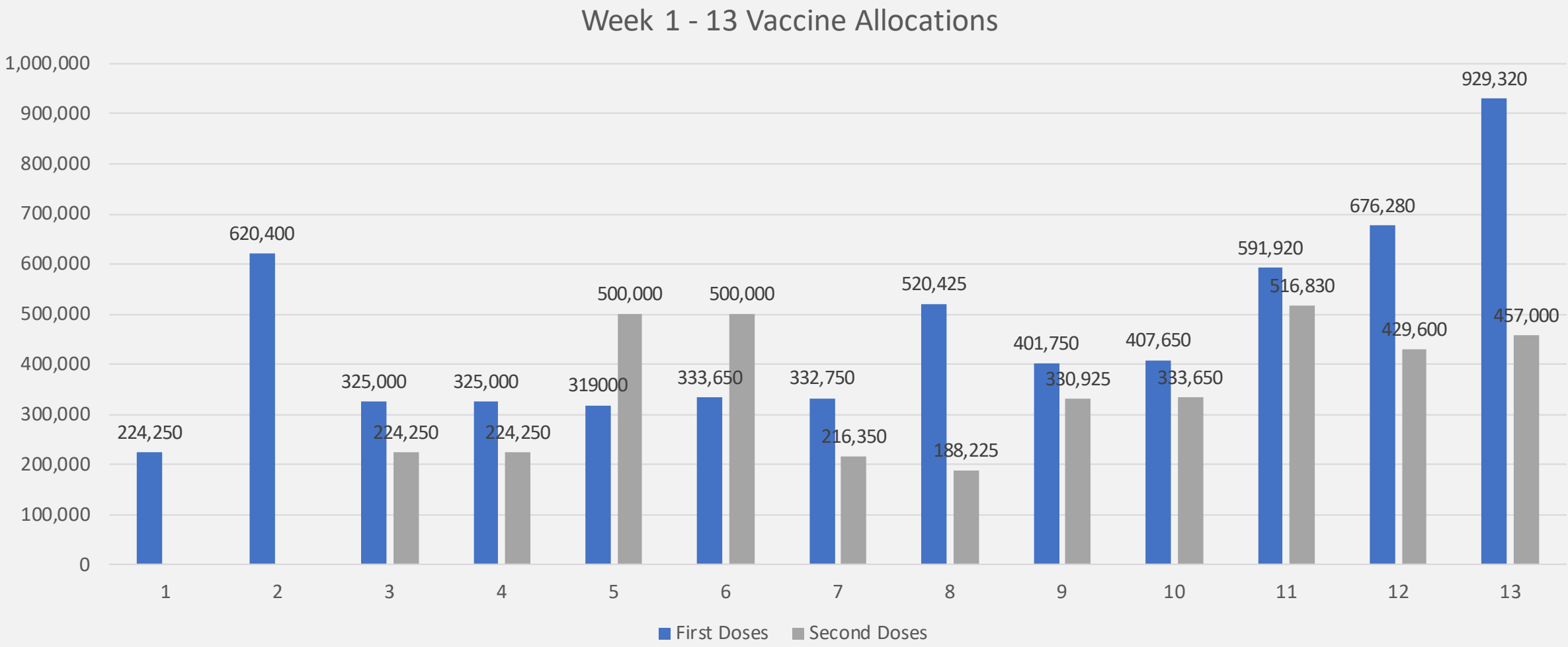
- Administering doses in Harris, Dallas, and Tarrant Counties
- Doses are on top of state's normal allotment
- EVAP redistributing allocations with excess doses to address needs in other counties to maintain geographic equity

Federally Qualified Health Centers (FQHC)

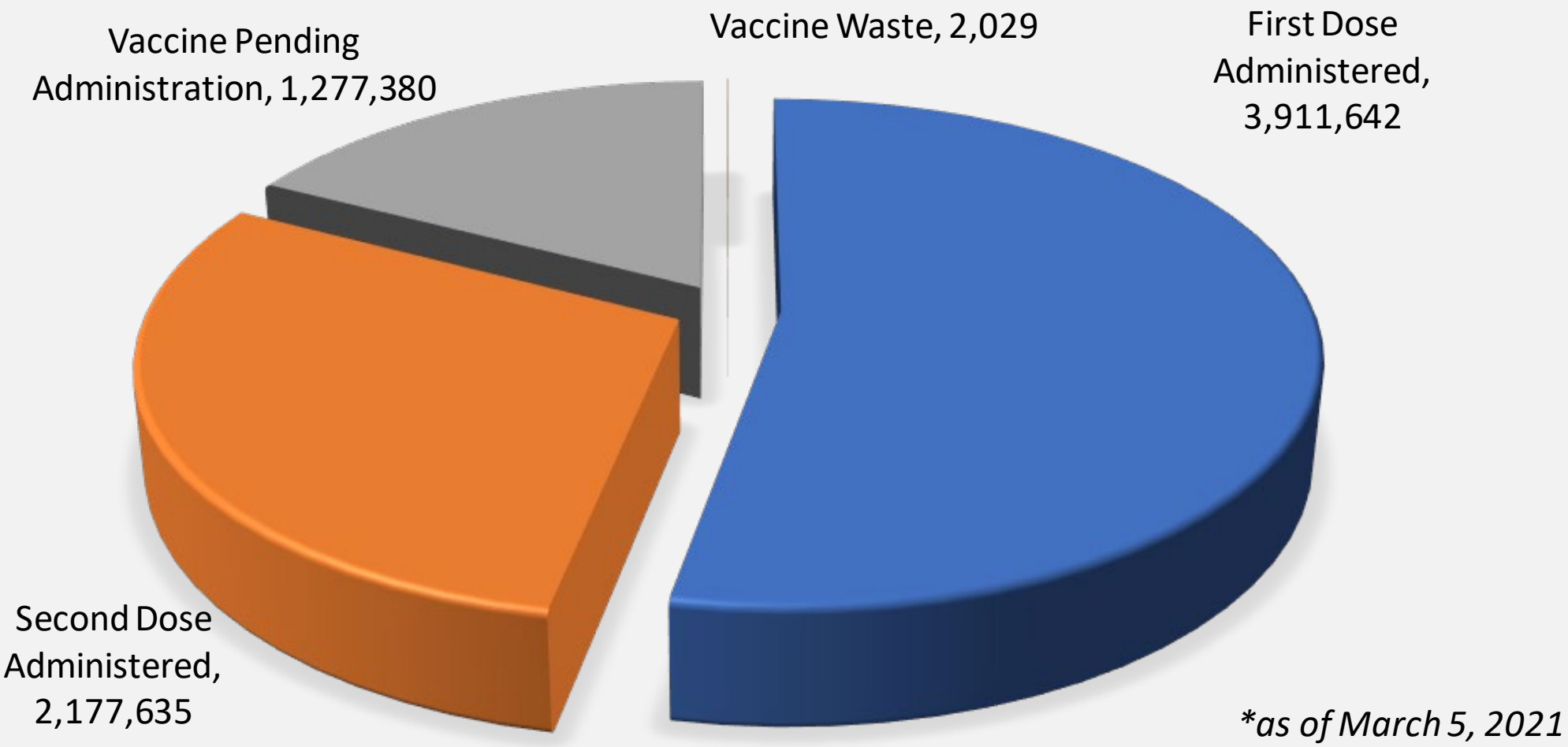
- Receiving direct allocations from the Federal Government
- 38 Texas facilities have been announced to receive allotments

