The Front Lines of the Fight Against COVID-19

A TOWN HALL CONVERSATION XVIII

We will begin at 10 a.m.
Influenza

Background

• Single-strand RNA virus in Orthomyxovirus family
• Respiratory transmission
  ▪ Incubation period: 2 days
  ▪ Viral shedding: 5-10 days
• Illness can range from mild to severe
• Complications
  ▪ Secondary bacterial pneumonia
  ▪ Otitis media
  ▪ Exacerbation of underlying respiratory conditions

Influenza

Background

Understanding Influenza (Flu) Infection: An Influenza Virus Binds to a Respiratory Tract Cell

After Influenza viruses enter the human body, they attach to cells within the nasal passages and throat (i.e., the respiratory tract). The hemagglutinin (HA) surface proteins of the influenza virus bind to the sialic acid receptors on the surface of a human cell like a key to a lock. The influenza virus is then able to enter and infect the cell. This marks the beginning of a flu infection.
Influenza

Background

- Four types of influenza virus (A, B, C, and D)
  - Types A and B cause seasonal epidemics
- Influenza A viruses are subtyped based on two proteins on the viral surface
  - Hemagglutinin (H)
  - Neuraminidase (N)
- Antigenic drift accounts for seasonal recurrence
- Antigenic shift causes epidemics and pandemics
• Seasonal flu vaccines include four strains that are most likely to cause endemic illness each year
  - Based on biannual research done by the WHO from each hemisphere ahead of their upcoming flu season
  - It takes at least six months to manufacture large quantities of the flu vaccine
Influenza Vaccines

- Three main types of flu vaccine
- All contain four flu strains so they are considered *quadrivalent*

<table>
<thead>
<tr>
<th>Inactivated Influenza Vaccine (IIV)</th>
<th>Recombinant Influenza Vaccine (RIV)</th>
<th>Live Attenuated Influenza Vaccine (LAIV)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Quadrivalent</td>
<td>• Quadrivalent</td>
<td>• Quadrivalent</td>
</tr>
<tr>
<td>• Egg vs cell-culture based</td>
<td>• IM</td>
<td>• Egg based</td>
</tr>
<tr>
<td>• IM</td>
<td>• IM</td>
<td>• Nasal</td>
</tr>
</tbody>
</table>

*IM = intramuscular*
• Whole virus is chemically inactivated, then grown and replicated in a non-human medium
  ▪ Egg based mediums are the most common given relatively low production cost & safety profile
  ▪ Cell-culture based mediums can also be used but they are more costly & have a lower viral yield
• Provides antigen to the immune system without causing active infection

• Specific antigens from the viral strain of interest are genetically inserted on a non-pathogenic vector

• Provides antigen delivery to the immune system without causing active infection
  ▪ Immune response is not quite as robust as with IIV
Live virus is attenuated via cold-adaptation to make it weaker
Virus is still propagated in egg based medium
Provides antigen to the immune system via replicating virus
- Very robust immune response as this closely mimics natural infection
- Not suitable for certain populations whose immune system is too weak to control attenuated virus

<table>
<thead>
<tr>
<th>Trade Name</th>
<th>Product</th>
<th>Indicated Age</th>
<th>Route</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>IIV – egg based</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Afluria Quadrivalent</td>
<td>0.25 mL PFS</td>
<td>6 to 35 mo</td>
<td>IM</td>
</tr>
<tr>
<td></td>
<td>0.5 mL PFS</td>
<td>&gt;3 years</td>
<td>IM</td>
</tr>
<tr>
<td></td>
<td>5 mL MDV</td>
<td>≥ 6 mo (needle/syringe)</td>
<td>IM</td>
</tr>
<tr>
<td></td>
<td></td>
<td>18 to 64 years (jet injector)</td>
<td></td>
</tr>
<tr>
<td>Fluarix Quadrivalent</td>
<td>0.5 mL PFS</td>
<td>≥ 6 mo</td>
<td>IM</td>
</tr>
<tr>
<td>FluLaval Quadrivalent</td>
<td>0.5 mL PFS</td>
<td>≥ 6 mo</td>
<td>IM</td>
</tr>
<tr>
<td>Fluzone Quadrivalent</td>
<td>0.5 mL PFS</td>
<td>≥ 6 mo</td>
<td>IM</td>
</tr>
<tr>
<td></td>
<td>0.5 mL SDV</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>5 mL MDV</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fluzone High-Dose Quadrivalent</td>
<td>0.7 mL PFS</td>
<td>≥ 65 years</td>
<td>IM</td>
</tr>
<tr>
<td>Fluad Quadrivalent (with MF59 adjuvant)</td>
<td>0.5 mL PFS</td>
<td>≥ 65 years</td>
<td>IM</td>
</tr>
<tr>
<td></td>
<td>5 mL MDV</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>IIV – cell culture based</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flucelvax Quadrivalent</td>
<td>0.5 mL PFS</td>
<td>≥ 2 years</td>
<td>IM</td>
</tr>
<tr>
<td></td>
<td>5 mL MDV</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

