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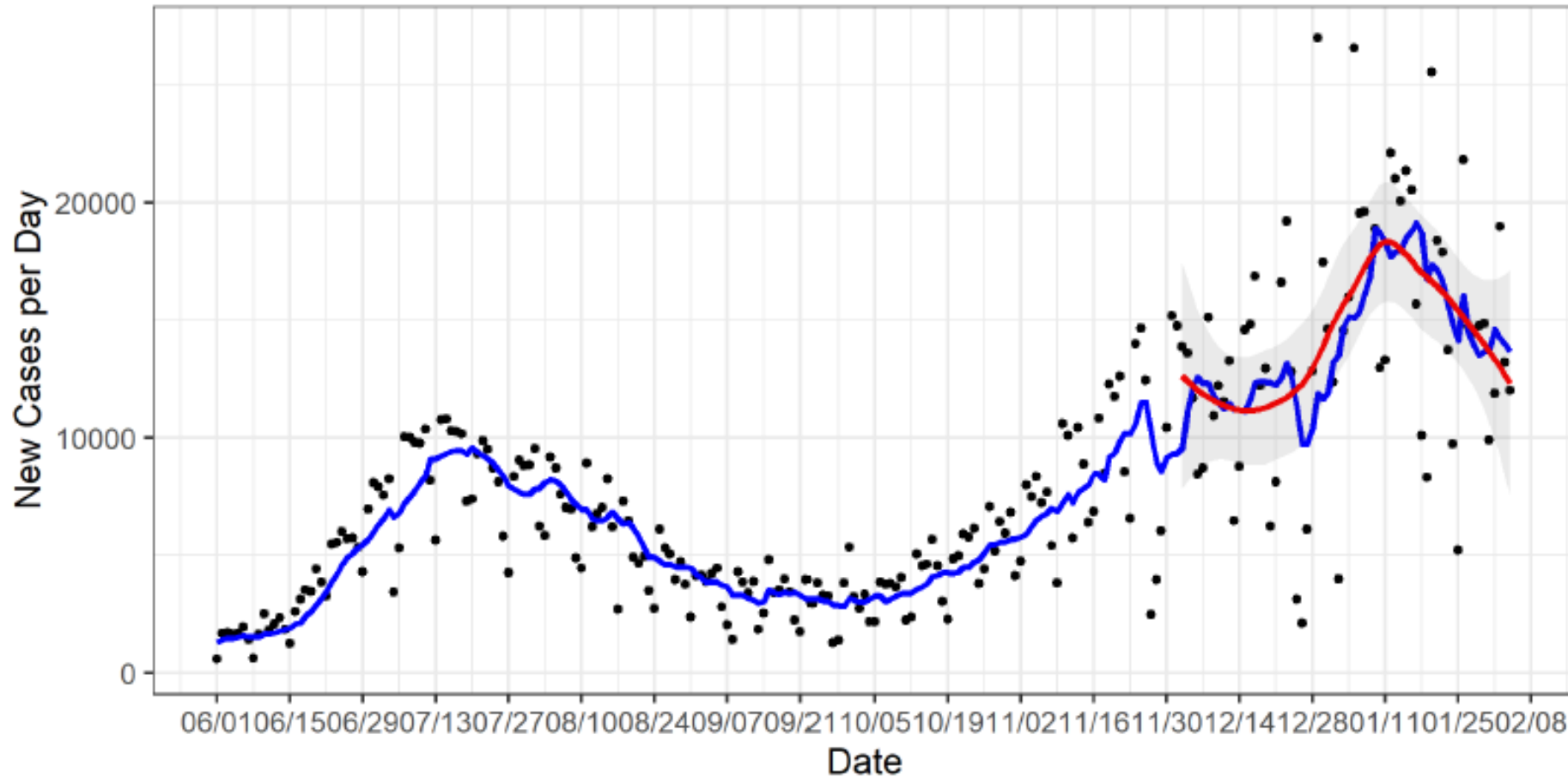
Future Considerations: Allocation and Distribution of COVID-19 Vaccine