Getting Vaccines to all Texans

Vaccine Allocations Per Week

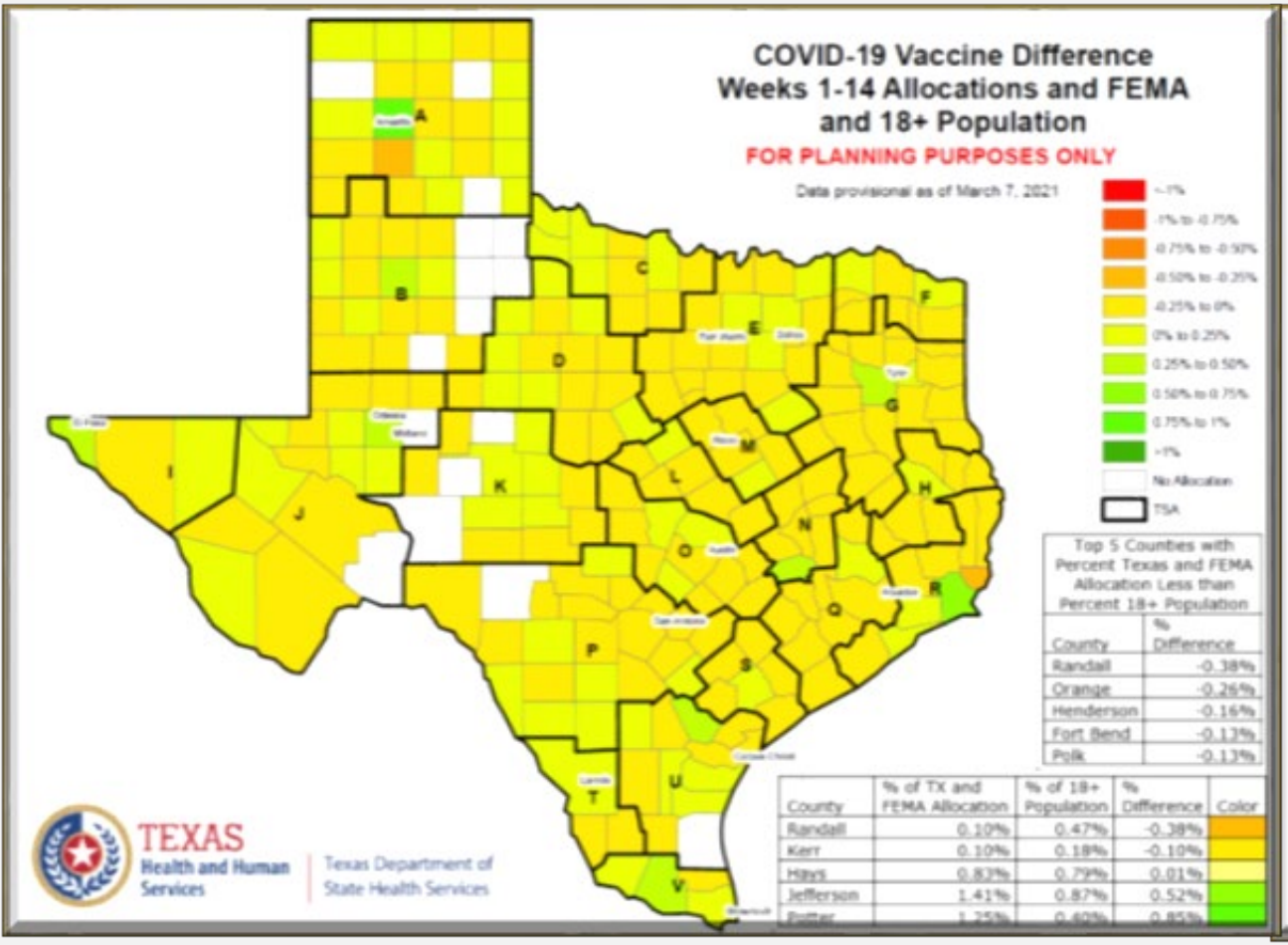


Vaccine Use Breakdown



*as of March 5, 2021

Source: Workbook: COVID-19 Vaccine in Texas and vaccine waste report at COVID19VaccineDosesWasted.pdf (texas.gov)