PFS = pre-filled syringe; MDV = multi-dose vial; SDV = single-dose vial; IM = intramuscular
<table>
<thead>
<tr>
<th>Trade Name</th>
<th>Product</th>
<th>Indicated Age</th>
<th>Route</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flublok Quadrivalent</td>
<td>0.5 mL PFS</td>
<td>≥18 years</td>
<td>IM</td>
</tr>
<tr>
<td>LAIV – egg based</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FluMist Quadrivalent</td>
<td>0.2 mL PFS via intranasal sprayer</td>
<td>2 to 49 years</td>
<td>Intranasal</td>
</tr>
</tbody>
</table>

PFS = pre-filled syringe; MDV = multi-dose vial; SDV = single-dose vial; IM = intramuscular
Influenza Vaccine

Additional Considerations

• Egg allergy
  ▪ Egg-free vaccines: cell-culture based IIV or RIV
  ▪ Persons who can eat scrambled eggs without issue are unlikely to be allergic to egg based vaccines

• High-dose vaccines should be given to persons ≥ 65 years of age
  ▪ Additionally, immunocompromised patients may benefit from high-dose formulations

• Flu and COVID vaccines can be administered at the same visit
  ▪ Patients with suspected or confirmed COVID can be vaccinated after criteria for ending isolation precautions are met
Influenza Reporting

Percentage of Visits for Influenza-like Illness (ILI) Reported by the U.S. Outpatient Influenza-like Illness Surveillance Network (ILINet), Weekly National Summary, 2020-2021 and Selected Previous Seasons

*This system monitors visits for ILI (fever and cough or sore throat), not laboratory confirmed influenza and may capture patient visits due to other respiratory pathogens that cause similar symptoms.

†These seasons did not have a week 53, so the week 53 value is an average of week 52 and week 1.
Summary

- Influenza is an endemic infectious disease that has pandemic potential
- Prevention of active infection via vaccination is the best way to curb viral mutation and spread
- Several influenza vaccines are currently available to meet the needs of patients
COVID-19 and Vaccine Update

Marc L. Boom, MD
October 19, 2021
Houston Methodist Hospital
Recognition of Service

Recognition of our service to the State of Texas as a major vaccination hub

COVID-19 VACCINE TRACKER

944,349 Vaccines Administered*
453,210 Vaccinations Dose 1*
433,795 Vaccinations Dose 2*
57,344 Vaccinations Dose 3*

At Houston Methodist as of end of day 10/17/2021

State of Texas
Office of the Governor

To all to whom these presents shall come, Greetings:

Know ye that this official certificate is presented to:

Houston Methodist Hospital

As Governor of Texas, I am honored to thank you for your service to the state of Texas as a major vaccination hub. Your hard work has helped to mitigate the spread of COVID-19 in our communities while also safeguarding crucial state resources and ensuring the protection of our most vulnerable Texans.

I often say it is not our challenges that define us, but rather how we rise above them. You have demonstrated this ideal through your sincere efforts to serve your fellow Texans, and on behalf of the entire state, I thank you. You truly exemplify the very best of the Lone Star State.

First Lady Cecilia Abbott joins me in sending our deepest appreciation for your commitment to the people of Texas.

Under the laws of the State of Texas, with all rights, privileges, and emoluments appertaining to said office, I grant this official recognition. In testimony whereof, I have signed my name and caused the Seal of the State to be affixed at the City of Austin, this the 29th day of September, 2021.

Greg Abbott
Governor of Texas
Multiple Hospitals Announce COVID-19 Vaccine Mandate for Employees

March 31, 2021
First Health System to Mandate the Vaccine

April – Mid July

Late July – Early August

August

September

Now

Over 2,500+ Hospitals and Health Systems
Texas Vaccination Stats

As of Oct. 16, about 52.2% of Texas' 29.1 million people have been fully vaccinated. According to the Census Bureau's 2019 Vintage population estimates, 83% of Texans are age 12 and older and thus eligible for a vaccine.

The percentage of residents vaccinated by age shows which age groups have been vaccinated at higher rates. Among the first groups eligible for vaccines in late December 2020 were Texans age 65 and older. Texas' population skews younger — about 17% are under 12.