Jennifer A. Shuford, MD, MPH

**Texas Collaborative for Healthy Mothers and Babies 2021 Summit
February 12, 2021**

Texas New Cases per Day

Pop: 29.7M; Slope: -322.2; 100k: -1.1; 7 Day Avg: 13,645.4; 7/14 Day Avg Δ : 61.6/-161.1



Blue line is 7 Day Moving Average. Δ is the change in the 7 Day Moving Average over a 7 or 14 day period.
These preliminary data are current as of 02/04/2021



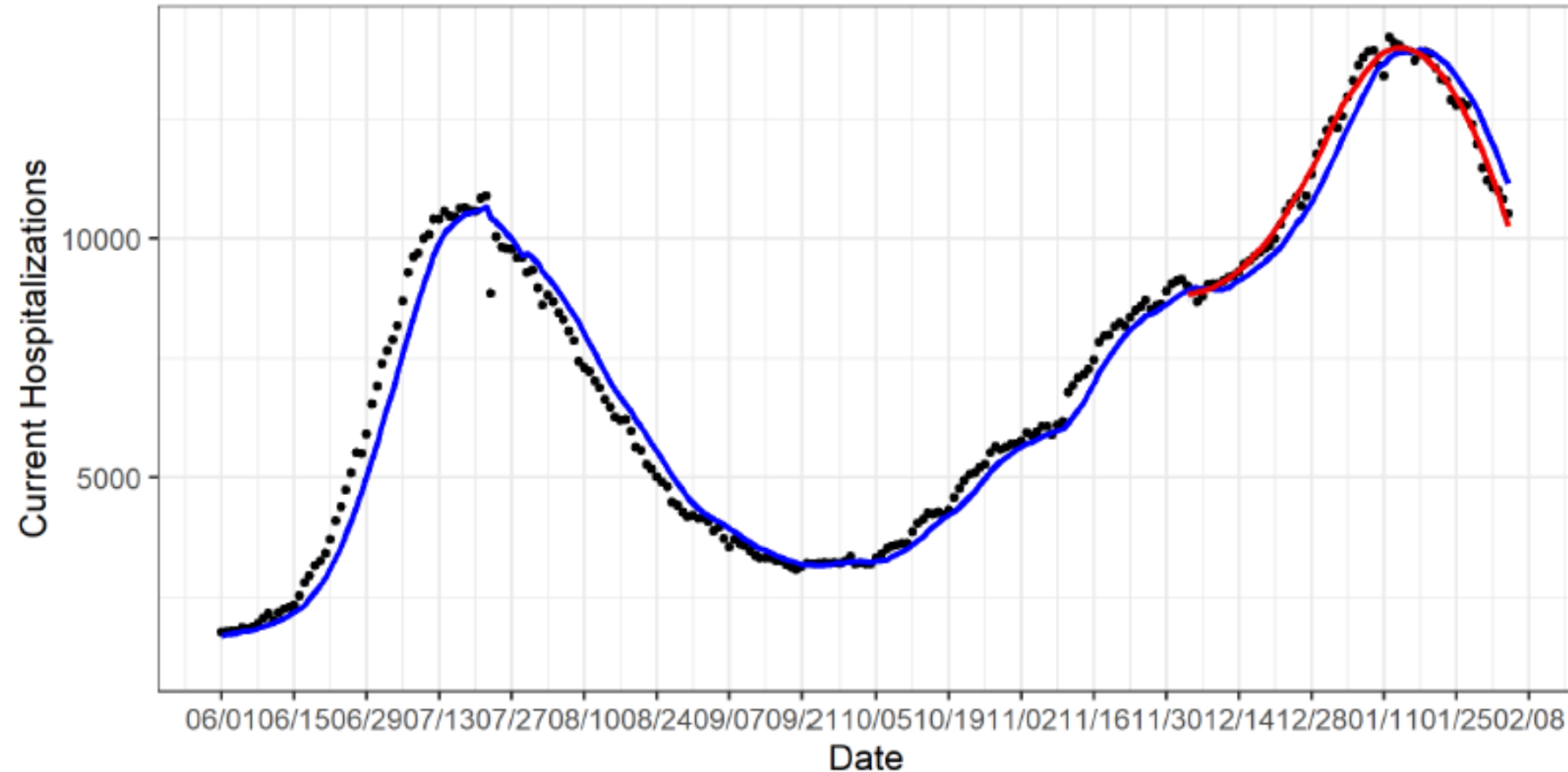
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Texas Hospitalizations Over Time