COVID-19 Vaccine Difference
Weeks 1-14 Allocations and FEMA
and 18+ Population
FOR PLANNING PURPOSES ONLY
Data provisional as of March 7, 2021
TSA
No Allocation
Top 5 Counties with Percent Texas and FEMA Allocation Less than Percent 18+ Population
County | % Difference
Randall | -0.38%
Orange | -0.26%
Henderson | -0.16%
Fort Bend | -0.12%
Polk | -0.12%
County | % of TX and FEMA Allocation | % of 18+ Population | % Difference | Color
Randall | 0.10% | 0.47% | -0.38%
Kerr | 0.10% | 0.18% | -0.10%
Hays | 0.83% | 0.79% | 0.01%
Jefferson | 1.41% | 0.87% | 0.52%
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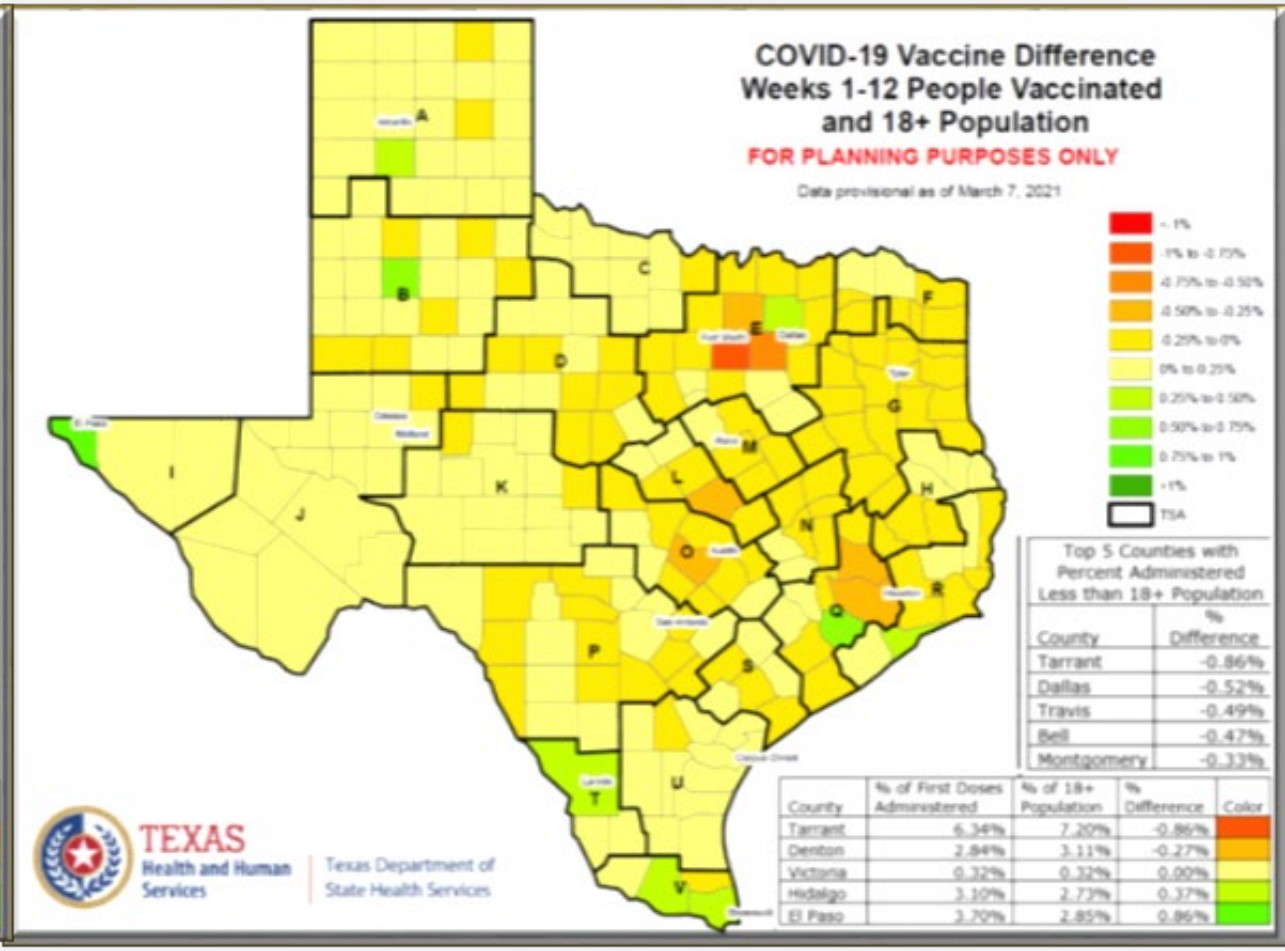
COVID-19 Vaccine Difference
Weeks 1-12 People Vaccinated
and 18+ Population
FOR PLANNING PURPOSES ONLY