829,857 Texans are 80 years or older
7.9 million Texans are 50 to 79 years old
13.7 million Texans are 16 to 49 years old
1.7 million Texans are 12 to 15 years old

Source: https://apps.texastribune.org/features/2020/texas-coronavirus-cases-map/
New Vaccination/Testing Requirements: Private Employers & Federal Contractors

Source: https://www.whitehouse.gov/covidplan/

Key Requirements

- Requiring All Employers with 100+ Employees to Ensure their Workers are Vaccinated or Tested Weekly
- Requiring Vaccinations for all Federal Workers and for Millions of Contractors that Do Business with the Federal Government
- Requiring COVID-19 Vaccinations for Over 17 Million Health Care Workers at Medicare and Medicaid Participating Hospitals and Other Health Care Settings
- Calling on Large Entertainment Venues to Require Proof of Vaccination or Testing for Entry
- Requiring Employers to Provide Paid Time Off to Get Vaccinated
Texas Executive Order Prohibiting Vaccine Mandates

STATE OF TEXAS
Office of the Governor

MESSAGE

TO THE SENATE AND HOUSE OF REPRESENTATIVES OF THE EIGHTY-SEVENTH TEXAS LEGISLATURE, THIRD CALLED SESSION:

I, GREG ABBOTT, Governor of the State of Texas, by the authority vested in me by Article III, Section 40, and Article IV, Section 8, of the Texas Constitution, do hereby present the following additional subject to the 87th Texas Legislature, Third Called Session, for consideration:

Legislation establishing that no entity in Texas can compel receipt of a COVID-19 vaccine by any individual, including an employee or a consumer, who objects to such vaccination for any reason of personal conscience, based on a religious belief, or for medical reasons, including prior recovery from COVID-19.

Respectfully submitted,

GREG ABBOTT
Governor

Austin, Texas
October 11, 2021

Governor Greg Abbott

October 11, 2021

Mr. Joe A. Esparza
Deputy Secretary of State
State Capitol Room 1E.8
Austin, Texas 78701

Dear Deputy Secretary Esparza:

Pursuant to his powers as Governor of the State of Texas, Greg Abbott has issued the following:

Executive Order No. GA-40 relating to prohibiting vaccine mandates, subject to legislative action.

The original executive order is attached to this letter of transmittal.

Respectfully submitted,

Gregory S. Davis
Executive Clerk to the Governor
GSD/ gad

Attachment
Deaths have been concentrated among the unvaccinated, federal data show. The CDC released studies on Friday showing that unvaccinated Americans were 4.6 times as likely to be infected, 10 times as likely to be hospitalized and 11 times as likely to die.

Younger age groups have represented a growing share of deaths since vaccines became available, a trend that has continued into the summer’s Delta surge.

Age is a major risk factor for people with Covid-19. **People in their 30s are four times as likely to die from infections as people ages 18 to 29**, according to the CDC. For people ages 75 to 84, the risk of death is 220 times as high.

## Houston Methodist Mortality: Vaccinated vs. Unvaccinated

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Count Discharged Encounters</th>
<th>Mortality Count</th>
<th>Mortality Rate</th>
<th>Count Discharged Encounters</th>
<th>Mortality Count</th>
<th>Mortality Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>below 18</td>
<td>4</td>
<td>0</td>
<td>0.0%</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>18 - 24</td>
<td>142</td>
<td>0</td>
<td>0.0%</td>
<td>11</td>
<td>0</td>
<td>0.0%</td>
</tr>
<tr>
<td>25 - 40</td>
<td>1,041</td>
<td>38</td>
<td>3.7%</td>
<td>98</td>
<td>2</td>
<td>2.0%</td>
</tr>
<tr>
<td>41 - 50</td>
<td>965</td>
<td>69</td>
<td>7.2%</td>
<td>163</td>
<td>9</td>
<td>5.5%</td>
</tr>
<tr>
<td>51 - 60</td>
<td>892</td>
<td>66</td>
<td>7.4%</td>
<td>200</td>
<td>8</td>
<td>4.0%</td>
</tr>
<tr>
<td>61 - 70</td>
<td>744</td>
<td>66</td>
<td>8.9%</td>
<td>364</td>
<td>23</td>
<td>6.3%</td>
</tr>
<tr>
<td>71 - 80</td>
<td>479</td>
<td>40</td>
<td>8.4%</td>
<td>384</td>
<td>22</td>
<td>5.7%</td>
</tr>
<tr>
<td>Over 80</td>
<td>232</td>
<td>26</td>
<td>11.2%</td>
<td>299</td>
<td>20</td>
<td>6.7%</td>
</tr>
<tr>
<td>Overall</td>
<td>4,499</td>
<td>305</td>
<td>6.8%</td>
<td>1,519</td>
<td>84</td>
<td>5.5%</td>
</tr>
</tbody>
</table>

Data from July 15, 2021-October 14, 2021

### Estimated Effectiveness against Hospitalizations:
- **Under 60**: 90 – 93%
- **60 – 80**: 86 – 88%
- **Over 80**: 77%

### Estimated Effectiveness against Death:
- **Under 60**: 95 – 96%
- **60 – 80**: 90 – 91%
- **Over 80**: 86%
Preventing Employee Hospitalizations

**Employee Vaccination Status**

- **Vaccinated**: 98.3%
- **Unvaccinated**: 1.7%

**Employees Hospitalized (Current Surge)**

<table>
<thead>
<tr>
<th></th>
<th>Vaccinated</th>
<th>Unvaccinated</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total Employees</strong></td>
<td>26,124</td>
<td>454</td>
</tr>
<tr>
<td><strong>Employees Hospitalized</strong></td>
<td>8</td>
<td>6</td>
</tr>
<tr>
<td><strong>% Employees Hospitalized</strong></td>
<td>0.03%</td>
<td>1.32%</td>
</tr>
</tbody>
</table>

Unvaccinated employees are **44 times** more likely to be hospitalized.