Pop: 29.7M; Slope: -302.7; 100k: -1; 7 Day Avg: 11,157.1; 7/14 Day Avg Δ : -258.5/-201.9



Blue line is 7 Day Moving Average. Δ is the change in the 7 Day Moving Average over a 7 or 14 day period.
These preliminary data are current as of Thu Feb 04 10:54:43 2021



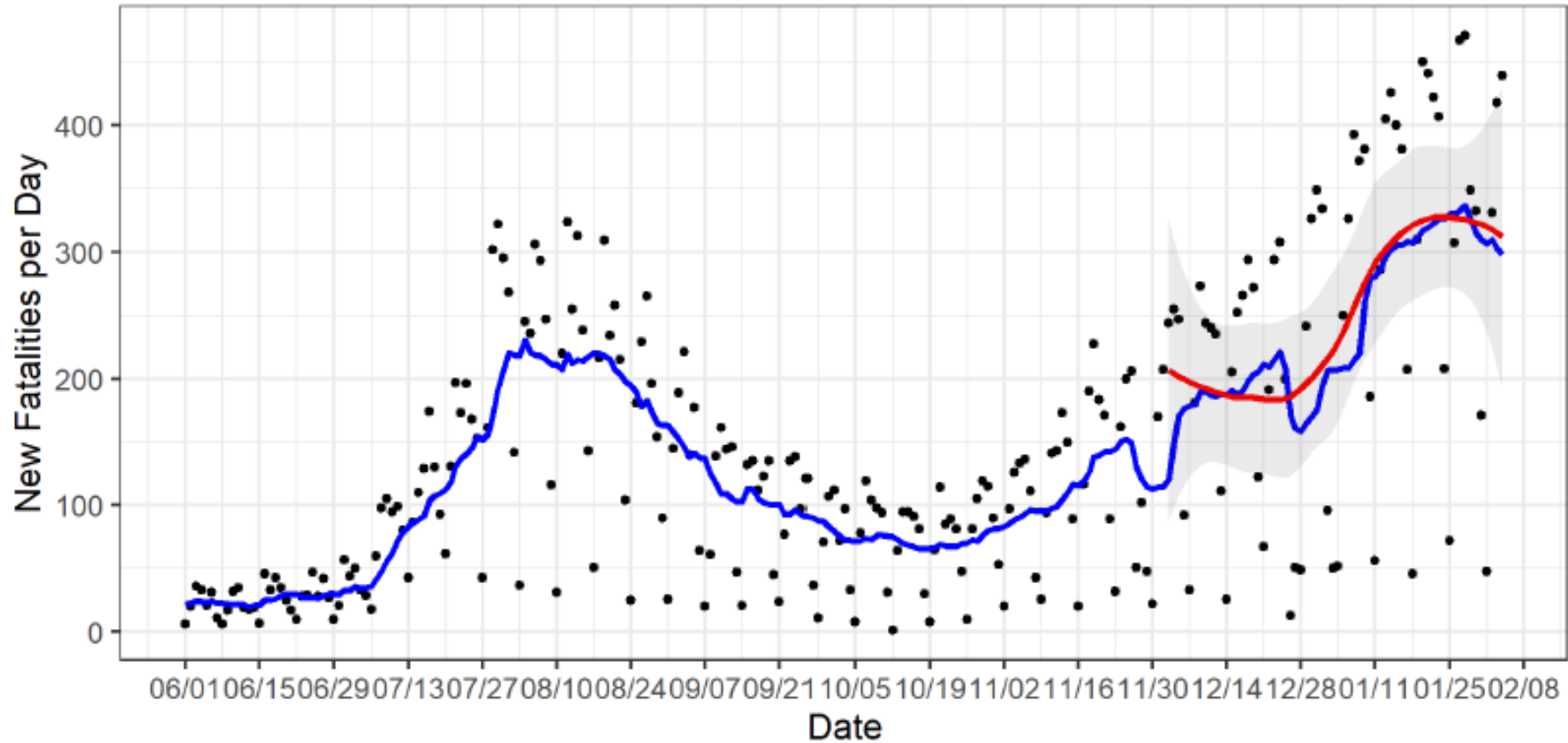
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Texas New Fatalities per Day