Data provisional as of March 7, 2021
TSA
Top 5 Counties with Percent Administered Less than 18+ Population
County | % Difference
Tarrant | -0.86%
Dallas | -0.52%
Travis | -0.49%
Bell | -0.47%
Montgomery | -0.33%
County | % of First Doses Administered | % of 18+ Population | % Difference | Color
Tarrant | 6.34% | 7.20% | -0.86%
Denton | 2.84% | 3.11% | -0.27%
Victoria | 0.32% | 0.32% | 0.00%
Hidalgo | 3.10% | 2.73% | 0.37%
El Paso | 3.70% | 2.85% | 0.86%
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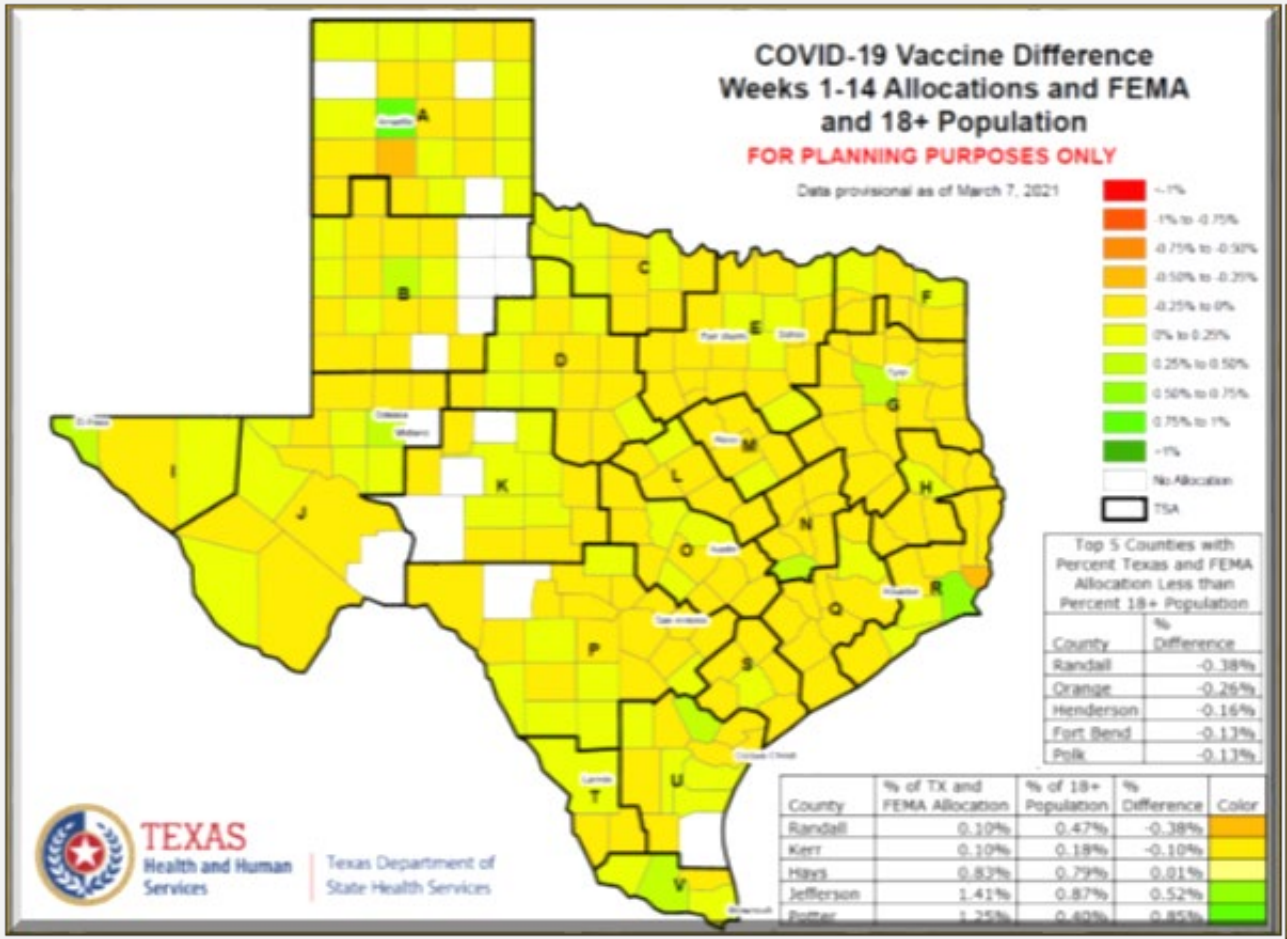
COVID-19 Vaccine Difference
Weeks 1-14 Allocations and FEMA
and 18+ Population
FOR PLANNING PURPOSES ONLY
Data provisional as of March 7, 2021
<-1%
-1% to -0.75%
-0.75% to -0.50%
-0.50% to -0.25%
-0.25% to 0%