**Vaccine Effectiveness at Preventing Employee Hospitalizations**

- **97.73%**

Source: HM Employee Health, as of October 18, 2021
Combating Misinformation in the Community

Examples of Opinions based on Misinformation:

“THE VAX IS A DEATH SENTENCE TO MANY – 80,000 people have thus far died from the Vax, 200,000 have been injured, many permanently (this is stats from the whistleblower)”

“I know people with serious illnesses that would rather die at home in peace than be put through the torture this vax brings to far too many. No one wants to play Russian Roulette.”

“Many doctors now are very interested in de-population.”

“They do not report deaths that occur for 14 days after the vax when many people die.”

“This is against the Nuremberg Code.”

“Sincerely, A Concerned Citizen Completely Against Doctors Murdering People For Their Political Overlords”

Examples of Misinformed Data:

“Death”

Comparison between EMA, WHO and VAERS Data of COVID-19 vaccines

Absolute frequency

<table>
<thead>
<tr>
<th>Database</th>
<th>EMA</th>
<th>WHO</th>
<th>VAERS</th>
<th>EMA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incidence</td>
<td>36.1%</td>
<td>36.1%</td>
<td>36.0%</td>
<td>50.0%</td>
</tr>
<tr>
<td>Relative frequency</td>
<td>20.8%</td>
<td>14.0%</td>
<td>14.0%</td>
<td>14.0%</td>
</tr>
</tbody>
</table>

Examples of Misinformed Data:

“Death” (relative frequency, year: 2021)

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>MP</th>
<th>AZ</th>
<th>J&amp;J</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incidence</td>
<td>36.1%</td>
<td>36.1%</td>
<td>36.1%</td>
</tr>
<tr>
<td>Total</td>
<td>100,000 entries</td>
<td>100,000 entries</td>
<td>100,000 entries</td>
</tr>
<tr>
<td>Deaths</td>
<td>36,100</td>
<td>36,100</td>
<td>36,100</td>
</tr>
</tbody>
</table>

Example of Misinformed Data:

“Sincerely, A Concerned Citizen Completely Against Doctors Murdering People For Their Political Overlords”
Preventing Employee Hospitalizations

Employee Vaccination Status

- Vaccinated: 98.3%
- Unvaccinated (Exempt or Deferred): 1.7%

Employees Hospitalized (Current Surge)

<table>
<thead>
<tr>
<th></th>
<th>Vaccinated</th>
<th>Unvaccinated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Employees</td>
<td>26,124</td>
<td>454</td>
</tr>
<tr>
<td>Employees Hospitalized</td>
<td>8</td>
<td>6</td>
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<tr>
<td>% Employees Hospitalized</td>
<td>0.03%</td>
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</tbody>
</table>

Vaccine Effectiveness at Preventing Employee Hospitalizations: 97.73%

Unvaccinated employees are **44 times** more likely to be hospitalized.

Source: HM Employee Health, as of October 18, 2021
# Who can get a Pfizer booster?

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Self Schedule</th>
<th>CDC Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Received Pfizer more than six months ago</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>65 years and older</td>
<td>✓</td>
<td>Should</td>
</tr>
<tr>
<td>Residents in long-term care settings</td>
<td>✓</td>
<td>Should</td>
</tr>
<tr>
<td>50-64 years of age with <strong>underlying medical conditions</strong></td>
<td>✓</td>
<td>Should</td>
</tr>
<tr>
<td>18-49 years of age with <strong>underlying medical conditions</strong></td>
<td>✓</td>
<td>May</td>
</tr>
<tr>
<td>18-64 years of age who are at increased risk for COVID-19 exposure and transmission because of occupational or institutional setting</td>
<td>✓</td>
<td>May</td>
</tr>
<tr>
<td>18-64 years of age who do not meet any of the criteria above</td>
<td></td>
<td>Discuss with your physician</td>
</tr>
<tr>
<td><strong>Received Pfizer less than six months ago</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12+ years of age who are immunocompromised</td>
<td>✓</td>
<td>Should</td>
</tr>
<tr>
<td>All individuals</td>
<td></td>
<td>Discuss with your physician</td>
</tr>
<tr>
<td><strong>Received any other vaccine besides Pfizer</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All individuals</td>
<td></td>
<td>Discuss with your physician</td>
</tr>
</tbody>
</table>

**Symbol Key:**
- **✓** Yes – please schedule your booster
- **<<(icon)>>** You need a physician’s order to schedule

**Pfizer** is available at all Houston Methodist locations
Houston Methodist COVID-19 Vaccine Scheduling Options

COVID-19 Vaccine Scheduling Options

Everyone 12 and older can receive a COVID-19 vaccine in Texas. Before scheduling your appointment, please make sure you meet the criteria for each dose as described in the boxes below.