Pop: 29.7M; Slope: -2; 100k: 0; 7 Day Avg: 298.3; 7/14 Day Avg Δ : -3.8/-2.3



Blue line is 7 Day Moving Average. Δ is the change in the 7 Day Moving Average over a 7 or 14 day period.
Preliminary data as of 02/04/2021. Data source are New Fatalities by Date Recorded.
Last date of data is 02/04/2021



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Update: Characteristics of Symptomatic Women of Reproductive Age with Laboratory-Confirmed SARS-CoV-2 Infection by Pregnancy Status — United States, January 22–October 3, 2020

Laura D. Zambrano, PhD^{1,*}; Sascha Ellington, PhD^{1,*}; Penelope Strid, MPH¹; Romeo R. Galang, MD¹; Titilope Oduyebo, MD¹; Van T. Tong, MPH¹; Kate R. Woodworth, MD¹; John F. Nahabedian III, MS¹; Eduardo Azziz-Baumgartner, MD¹; Suzanne M. Gilboa, PhD¹; Dana Meancy-Delman, MD¹; CDC COVID-19 Response Pregnancy and Infant Linked Outcomes Team

- After adjusting for age, race/ethnicity, and underlying medical conditions, pregnant women were significantly more likely than were nonpregnant women to:
 - Be admitted to an ICU (aRR = 3.0; 95% CI = 2.6–3.4)
 - Receive invasive ventilation (aRR = 2.9; 95% CI = 2.2–3.8)
 - Receive ECMO (aRR = 2.4; 95% CI = 1.5–4.0)
 - Die (aRR = 1.7; 95% CI = 1.2–2.4)
- Absolute risk for severe outcomes in pregnant women was low, but pregnant women had increased risk for severe COVID-19



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Phase III Vaccine Candidates	Technology Platform	Storage & Handling	Dose (Intramuscular Injection)	Status
	m-RNA	Ultra-low frozen: 6mos Refrigerated: 5 days	2 (0, 21 days)	EUA (≥16 yrs)
	m-RNA	Frozen: 6mos Refrigerated: 30 days	2 (0, 28 days)	EUA (≥18 yrs)
	Viral Vector (Non-Replicating)	Frozen: 2 years Refrigerated: 3mos	1	EUA Filed (≥18 yrs)
	Viral Vector (Non-Replicating)	Refrigerated: 6mos	2 (0, 28 days)	Phase 3 (Tentative US EUA Filing April) EUA in other countries including UK
	Recombinant Subunit Adjuvant (Matrix M™)	Refrigerated: 3mos	2 (0, 21 days)	Phase 3 (Interim UK Data)

Vaccination: Pregnant Women



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- **Vaccination during pregnancy**
 - Few data on safety of COVID-19 vaccines in pregnant people
 - No safety concerns in rats that received Moderna vaccine prior to/during gestation
 - Manufacturers following outcomes in people who became pregnant during trials
 - Studies in pregnant people planned
 - Experts believe mRNA vaccines unlikely to pose risk to a pregnant person or fetus
 - mRNA vaccines not live vaccines
 - Vaccine mRNA is degraded quickly in the cell and does not enter the nucleus
 - Pregnant people may choose to be vaccinated if part of a recommended group
 - Discussion with clinical team is encouraged but not required
- **Moderna Pregnancy Registry**
 - Women vaccinated with Moderna COVID-19 vaccine during pregnancy are encouraged to enroll in the registry: 1-866-MODERNA (1-866-663-3762)

