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Down Syndrome Medical Interest Group-USA

Intellectual and Developmental Disability COVID-19 Vaccination Position Statement

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Our world has been extensively changed by the COVID-19 pandemic. This virus has altered many aspects of our daily lives and impacted our physical, mental, and social well-being. It has caused a great deal of illness and death. Over 580,000 people in the United States and over 3.3 million people worldwide have died from COVID-19. Sadly, people with Down syndrome and other intellectual disabilities have been disproportionally affected by the COVID-19 pandemic compared to the general population (1,2).

For months, it seemed like there was no end in sight. Fortunately, COVID-19 vaccines are now becoming available, and we are rapidly moving in a positive direction. COVID-19 vaccines developed by Pfizer-BioNTech, Moderna, and Johnson and Johnson received Emergency Use Authorizations from the U.S. Food and Drug Administration (FDA). Dr. Anthony Fauci, director of the National Institute of Allergy and Infectious Diseases, stated, "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" (3).

Like Dr. Fauci, we are hopeful that the vaccine will be a major contributor to the end of the pandemic. However, some have expressed concern about whether the vaccine is safe for people with Down syndrome or other intellectual disabilities.

At this time, 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 (as described below).

Our recommendation is consistent with national and local guidelines for receiving the COVID-19 vaccine. This document contains additional information supporting our recommendation as well as answers to questions we have received. If individuals with Down syndrome or another intellectual disability have concerns about the vaccine, we recommend discussing their concerns with their health care provider.

Are people with Down syndrome and other intellectual disabilities more at risk for severe illness and death from COVID-19 infection?

- People with intellectual disabilities have been disproportionally affected by the COVID-19 pandemic in terms of the impact on their daily lives, the reduction in their support systems, and the serious illness from COVID-19 infection (1,2).
- The Centers for Disease Control added Down syndrome to their list of medical conditions that put adults at increased risk for severe illness from COVID-19 (4).
- People with Down syndrome also have a higher rate of some of the other medical conditions that increase the risk for severe illness from COVID-19. The risk factors include:

    - chronic cardiac disease
    - chronic pulmonary disease
    - chronic kidney disease
    - obesity
- An international survey found that people with Down syndrome older than 40 years of age were 2.9 times more likely to die from COVID-19 compared to those of the same age in the general population (2).
- Children with and without DS do not commonly get severely sick from COVID-19 and risk seems to be related to additional underlying medical conditions. The survey referenced above found that people with Down syndrome younger than 40 years of age were 2.4 times more likely to die from COVID-19; however, this increased risk was accounted for by other risk factors.

Information about the COVID-19 vaccines

- The Pfizer- BioNTech and Moderna COVID-19 vaccines are messenger RNA vaccines. This type of vaccine causes human cells to make a harmless piece of the "spike protein" of the COVID-19 virus. The immune system then develops immunity against the protein (5). These two vaccines are given in a 2-shot series. The Johnson and Johnson COVID-19 vaccine is DNA based (versus RNA for the other two) and is carried by a non-infectious adenovirus as the way to inject it into the body. This vaccine requires only one injection.
- As stated above, the vaccines are available because the FDA issued Emergency Use Authorizations (EUAs). In the event of a public health emergency, such as the COVID-19 pandemic, the FDA can issue EUAs to allow use of medical products before they are fully approved (6). The COVID-19 vaccines were studied in clinical trials and met safety and effectiveness requirements before receiving EUAs.

Who was included in studies of the COVID-19 vaccine?

- Tens of thousands of people have participated in the studies of the COVID-19 vaccine. These are well-studied vaccines. Children are also now included in the studies.
- The reports of the vaccine studies do not indicate people with Down syndrome or other intellectual disabilities were included in the study population.
- People with Down syndrome and other intellectual disabilities are not usually included in studies of vaccines, medications, or supplements before they are released/distributed. Therefore, from this standpoint, this is not different than the usual approval process.
- Occasionally a vaccine or medication will be tested specifically in people with Down syndrome or another intellectual disability post-market (after it has been released for general use). We are aware that this type of study has now been initiated for people with Down syndrome for COVID-19 vaccines.
- The vaccines are now being studied in children. At this time, the Pfizer-BioNTech vaccine is recommended for people ages 12 years and older, the Moderna vaccine is recommended for adults ages 18 years and older, and the Johnson and Johnson vaccine is recommended for adults ages 18 years and older.

Are there people who shouldn't get the vaccine?