0% to 0.25%
0.25% to 0.50%
0.50% to 0.75%
0.75% to 1%
>1%
No Allocation
TSA
Top 5 Counties with Percent Texas and FEMA Allocation Less than Percent 18+ Population
County | % Difference
Randall | -0.38%
Orange | -0.26%
Henderson | -0.16%
Fort Bend | -0.13%
Polk | -0.13%
County | % of TX and FEMA Allocation | % of 18+ Population | % Difference | Color
Randall | 0.10% | 0.47% | -0.38%
Kerr | 0.10% | 0.18% | -0.10%
Hays | 0.83% | 0.79% | 0.01%
Jefferson | 1.41% | 0.87% | 0.52%
Potter | 1.25% | 0.40% | 0.85%
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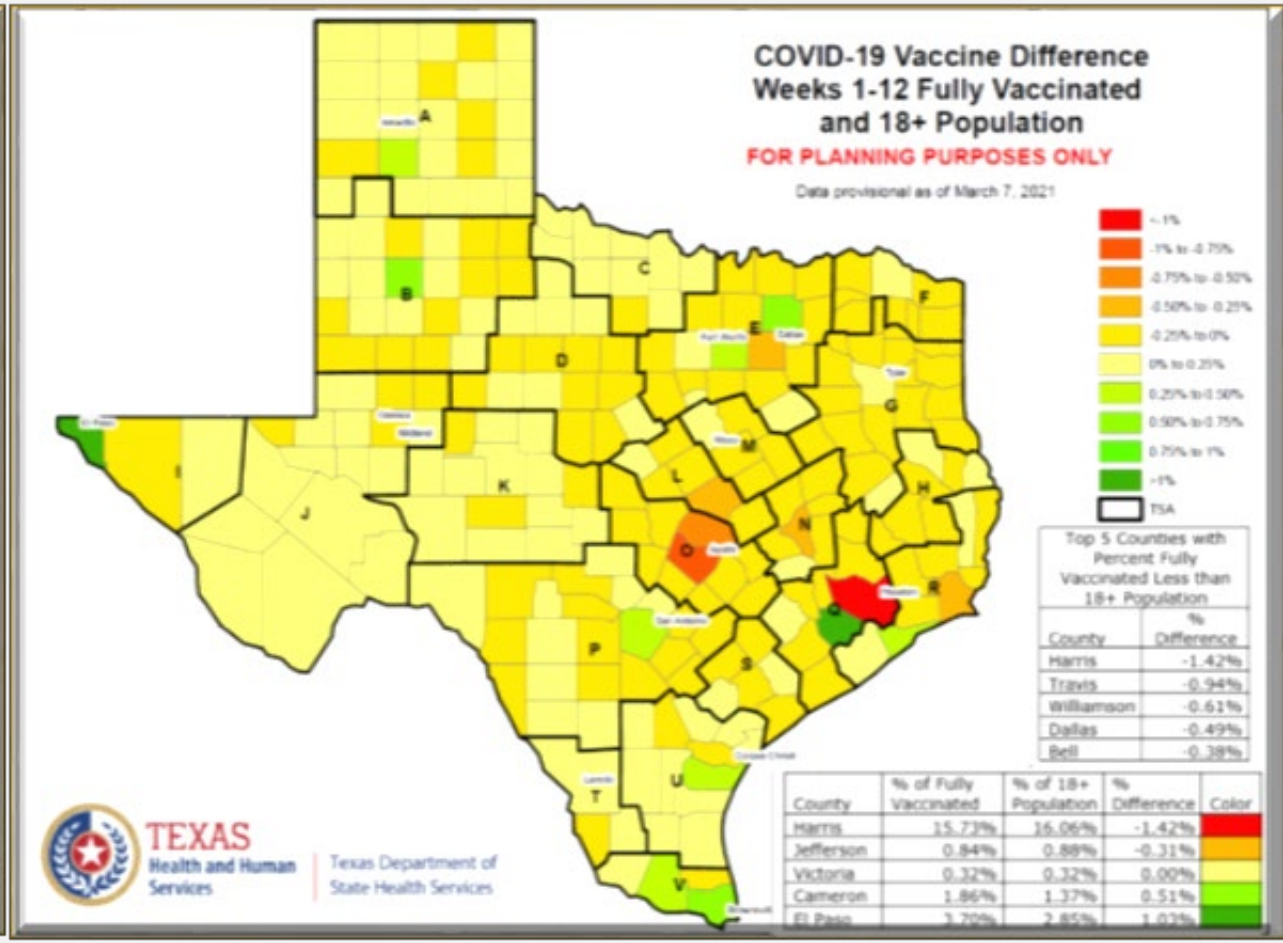
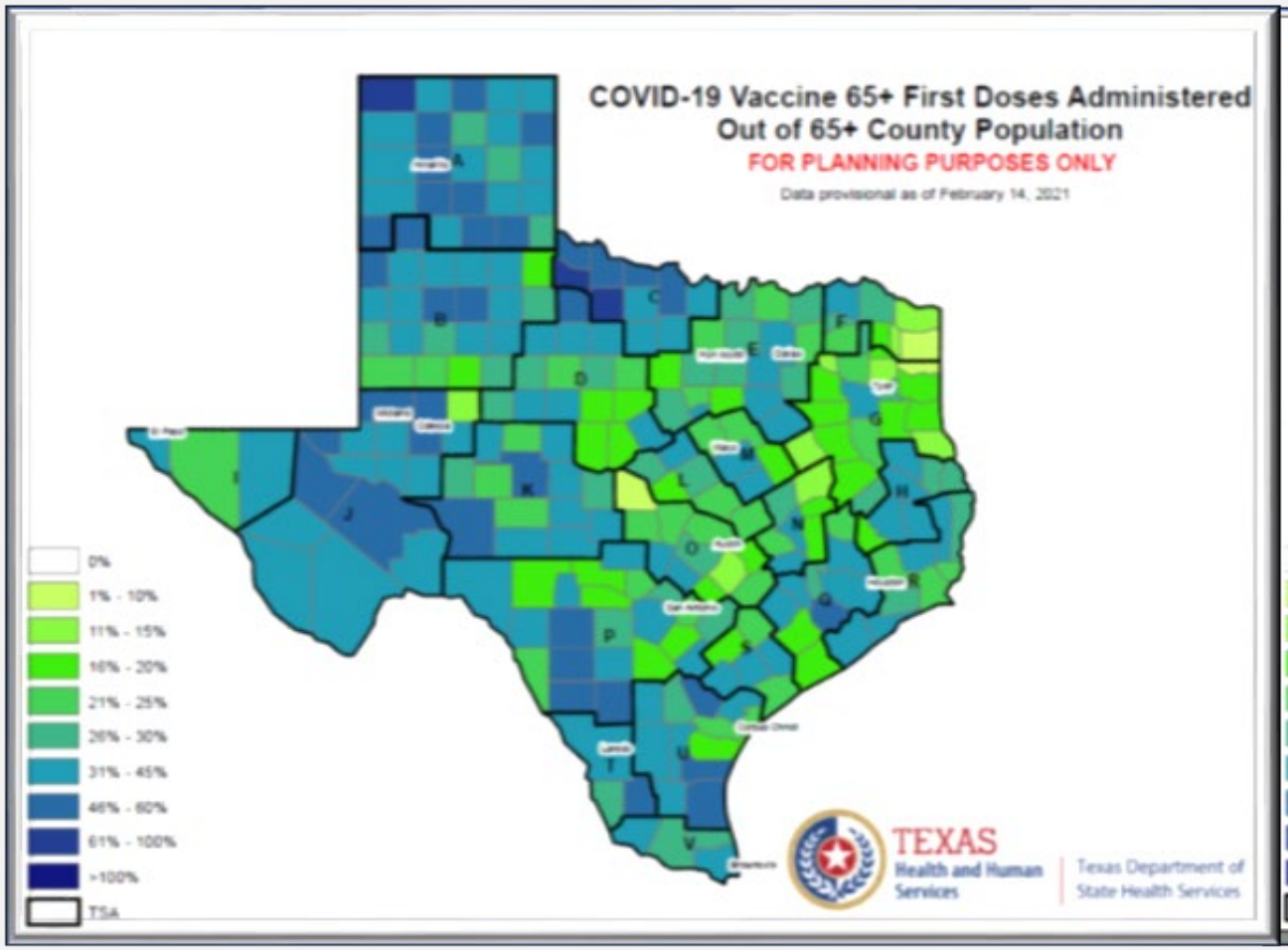
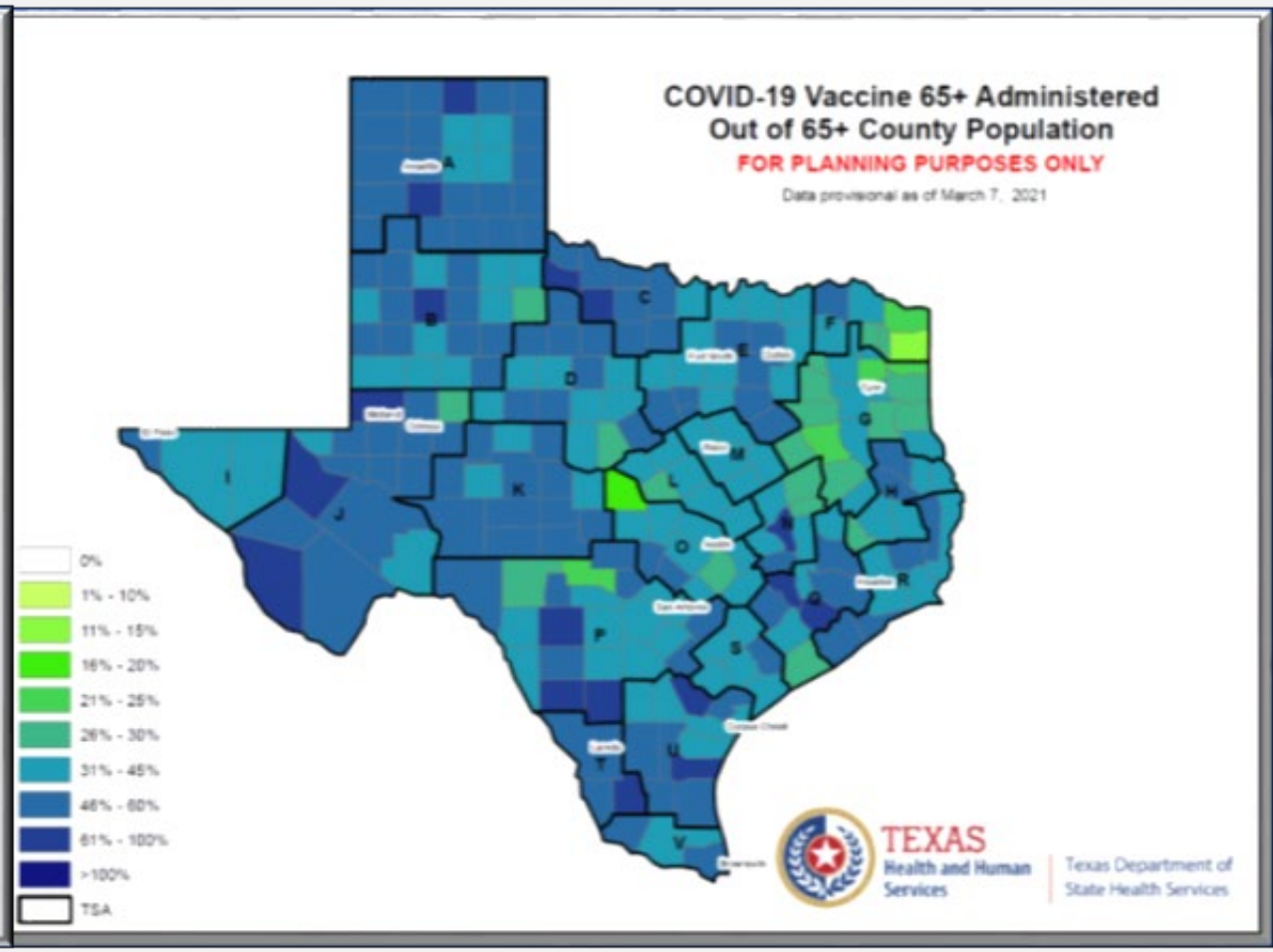
Health and Human Services
Texas Department of State Health Services