Vaccination: Lactating Women



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- **Vaccination while lactating**

- No data on safety of COVID-19 vaccines in lactating people, infant, milk production
- mRNA vaccines are not thought to be a risk to the breastfeeding infant
- Lactating people may choose to be vaccinated if part of a recommended group

Appendix A: Triage of persons presenting for mRNA COVID-19 vaccination

	MAY PROCEED WITH VACCINATION	PRECAUTION TO VACCINATION	CONTRAINDICATION TO VACCINATION
CONDITIONS	<p>CONDITIONS</p> <ul style="list-style-type: none"> Immunocompromising conditions Pregnancy Lactation <p>ACTIONS</p> <ul style="list-style-type: none"> Additional information provided* 15 minute observation period 	<p>CONDITIONS</p> <ul style="list-style-type: none"> Moderate/severe acute illness <p>ACTIONS</p> <ul style="list-style-type: none"> Risk assessment Potential deferral of vaccination 15-minute observation period if vaccinated 	<p>CONDITIONS</p> <ul style="list-style-type: none"> None <p>ACTIONS</p> <ul style="list-style-type: none"> N/A
ALLERGIES	<p>ALLERGIES</p> <p>History of allergies that are unrelated to components of an mRNA COVID-19 vaccine¹; other vaccines, injectable therapies, or polysorbate, such as:</p> <ul style="list-style-type: none"> Allergy to oral medications (including the oral equivalent of an injectable medication) History of food, pet, insect, venom, environmental, latex, etc., allergies Family history of allergies <p>ACTIONS</p> <ul style="list-style-type: none"> 30-minute observation period: Persons with a history of anaphylaxis (due to any cause) 15-minute observation period: All other persons 	<p>ALLERGIES</p> <ul style="list-style-type: none"> History of any immediate allergic reaction¹ to vaccines or injectable therapies (except those related to component of mRNA COVID-19 vaccines¹ or polysorbate, as these are contraindicated) <p>ACTIONS:</p> <ul style="list-style-type: none"> Risk assessment Consider deferral of vaccination and/or referral to allergist-immunologist 30-minute observation period if vaccinated 	<p>ALLERGIES</p> <p>History of the following are contraindications to receiving either of the mRNA COVID-19 vaccines¹:</p> <ul style="list-style-type: none"> Severe allergic reaction (e.g., anaphylaxis) after a previous dose of an mRNA COVID-19 vaccine or any of its components Immediate allergic reaction¹ of any severity to a previous dose of an mRNA COVID-19 vaccine or any of its components² (including polyethylene glycol)[#] Immediate allergic reaction of any severity to polysorbate^{2#} <p>ACTIONS</p> <ul style="list-style-type: none"> Do not vaccinate[#] Consider referral to allergist-immunologist



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Vaccination: Shared Decision Making



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- Pregnant person may choose to be vaccinated
- When making a decision, the patient and HCP should consider the:
 - level of COVID-19 community transmission
 - patient's personal risk of contracting COVID-19
 - risks of COVID-19 to the patient and potential risks to the fetus
 - efficacy of the vaccine
 - side effects of the vaccine
 - lack of data about the vaccine during pregnancy



Vaccination: Shared Decision Making



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I'm pregnant. Should I get the COVID vaccine?

For most people, getting the COVID vaccine as soon as possible is the safest choice.

However, trials testing the vaccine in pregnant and breastfeeding women have not been completed.

The information below will help you make an informed choice about whether to get the COVID vaccine while you are pregnant or trying to get pregnant.

Your options:



Get the COVID vaccine as soon as it is available



Wait for more information about the vaccine in pregnancy

What are the benefits of getting the COVID Vaccine?