Schedule Your Pfizer COVID-19 Vaccine

1. First Dose
   You are 12 or older and this is the first time you will be receiving the Pfizer COVID-19 vaccine. Your second Pfizer dose will be scheduled during your appointment.

2. Second Dose
   You received your first dose of the Pfizer vaccine somewhere else, but would like to schedule your second Pfizer dose at Houston Methodist. You must schedule this second dose at least 3 weeks after your first dose.

3. Third Dose
   If it has been 6 months after your initial Pfizer series, anyone 65+, any long-term care resident and anyone 18-64 with underlying medical conditions or increased risk to COVID-19 exposure, including job and institutional settings, can schedule a third dose.

   In addition, immunocompromised 12+ can schedule a third dose 28 days after the second dose of the Pfizer (or Moderna) vaccine.

4. Doctor-Prescribed Dose
   This Pfizer dose has been prescribed for you outside of FDA criteria and/or timelines. You must have a physician’s order with you or in Houston Methodist’s Electronic Medical Record (EMR) to receive this Pfizer dose.

Schedule Your Vaccine
Who can get a Moderna or J&J booster?

If approved by the CDC...

- A **Moderna** booster will be available to the same approved groups as Pfizer; however, it will not be available for those who need a physician’s order until it receives full FDA approval.

- A **J&J** booster will be available to everyone 18+, two months after their initial dose.
Pfizer Vaccine Approval for Children Aged 5-11

The New York Times

Pfizer Asks F.D.A. to Authorize Its Covid-19 Vaccine for Children 5 to 11

The agency has promised to move quickly on the request and tentatively plans to meet on Oct. 26 to consider it. A decision could come soon after Halloween.

Food and Drug Administration meeting is scheduled for Oct. 26

Centers for Disease Control and Prevention is scheduled for Nov. 2 and 3
Six Rules That Will Define Our Second Pandemic Winter

1. The role of vaccines has changed (again)

Vaccines work more like dimmer switches than on/off buttons, and as their protection fades out, there are three thresholds that we care about: protection against infection, against symptoms, and against severe disease.

2. The proportion of vaccinated people matters, but who they are and how they cluster also matters

The difference between the U.K. and the U.S. isn’t just that fewer Americans are vaccinated. It’s that fewer of the most vulnerable Americans are vaccinated, and they tend to cluster together.

3. The people at greatest risk from the virus will keep changing

Relative risk will keep shifting, even if the virus somehow stops mutating and becomes a static threat.

4. As vaccination increases, a higher proportion of cases will appear in vaccinated people—and that’s what should happen

The denominators in these calculations also change, dragging the numerators higher along with them. As surges grow, so too will the number of infected people.

5. Rare events are common at scale

The assessment for both how relatively common they are and how much they cost each affected individual will change as the pandemic waxes and wanes, and as the virus itself continues to mutate.

6. There is no single “worst” version of the coronavirus

All variants will have some common weakness: they can be stopped through the combined measures of vaccines, masks, distancing, and other measures that cut the conduits they need to travel.

Get your flu shot!

GET YOURSELF AND YOUR FAMILY VACCINATED!

A yearly flu vaccine is the first and most important step in protecting against flu viruses.

#FIGHTFLU

CDC
Controlling the Pandemic

Town Hall, October 19, 2021

H. Dirk Sostman, MD FACR
Ernest Cockrell, Jr. Presidential Distinguished Chair
EVP & Chief Academic Officer
The Big Picture: Controlling Infectious Diseases

We Now Have All of These Measures Available to Fight COVID-19 and They Will Continue to Improve

Controlling Infection

Preventing Infection

Treatment

Testing

Vaccination

Control of Disease

Masks, Hand Hygiene & Other Precautions
Preventing Infection

Hand Hygiene Remains Important

But We Now Know That Airborne and Droplet Transmission Are The Dominant Modes
Masks!