COVID-19 Vaccine Difference
Weeks 1-12 Fully Vaccinated
and 18+ Population
FOR PLANNING PURPOSES ONLY
Data provisional as of March 7, 2021
<-1%
-1% to -0.75%
-0.75% to -0.50%
-0.50% to -0.25%
-0.25% to 0%
0% to 0.25%
0.25% to 0.50%
0.50% to 0.75%
0.75% to 1%
>1%
TSA
Top 5 Counties with Percent Fully Vaccinated Less than 18+ Population
County | % Difference
Harris | -1.42%
Travis | -0.94%
Williamson | -0.61%
Dallas | -0.49%
Bell | -0.38%
County | % of Fully Vaccinated | % of 18+ Population | % Difference | Color
Harris | 15.73% | 16.06% | -1.42%
Jefferson | 0.84% | 0.88% | -0.31%
Victoria | 0.32% | 0.32% | 0.00%
Cameron | 1.86% | 1.37% | 0.51%
El Paso | 3.70% | 2.65% | 1.03%
TEXAS
Health and Human Services
Texas Department of State Health Services


COVID-19 Vaccine 65+ First Doses Administered
Out of 65+ County Population
FOR PLANNING PURPOSES ONLY
Data provisional as of February 14, 2021
0%
1% - 10%
11% - 15%
16% - 20%
21% - 25%
26% - 30%
31% - 45%
46% - 60%
61% - 100%
>100%
TSA
TEXAS
Health and Human Services
Texas Department of State Health Services