1. COVID is dangerous. It is more dangerous for pregnant women.

- COVID patients who are pregnant are 5 times more likely to end up in the intensive care unit (ICU) or on a ventilator than COVID patients who are not pregnant.¹
- Preterm birth may be more common for pregnant women with severe COVID, but other obstetric complications such as stillbirth do not appear to be increased.²
- Pregnant women are more likely to die of COVID than non-pregnant women with COVID who are the same age.^{3,4}



2. The COVID vaccine will prevent 95% of COVID infections.

- As COVID infections go up in our communities, your risk of getting COVID goes up too.
- Getting the vaccine will prevent you from getting COVID and will help keep you from giving COVID to people around you.

3. The COVID vaccine cannot give you COVID.

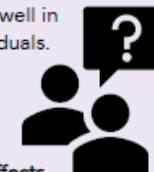
- The COVID vaccine has no live virus.⁵
- The COVID vaccine does NOT contain ingredients that are known to be harmful to pregnant women or to the fetus.
- Many vaccines are routinely given in pregnancy and are safe (for example: tetanus, diphtheria, and flu).

More details about how the vaccine works can be found on page 5.

What are the risks of getting the COVID vaccine?

1. The COVID vaccine has not yet been tested in pregnant women.

- The vaccine was tested in over 20,000 people, and there were no serious side effects. However, it was not tested in pregnant women.
- We do not have data on whether the vaccine works as well in pregnancy as it did in the study of non-pregnant individuals.
- We do not have data on whether there are unique downsides in pregnancy, like different side effects or an increased risk of miscarriage or fetal abnormalities.



2. People getting the vaccine will probably have some side effects.

- Although there were no serious side effects reported, many people had some side effects. The side effects of the vaccine were:
 - injection site reactions like sore arm (84%)
 - fatigue (62%)
 - headache (55%)
 - muscle pain (38%)
 - chills (32%)
 - joint pain (24%)
 - fever (14%)
- About 1% of people will get a high fever (over 102°F). A persistent high fever during the first trimester of pregnancy might increase the risk of congenital defects or miscarriage. For those reasons, you may choose to delay your COVID vaccine until after the first trimester.
- The CDC recommends using Tylenol (acetaminophen) during pregnancy if you have a high fever.

What do the experts recommend?

COVID is very dangerous and can spread very easily. Because of this, *"the Pfizer-COVID vaccine is recommended for persons 16 years of age and older in the U.S. population under the FDA's Emergency Use Authorization."* (CDC)⁶

However, because there are no studies of pregnant women yet, there are no clear recommendations for pregnant women. This is standard for a new drug and is not due to any particular concern with this vaccine.

COVID-19: Risk Reduction



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- With or without vaccine, pregnant people and household members need to protect themselves from COVID-19 by:
 - Limiting interactions with people who might have been exposed to or who might have COVID-19
 - Wearing masks, especially when difficult to distance
 - Avoiding others who are not wearing masks
 - Physical distancing by at least 6 feet from people outside their household
 - Washing/sanitizing hands
 - Avoiding activities where these steps can't be taken



COVID-19 Vaccines in Texas

What's Next with the COVID-19 Vaccine in Texas

We Are Here

LIMITED SUPPLY

- 1A: Direct Care - Hospital, Long-Term Care, EMS 9-1-1, Home Health, Outpatient, ER/Urgent Care, Pharmacies, Last Responders, School Nurses
- 1A: Long-Term Care - Residents of Long-Term Care Facilities
- 1B: Persons 65+ or 16+ with at least one chronic medical condition, including pregnancy