Aerosols
- Within and beyond 1 meter
- Can float in air for hours
- Can be inhaled
  - <5 μm
  - 5-100 μm

Droplets
- Can travel less than 1 meter
- Fall to the ground in under 5 seconds
- Cannot be inhaled
  - >100 μm

Fomites: contaminated surfaces

Particle size (μm)

- Maximum exposure
- Minimum exposure
Studies Showing Mask Effectiveness
Brooks & Butler, JAMA March 2021

Table. Studies of the Effect of Mask Wearing on SARS-CoV-2 Infection Risk

<table>
<thead>
<tr>
<th>Source</th>
<th>Location</th>
<th>Population studied</th>
<th>Intervention</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hendrix et al</td>
<td>Hair salon in Springfield, Missouri</td>
<td>139 Patrons at a salon with 2 infected and symptomatic stylists</td>
<td>Universal mask wearing in salon (by local ordinance and company policy)</td>
<td>No COVID-19 infections among 67 patrons who were available for follow-up</td>
</tr>
<tr>
<td>Payne et al</td>
<td>USS Theodore Roosevelt, Guam</td>
<td>382 US Navy service members</td>
<td>Self-reported mask wearing</td>
<td>Mask wearing reduced risk of infection by 70% (unadjusted odds ratio, 0.30 [95% CI, 0.17-0.52])</td>
</tr>
<tr>
<td>Wang Y et al</td>
<td>Households in Beijing, China</td>
<td>124 Households of diagnosed cases comprising 335 people</td>
<td>Self-reported mask wearing by index cases or ≥1 household member prior to index case's diagnosis</td>
<td>Mask wearing reduced risk of secondary infection by 79% (adjusted odds ratio, 0.21 [95% CI, 0.06-0.79])</td>
</tr>
<tr>
<td>Doung-ngern et al</td>
<td>Bangkok, Thailand</td>
<td>839 Close contacts of 211 index cases</td>
<td>Self-reported mask wearing by contact at time of high-risk exposure to case</td>
<td>Always having used a mask reduced infection risk by 77% (adjusted odds ratio, 0.23 [95% CI, 0.09-0.60])</td>
</tr>
<tr>
<td>Gallaway et al</td>
<td>Arizona</td>
<td>State population</td>
<td>Mandatory mask wearing in public</td>
<td>Temporal association between institution of mask wearing policy and subsequent decline in new diagnoses</td>
</tr>
<tr>
<td>Rader et al</td>
<td>US</td>
<td>374 021 Persons who completed web-based surveys</td>
<td>Self-reported mask wearing in grocery stores and in the homes of family or friends</td>
<td>A 10% increase in mask wearing tripled the likelihood of stopping community transmission (adjusted odds ratio, 3.53 [95% CI, 2.03-6.43])</td>
</tr>
<tr>
<td>Wang X et al</td>
<td>Boston, Massachusetts</td>
<td>9850 Health care workers (HCWS)</td>
<td>Universal masking of HCWs and patients in the Mass General Brigham health care system</td>
<td>Estimated weekly decline in new diagnoses among HCWs of 3.4% after full implementation of the mask wearing policy</td>
</tr>
<tr>
<td>Mitze et al</td>
<td>Jena (Thuringia), Germany</td>
<td>City population aged ≥15 y</td>
<td>Mandatory mask wearing in public spaces (eg, public transport, shops)</td>
<td>Estimated daily decline in new diagnoses of 1.32% after implementation of the mask mandate</td>
</tr>
<tr>
<td>Van Dyke et al</td>
<td>Kansas</td>
<td>State population</td>
<td>Mandatory mask wearing in public</td>
<td>Estimated case rate per 100,000 persons decreased by 0.08 in counties with mask mandates but increased by 0.11 in those without</td>
</tr>
<tr>
<td>Lyu and Wehby</td>
<td>15 US states and Washington, DC</td>
<td>State populations</td>
<td>Mandatory mask wearing in public</td>
<td>Estimated overall initial daily decline in new diagnoses of 0.9% grew to 2.0% at 21 days following mandates</td>
</tr>
<tr>
<td>Karainov et al</td>
<td>Canada</td>
<td>Country population</td>
<td>Mandatory mask wearing indoors</td>
<td>Estimated weekly 25%-40% decline in new diagnoses following mask mandates</td>
</tr>
</tbody>
</table>

* See the Supplement for the complete table.
Use a Good Mask: Types That Work Best
Filtration + Fit Both Matter a Lot

N95

Surgical
ASTM Level 3
+/-
Cloth mask

KF94

KN95

Recommended Mask Info
Air Filters & Ventilation

Portable air cleaner with HEPA filter

MERV 13 or higher AC filter

https://tinyurl.com/FAQ-aerosols

Portable air cleaner with HEPA filter
Should You Take Precautions?

Common Sense Approach

• How susceptible are you?
  😊 Vaccinated?
  😱 Risk factors for severe disease?

• How prevalent is infection in the community?

• What kind of exposure will you encounter?
  😊 Vaccinated small gathering
  🎤 Restaurant
  😞 Indoors
  😊 Outdoors
  😊 Quiet (watching TV)
  🎤 Aerosol generating (choir practice)
  😊 Brief
  😞 Extended

• What’s the downside?
  😷 Infection vs. inconvenience
• As time passes, vaccines offer less immediate protection against infection
  – Related to lower levels of circulating antibodies
  – May also have other causes (vulnerable groups vaccinated first, community surges, etc.)
  – mRNA more potent initially, less durable than viral vector vaccines
• Protection against severe disease seems to be more durable
  – Likely related to cellular immunity
  – Big question: will this continue? Time will tell
• Moderna vaccine holding up better than Pfizer so far
  – Higher dose, longer interval between doses, other factors?
  – Will it continue? Probably not

Question: Is the Purpose of Vaccines Only to Reduce Severe Disease? Or Also to Reduce Infection?
Summary: What’s Happening with Vaccines?

