Adult Down Syndrome Center
Park Ridge, IL
Introduction to DSMIG-USA

• Group of health professionals from a variety of disciplines who provide care to individuals with Down syndrome and/or their families.

• Committed to promoting the optimal health care and wellness of individuals with DS across the lifespan.

https://dsmig-usa.org
Who contributed to the position statement?

• DSMIG members experienced with COVID-19 in people with DS/IDD
Why is this statement important?

• United States statistics
  – >20 million cases
  – >350,000 deaths

• People with Down syndrome and other intellectual disabilities have been disproportionately affected by the COVID-19 pandemic compared to the general population
“Certainly, it’s not going to be a pandemic for a lot longer, because I believe the vaccines are going to turn that around. Vaccines will help us. What we’ve got to do is just hang on and continue to double down on the public health measures”

Dr. Anthony Fauci
Director of the National Institute of Allergy and Infectious Diseases
DMSIG-USA Position Statement

We recommend the COVID-19 vaccine for individuals with Down syndrome or other intellectual disabilities who do not have a specific contraindication to the vaccine.
Information about the COVID-19 vaccines

• Messenger RNA vaccines

• U.S. Food and Drug Administration (FDA) has issued Emergency Use Authorizations (EUAs) for 2 COVID-19 vaccines: Pfizer-BioNTech and Moderna
  • Studied in clinical trials and met safety and effectiveness requirements.
COVID-19 vaccine trials by the numbers
As of November 30, 2020

Pfizer/BioNTech
- 43,931 enrolled
- 150 clinical sites
  - 39 U.S. states
- Racial/ethnic distribution
  - 13% - Hispanic
  - 10% - African American
  - 6% - Asian
  - 1% - Native American
- 45% ages 56-85

Modern
- 30,000 enrolled
- 89 clinical sites
  - 32 U.S. states
- Racial/ethnic distribution
  - 63% - White
  - 20% - Hispanic
  - 10% - African American/Black
  - 4% - Asian
  - 3% - All others
- 64% ages 45 and older
  - 39% ages 45-64
  - 25% ages 65+

Sources: [https://www.pfizer.com/science/coronavirus/vaccine](https://www.pfizer.com/science/coronavirus/vaccine); [https://www.modernatx.com/cove-study](https://www.modernatx.com/cove-study)
For more information, visit [www.clinicaltrials.gov](http://www.clinicaltrials.gov)
mRNA vaccines

• Cause human cells to make a harmless piece of the “spike protein” of the COVID-19 virus
• Immune system develops immunity against the protein
• Do NOT contain a live virus
• Do NOT affect or interact with a person’s DNA
Who was **not** included in the studies?

- People with Down syndrome or other intellectual disabilities
  - People with DS/IDD are not usually included in studies of vaccines, medications, or supplements
- Children
  - Pfizer-BioNTech vaccine for 16 years and older
  - Moderna vaccine for ages 18 years and older
# Pfizer-BioNTech vs. Moderna

<table>
<thead>
<tr>
<th></th>
<th>Pfizer – BioNTech</th>
<th>Moderna</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type of vaccine</td>
<td>mRNA</td>
<td>mRNA</td>
</tr>
<tr>
<td>EUA date</td>
<td>12/11/2020</td>
<td>12/18/2020</td>
</tr>
<tr>
<td># of shots</td>
<td>2 shots, 21 days apart</td>
<td>2 shots, 28 days apart</td>
</tr>
<tr>
<td>Age</td>
<td>16 +</td>
<td>18 +</td>
</tr>
<tr>
<td>Storage</td>
<td>Can be stored in refrigerator for 5 days</td>
<td>Can be stored in refrigerator for 30 days</td>
</tr>
<tr>
<td>Effectiveness</td>
<td>95%</td>
<td>94.1%</td>
</tr>
</tbody>
</table>
Potential side effects

• In the arm where you got the shot:
  – Pain/soreness
  – Swelling
  – Redness

• Throughout the rest of your body:
  – Chills
  – Tiredness
  – Headache
  – Muscle aches
  – Fever

Similar to other vaccines; normal signs that your body is building protection
Are there people who should not get the vaccine?

• Severe allergic reaction (anaphylaxis) in response to the first dose of the COVID-19 vaccine.

• If a person had a severe allergic reaction (anaphylaxis) to a previous different injectable therapy (medication or vaccine), consider potential deferral of vaccination.
Immune system and COVID-19 vaccine

- People with immunocompromised conditions
- Autoimmunity and Interferon
- Guillain-Barre syndrome (GBS)
Summary

- Lack of data in people with DS/IDD
- Well-studied in general population
- The disproportionate effect of the pandemic on DS/IDD
- Experience with previous vaccines
Studies to date indicate the vaccine is a safe path to reduce symptomatic COVID-19 with the potential to save lives and aid in a more rapid return to the many aspects of our lives that have been altered.
DMSIG-USA Position Statement

We recommend the COVID-19 vaccine for individuals with Down syndrome or other intellectual disabilities who do not have a specific contraindication to the vaccine.
References

- https://www.medrxiv.org/content/10.1101/2020.11.03.20225359v1
- https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained
Additional slides
### Ingredients* included in mRNA COVID-19 vaccines

<table>
<thead>
<tr>
<th>Description</th>
<th>Pfizer-BioNTech</th>
<th>Moderna</th>
</tr>
</thead>
<tbody>
<tr>
<td>mRNA</td>
<td>Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2</td>
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<tr>
<td>Lipids</td>
<td>2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide</td>
<td>Polyethylene glycol (PEG) 2000 dimyristoyl glycerol (DMG)</td>
</tr>
<tr>
<td></td>
<td>1,2-distearoyl-sn-glycero-3-phosphocholine</td>
<td>1,2-distearoyl-sn-glycero-3-phosphocholine</td>
</tr>
<tr>
<td></td>
<td>Cholesterol</td>
<td>Cholesterol</td>
</tr>
<tr>
<td></td>
<td>(4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate)</td>
<td>SM-102</td>
</tr>
<tr>
<td>Salts, sugars, buffers</td>
<td>Potassium chloride</td>
<td>Tromethamine</td>
</tr>
<tr>
<td></td>
<td>Monobasic potassium phosphate</td>
<td>Tromethamine hydrochloride</td>
</tr>
<tr>
<td></td>
<td>Sodium chloride</td>
<td>Acetic acid</td>
</tr>
<tr>
<td></td>
<td>Dibasic sodium phosphate dihydrate</td>
<td>Sodium acetate</td>
</tr>
<tr>
<td></td>
<td>Sucrose</td>
<td>sucrose</td>
</tr>
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</table>

*As reported in the prescribing information*
Vaccine distribution

• Federal government oversees centralized system to order, distribute, and track COVID-19 vaccines.

• The CDC worked with state and local governments to develop COVID-19 vaccination plans for their areas.
What if I have had COVID?

• CDC recommendation is to get the vaccine after illness has resolved and you no longer need to isolate.

• Delay 90 days?
  – Current evidence suggests that it is uncommon to become reinfected with the COVID-19 vaccine during the 90 days after initial infection.
Why do I still need to wear a mask and practice physical distancing?

- Vaccine is a 2-dose series, takes 1-2 weeks following the 2\textsuperscript{nd} dose to be considered fully vaccinated
- Not clear if vaccine prevents transmission
- How long immunity lasts
- Herd immunity
Will I test positive for COVID after I get the vaccine?

• Cannot get COVID-19 from the vaccine
• Receiving the COVID-19 vaccine will not affect results of viral tests (e.g. nose swabs)
• May test positive on some antibody tests