ADDITIONAL SUPPLY

- 1C: Under consideration
- 2: Under consideration

BROAD SUPPLY

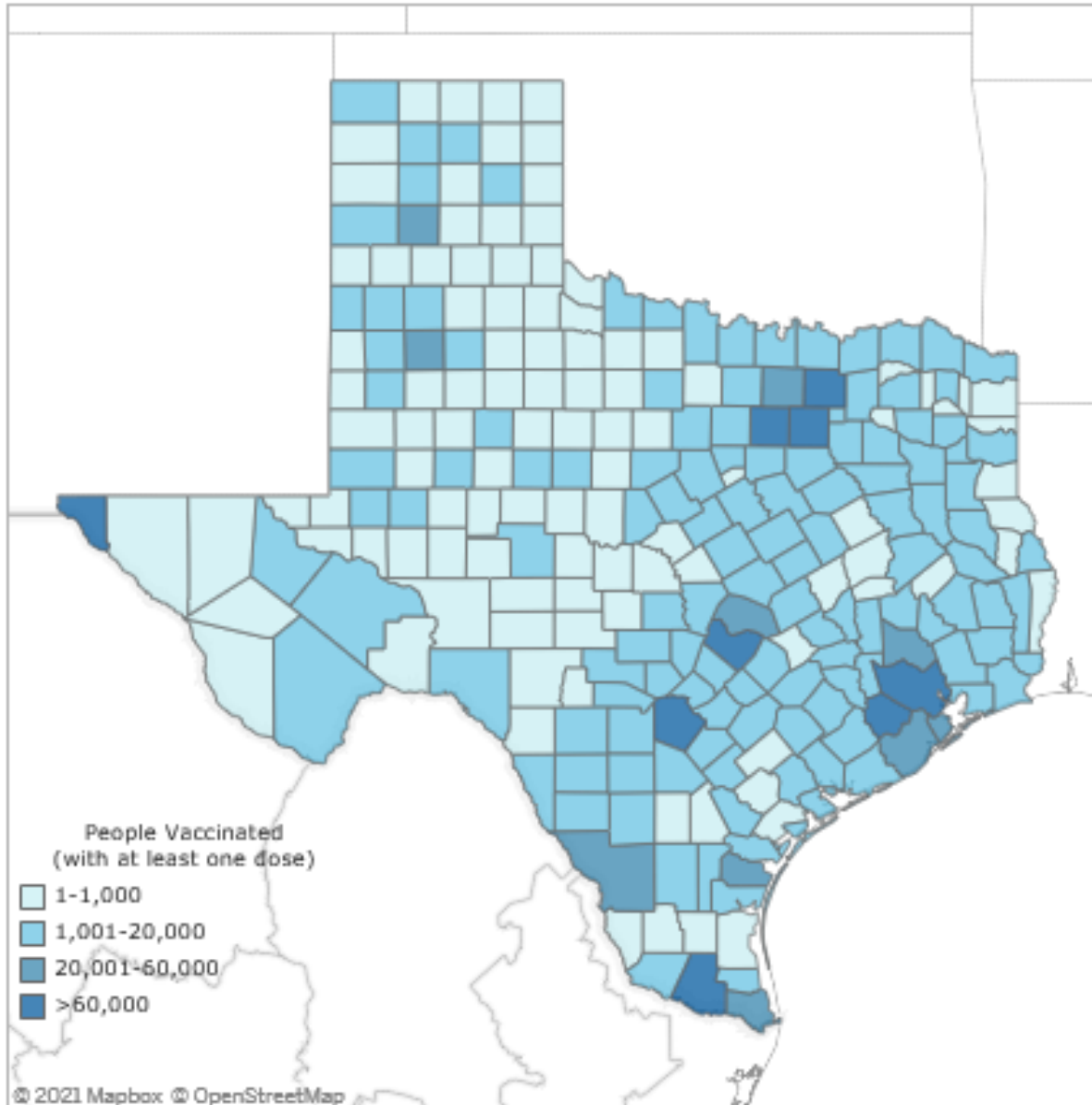
- 3: Under consideration



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Texans Vaccinated for COVID-19



Doses Allocated

4,468,600

Doses Shipped

3,864,425

People Vaccinated with at least One Dose

2,214,644

People Fully Vaccinated

668,743

Doses Administered

2,883,387

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Thank you!

Jennifer A. Shuford, MD, MPH
Jennifer.Shuford@dshs.texas.gov