- There is some concern about the vaccine for people who have severe allergic reactions.
- If the allergy is severe, such as anaphylaxis (which includes difficulty breathing, reduced blood pressure, and other symptoms) in response to the first dose of the COVID-19 vaccine (Pfizer-BioNTech and Moderna), the second dose is not recommended.

- If the person has a history of severe allergic reaction, including anaphylaxis, to components of the vaccine, the vaccine is not recommended. For example, CDC highlighted polyethylene glycol, which is often used in laxatives.
- If a person had a severe allergic reaction (anaphylaxis) to a previous different injectable therapy (medication or vaccine), caution is recommended. The CDC does not specifically recommend against the vaccine in that situation but recommends discussing "potential deferral of vaccination" with the individual's health care provider.
    - For people receiving the injection, the CDC recommends observation for 15-30 minutes after the injection. In those with concerns regarding allergies, a 30-minute observation period is recommended.

What about people with immunocompromising conditions (reduced immunity)?

Recommendation is to proceed with the vaccine.

What about the effect on the immune system (including interferon)?

- Some individuals have expressed a concern that the vaccine will trigger an increase in interferon or autoimmunity in people with Down syndrome.
    - Autoimmunity is a term to describe when a person's immune system attacks one's own body.
    - Interferon is part of the immune system and the level of interferon activity tends to be higher in people with Down syndrome.
- There are no reports of increased autoimmunity from the COVID-19 vaccines (although follow-up was on average only two months in the studies). This has also not been demonstrated in post-release side effect monitoring.
- No information has been provided from the study of these vaccines about the impact (or lack of impact) of the COVID-19 vaccine on the level or function of interferon. It does not appear to have been studied.
- All vaccines trigger the immune system and increased autoimmunity has not been reported in people with Down syndrome with other vaccines. However, we note that messenger RNA vaccines are a newer type of vaccine and we do not have evidence that experience with previous vaccines will remain the same for the COVID-19 m-RNA vaccines.
- Concern has been voiced about whether those with Guillain-Barre syndrome (GBS) should receive the vaccine. GBS is an autoimmune condition in which the immune system attacks nerves. GBS has not been reported as a side effect of the COVID-19 vaccines. The GBS | CIDP Foundation International released this statement:

  "To date, no cases of GBS have been associated with the COVID vaccines. However, the number of subjects in the clinical trials is too small to detect such a rare event, if it existed, and surveillance is ongoing. In the meantime, we would urge all to follow national and local guidelines about who should get the vaccine. At this time, there is no reason that those who had GBS in the past cannot get the current COVID vaccines. If they have concerns, they should speak to their local health care professionals" (7).

Summary

- We agree with the CDC recommendations that the COVID-19 vaccines are appropriate and recommended for most people. The vaccine may not be appropriate for people with severe allergies.

- People with Down syndrome, particularly those over 40 years of age and people less than 40 years of age with risk factors, are more susceptible to complications from COVID-19 infection.
- These vaccines specifically and messenger RNA vaccines in general have not been studied in people with Down syndrome or other intellectual disabilities. This is often the case for other vaccines, medications, and supplements.
- Since there is a lack of data regarding the benefits and risks of the COVID-19 vaccines for people with Down syndrome and other intellectual disabilities, this recommendation is based on the results of vaccine testing for people without Down syndrome or another intellectual disability. The disproportionate effect of the pandemic on this population was also considered.
- Previous vaccines that also trigger the immune system (albeit with different technology) have not had significantly different side effects for people with Down syndrome or other intellectual disabilities.
- Studies indicate the vaccine is a safe path to reduce symptomatic COVID-19, save lives, and aid in a more rapid return to the many aspects of our lives that have been altered.

Conclusion

After considering the risks as well as other factors, including the effect of the pandemic on people with Down syndrome and other intellectual disabilities, and the safety of the vaccines in the general population, 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 (such as allergies as noted above).

1. https://www.nih.gov/news-events/news-releases/people-intellectual-developmental- disabilities-disproportionately-affected-covid-19
2. https://www.medrxiv.org/content/10.1101/2020.11.03.20225359v1
3. https://www.bloomberg.com/news/articles/2020-11-12/covid-won-t-be-pandemic-for-long-thanks-to-vaccines-fauci-says
4. https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html
5. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/mrna.html
6. https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained
7. https://www.prnewswire.com/news-releases/guillain-barre-experts-clarify-covid-19-vaccine-confusion-with-open-letter-to-dr-as-fauci-301197070.html

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