• Vaccines remain effective against variants
  – Delta variant less sensitive to vaccines than wild type but still well covered
  – Beta variant least well covered by vaccines, but dying out worldwide

• What we know about boosters
  – They restore antibodies and protection against infection
  – Side effects from boosters same or less than primary series
  – Previous infection equivalent to one dose of vaccine (maybe better)

• Open questions about boosters
  – Role for mixed prime-boost series? (“Mix & Match”)
  – How long will renewed protection from infection last?
  – Who should get boosters and when?
Vaccine Effectiveness: Age, Delta, Infection vs. Hospitalization

Protection from Hospitalization
Protection from Infection
Infections 157% higher and severe disease 188% higher in those vaccinated 13 months vs 8 months ago. They are still very uncommon but it’s a worrisome data point.
Booster Shots

What do they do? Who needs them? How will we deliver them?
<table>
<thead>
<tr>
<th><strong>mRNA Vaccines (CDC pending for Moderna)</strong></th>
<th><strong>J&amp;J vaccine was authorized for all people 18 and older who received J&amp;J first doses at least two months ago</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>people &gt;65 years and residents in long-term care settings <strong>should</strong> receive a booster shot at least 6 months after their primary series,</td>
<td>FDA analysis:</td>
</tr>
<tr>
<td>people 50–64 years with <strong>underlying medical conditions</strong> <strong>should</strong> receive a booster shot vaccine at least 6 months after their primary series,</td>
<td></td>
</tr>
<tr>
<td>people 18–49 years with <strong>underlying medical conditions</strong> <strong>may receive</strong> a booster shot at least 6 months after their primary series, based on their individual benefits and risks, and</td>
<td></td>
</tr>
<tr>
<td>people 18–64 years with increased risk for COVID-19 exposure and transmission because of occupational or institutional setting <strong>may receive</strong> a booster shot at least 6 months after their primary series, based on their individual benefits and risks.</td>
<td></td>
</tr>
</tbody>
</table>

**FDA committee discussion really thought of the J&J vaccine as now being a two-dose vaccine** |

– had to call the second dose a booster because J&J is authorized as a one dose vaccine

**CDC Pending**

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**FDA / CDC Booster Authorization Summary**

As of October 15, 2021

**CDC ACIP committee meets October 21**
Disagreement about goal of vaccine – Prevent all disease? Or only severe disease?

Myocarditis risk with 3rd dose in young males?

Data that vaccinated front line workers are at risk?

Focusing on vaccinating the unvaccinated would have greater effect

Allowing people “at risk” from exposure would “throw the doors wide open”

How long would protection last? Repeated boosters needed?

Booster programs will overtax public health departments

If only Pfizer boosters, what do we do about Moderna / J&J recipients?

Increase inequity if only educated and wealthy could gain access to the system?

Are we messaging to the public that the vaccines don’t work?
Booster Shot In Vitro Data

COVID-19 Vaccine: 3rd Dose Strongly Boosts Neutralizing Titers Against Delta Strain

Immunogenicity After Boosting with Booster Dose of 50 µg of mRNA-1273

Post dose 3 titers vs. the Delta variant are >6-fold post dose 2 titers in 18-55 y/o & >11-fold post dose 2 titers in 65-85 y/o
Estimated potential for up to 100-fold increase in Delta neutralization post-dose three compared to pre-dose three

1. Initial data; 2. Samples were tested against each variant separately; PRNT: Plaque Reduction Neutralization Test; MT: Mix Type; GMR: Geometric Mean Ratio
Following the third dose, severe cases among vaccinated decreased sharply.

- Booster-dose to 60+ begins
- Unvaccinated (<20% of adults)
- Overall incidence declines after wide booster adoption in ages 16+
- Vaccinated 2+3 doses (>80% of adults)

Absolute rates of severe disease per 100,000 risk-days
- 12+ days following booster versus 2nd dose only.
- Based on data eligibility in age group until 9/29

Severe disease per 100,000 risk-days

Age group

Bar-on et al., [https://www.medrxiv.org/content/10.1101/2021.10.07.21264628v1.full.pdf](https://www.medrxiv.org/content/10.1101/2021.10.07.21264628v1.full.pdf)
Heterologous Prime Series ("Mix & Match")
Atmar et al, medRxiv October 13, 2021
Testing
• Currently available
  – BioFire Respiratory Pathogen Panel plus COVID-19 (RPPC) in the HMH Microbiology lab. Sample transported in from all sites.
  – Flu A/B and RSV antigens available on-site at all hospital labs and ECC’s.
  – COVID-19 PCR – on-site at all hospitals (Cepheid) and ECC’s (Roche Liat). Reagents limited and on allocation.