COVID-19 Vaccine 65+ Administered
Out of 65+ County Population
FOR PLANNING PURPOSES ONLY
Data provisional as of March 7, 2021
0%
1% - 10%
11% - 15%
16% - 20%
21% - 25%
26% - 30%
31% - 45%
46% - 60%
61% - 100%
>100%
TSA
TEXAS
Health and Human Services
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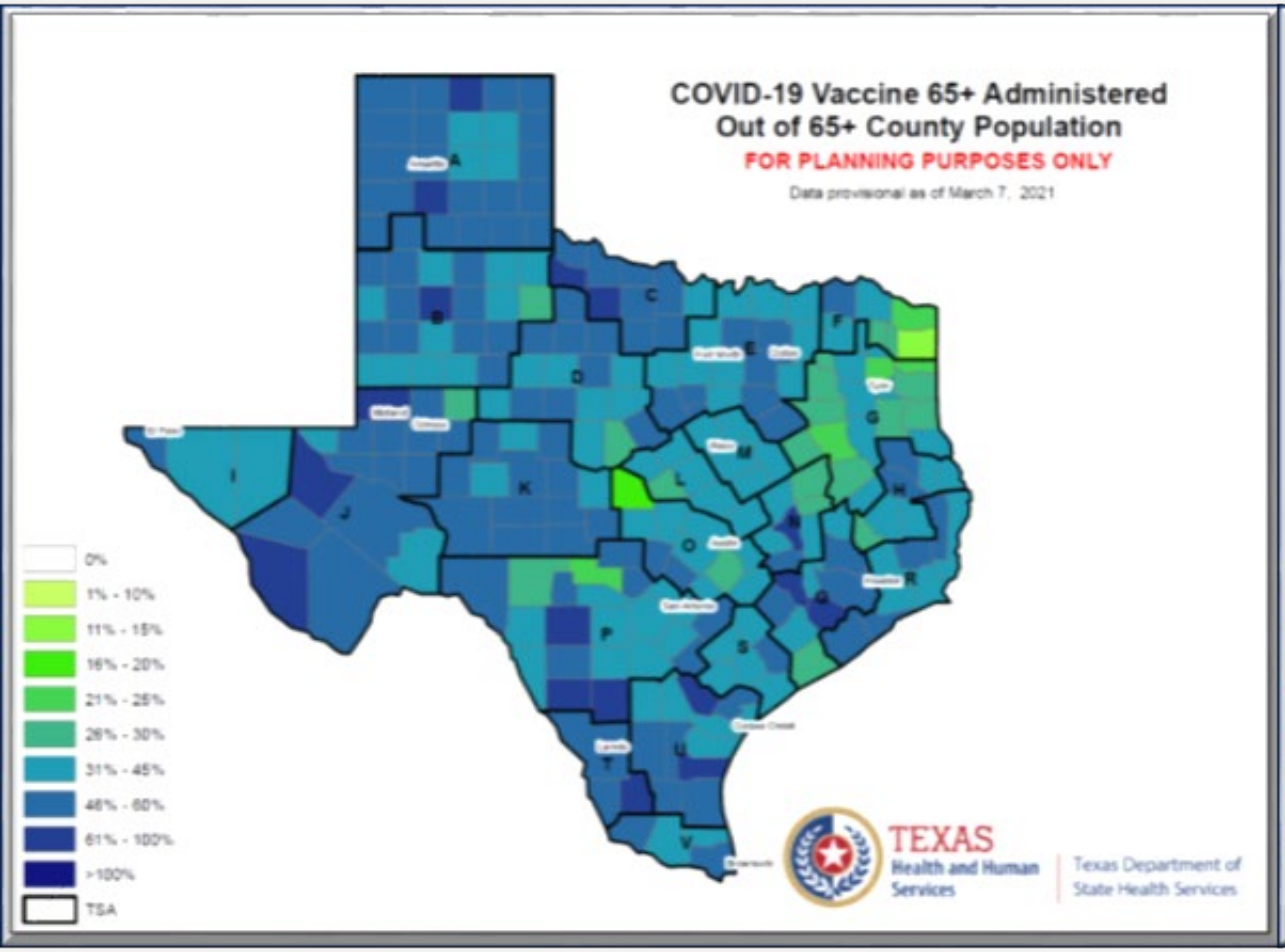
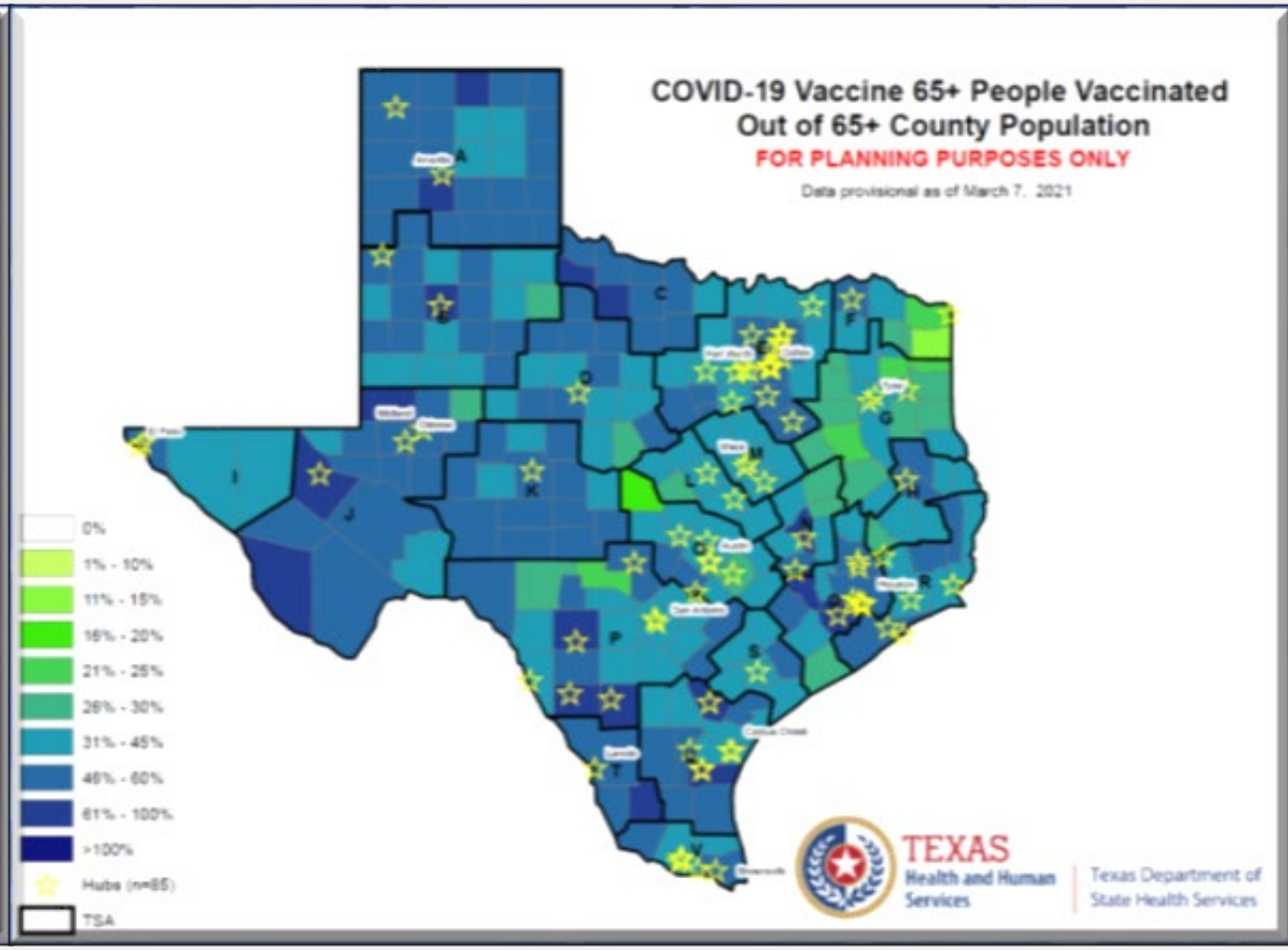
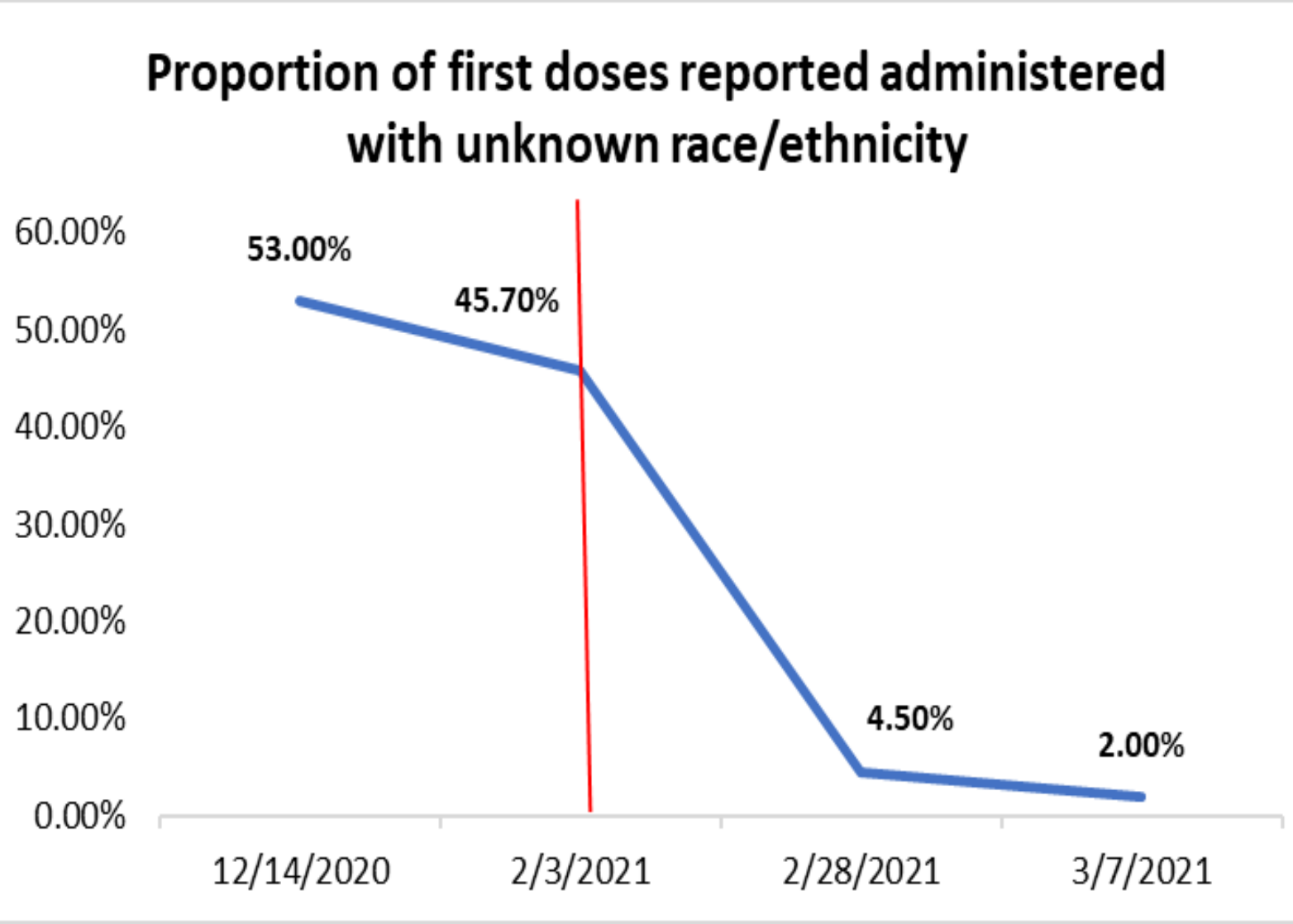
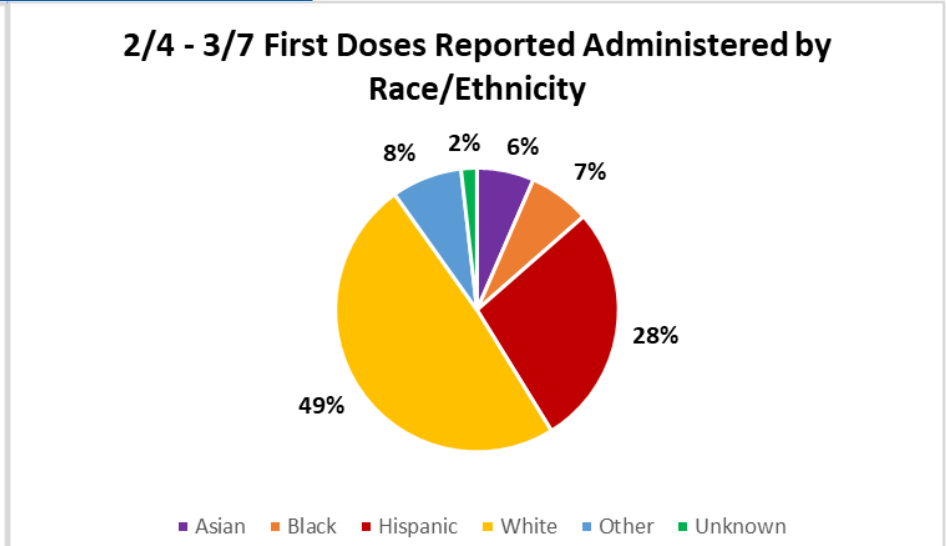
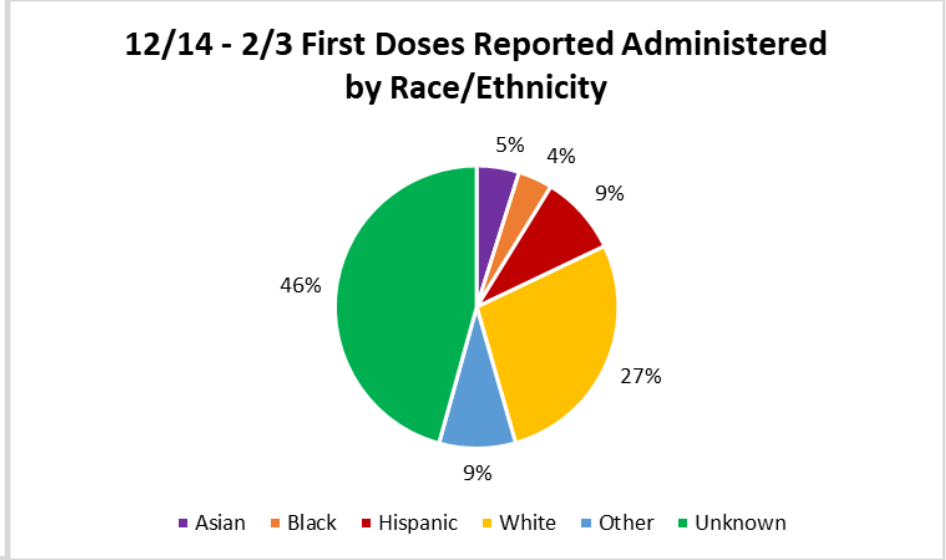