• In process
  – PCG Same day clinics – Cepheid waived COVID-19, Flu A/B and RSV PCR.
At Home Testing
FDA EUA as of 10/4/21

<table>
<thead>
<tr>
<th>Date EUA Issued or Last Updated</th>
<th>Entity</th>
<th>Diagnostic (Most Recent Letter of Authorization) and Date EUA Originally Issued</th>
<th>Attributes</th>
<th>Authorized Setting(s)</th>
<th>Authorization Document(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>06/24/2021</td>
<td>Boston, Dickinson and Company (BD)</td>
<td>BD Mantis Ac-Home COVID-19 Test 06/24/2021</td>
<td>Lateral Flow, Digital Read, Over the Counter (OTC) Home Testing, Serial Screening</td>
<td>Home, H, M, W</td>
<td>KCP Individuals, PI, EU (Home Test)</td>
</tr>
<tr>
<td>09/31/2021</td>
<td>Quidel Corporation</td>
<td>QuickVue At-Home OTC COVID-19 Test 09/31/2021</td>
<td>Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening</td>
<td>Home, H, M, W</td>
<td>KCP Individuals, PI, EU (Home Test)</td>
</tr>
</tbody>
</table>

Less accurate but useful because they are convenient, can be repeated often and best suited for high viral loads (transmissibility)
Outpatient Treatments

Early treatment of high risk outpatients is critical need
Data on Early mAb Therapy for COVID

• Lilly Long Term Care Prevention Study
  – 80% reduction in symptomatic infection in 299 Nursing Home residents who tested negative at study initiation
  – In 41 who tested positive at study start, 0/21 in treatment group died, 4/20 in placebo

• Regeneron Household Contacts Prevention
  – 100% prevention of symptomatic infection in people with household exposure to COVID
  – Reduction in asymptomatic infection (5.4% in mAB group versus 6.7% in placebo group)
  – Lower viral load and shorter duration of viral shedding

• Lilly Early Treatment Study (mAb “cocktail”)
  – 1,035 high risk patients with COVID
  – mAb group – 2.1% events, placebo group 7%
  – mAb group – 0 deaths, placebo – 10 deaths

• Action versus viral variants
  – Dual mAb cocktail is active against all variants
  – Recent data show sub-Q injection as effective as IV
  – Prophylaxis for immune compromised a realistic idea but not yet EUA; Regeneron starting trial
Drugs Under Active Investigation

• RNA polymerase inhibitors
  – Remdesivir (intravenous)
  – Favipiravir (oral)
  – Molnupiravir (oral)
  – AT-527 (oral)

• Protease inhibitors
  – PF-07304814 (intravenous)
  – PF-07321332 (oral)

• Combination therapy could be advantageous
Molnupiravir Clinical Trial
Press release and ISDA conference presentation

- 775 people with mild / moderate COVID
  + At least one risk factor for progression
  + Within five days of symptom onset
- Consistent efficacy across viral variants
- No safety signals
- Could be combined with other therapy
  – Protease inhibitor
  – mAb

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Treated</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospitalized</td>
<td>7.3%</td>
<td>14.1%</td>
</tr>
<tr>
<td>Death</td>
<td>0</td>
<td>2.1%</td>
</tr>
</tbody>
</table>
Delta has crushed other variants but has not yet infected every susceptible person
– therefore, lesser, endemic surges are likely
– if delta is “optimum fitness” this could be the last big surge
  • possible, but not the way to bet
– eventually COVID → common cold
  • “eventually” is a long way away

Effects of ongoing mutations – mostly uncorrelated
– increased or decreased severity of illness
– increased viral “fitness” for infection / transmission
– gradual immune escape under new selective pressure of population immunity

Sudden immune escape due to viral recombination
– requires same cells infected with different variants – rare
– crisis scenario requiring deployment of updated vaccines, mAbs, lockdowns, etc.
What Could Happen Next?

“The curve is shaped by public awareness. We’re sort of lurching between crisis and complacency.” Jennifer Nuzzo, epidemiologist

• Human behavior continues to be a “wild card” variable
  – Social behavior
  – Vaccine uptake
  – Social media misinformation / disinformation
  – Irresponsible political stunts

Facebook Takes Down Anti-Vax Hoax Network 'Primarily Conducted From Russia'
The tools to control the pandemic exist now. They will continue improving. We can stop the pandemic by using them with determination and consistency.

Control of Disease

Testing

Treatment

Vaccination

Masks, Hand Hygiene & Other Precautions
THANK YOU FOR ATTENDING OUR TOWN HALL CONVERSATION

If you’d like more information about the topics discussed today, or would like to support the COVID-19 Front-Line Heroes Appreciation Initiative, please contact us at foundation@houstonmethodist.org.

Take care and be well