COVID-19 Vaccine 65+ Administered
Out of 65+ County Population
FOR PLANNING PURPOSES ONLY
Data provisional as of March 7, 2021
0%
1% - 10%
11% - 15%
16% - 20%
21% - 25%
26% - 30%
31% - 45%
46% - 60%
61% - 100%
>100%
TSA
TEXAS
Health and Human
Services
Texas Department of
State Health Services


COVID-19 Vaccine 65+ People Vaccinated
Out of 65+ County Population
FOR PLANNING PURPOSES ONLY
Data provisional as of March 7, 2021
0%
1% - 10%
11% - 15%
16% - 20%
21% - 25%
26% - 30%
31% - 45%
46% - 60%
61% - 100%
>100%
Hubs (n=85)
TSA
TEXAS
Health and Human
Services
Texas Department of
State Health Services

Improved Race/Ethnicity Reporting







Therapeutics Research

Updated Food and Drug Administration Guidelines for Certain Monoclonal Antibodies

Monoclonal Antibodies Overview

- FDA issued Emergency Use Authorizations for three COVID -19 Monoclonal Antibody regimens
- Products intended for Outpatients with:
  - Mild to moderate COVID-19
  - High risk for progressing to severe disease and/or hospitalizations
- Federal government purchased doses of both monoclonal antibody regimens and is providing free of charge to qualified facilities
  - Previously, state health departments (DSHS) directed allocation process
  - In February 2021, allocation process shifted to direct ordering by facilities to the product distributor
  - If supplies run scarce, process will revert to state-directed allocation

Monoclonal Antibodies EUAs

- **November 2020:** Food and Drug Administration (FDA) issues Emergency Use Authorizations (EUA):
  - **Products:** bamlanivimab (Eli Lilly), casirivimab/imdevimab (Regeneron)
  - **Emergency Use Authorization:** based on phase 1 and 2 clinical trial data
  - **National Institutes of Health Guidelines:** insufficient data to recommend for or against the use of these products for their intended purposes under the EUA
- **February 2021:** FDA issues new Emergency Use Authorization for monoclonal antibodies
  - **Products:** bamlanivimab/etesevimab (Eli Lilly)
  - **Emergency Use Authorization:** based on phase 3 clinical trial data – which includes more robust analysis, including hospitalizations and deaths
  - **National Institutes of HealthGuidelines:** recommends use of this regimen for outpatient treatment for mild/moderate COVID-19 in outpatients that meet Emergency Use Authorization criteria

Thank you

Presentation to the Senate Committee on Health and Human Services

Dr. John Hellerstedt, Commissioner

Imelda Garcia, Associate Commissioner