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 760,000 people in the United States and over 5.1 million people worldwide have died from COVID-19. Sadly, people with Down syndrome and other intellectual disabilities have been disproportionately affected by the COVID-19 pandemic compared to the general population (1,2,3).

At the present time, the following vaccines are available in the United States:

- **Pfizer-BioNTech (Comirnaty):**
  - FDA approved for people 16 years and older
  - Emergency use authorization for children 5-11 years and 12-15 years
  - Booster shots available for those 18 years and older 6 months after 2nd dose

- **Moderna:**
  - Emergency use authorization for people 18 years and older
  - Booster shots available for those 18 years and older 6 months after 2nd dose

- **Janssen Johnson and Johnson:**
  - Emergency use authorization for people 18 years and older
  - Booster shots available for those 18 years and older 2 months after 1st dose

At this time, we recommend the COVID-19 vaccine and booster shots for all children and adults with Down syndrome or other intellectual disabilities who are eligible 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 disproportionately 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 (1,2,3).
- 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 Down syndrome do not commonly get severely sick from COVID-19 and risk seems to be related to additional underlying medical conditions. An international survey found that pediatric patients < 18 years of age who were hospitalized with COVID-19 and who had Down syndrome had higher incidence of pneumonia, acute respiratory distress syndrome, and acute renal failure than those without Down syndrome. Older age (teenagers), obesity, and epilepsy were risk factors for hospitalization with COVID-19 among children with Down syndrome. Older age and thyroid disorder were risk factors for acute respiratory distress syndrome (3).

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, and a booster dose is available and recommended. 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 is one injection, and a booster dose is available and recommended.

• 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. The Pfizer (Comirnaty) vaccine is now fully FDA approved for individuals 16 years and above (8).

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 have also been 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 5 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.

• New unpublished data from the T21 Research Society’s ongoing survey of COVID-19 vaccinations in about 2000 people with Down syndrome showed that the COVID-19 vaccinations in children ages 12-17 years and adults (ages 18 and older) with Down syndrome were both safe and effective. Results showed that the majority of people who received the vaccine had either no adverse reactions or only mild symptoms such as pain or redness at the injection site or tiredness, similar to the those in general population. The survey also showed that vaccines helped to protect against severe COVID-19 illness (9).

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 rapid onset of difficulty breathing, reduced blood pressure, face or tongue swelling and/or other serious side effects) in response to the
first dose of the COVID-19 vaccine (Pfizer- BioNTech and Moderna), the second dose is not recommended. (Some people with Down syndrome have developed mild dizziness that was not of rapid onset that may have been due to insufficient fluid intake. This is typically not a reason to avoid the second dose).

- 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 of nearly a year.
  - 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 these statements:

  “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”

  “At present, despite many millions of vaccinations in countries with extensive vaccination programmes such as the UK and the USA, no link has been identified. The risk of death or long term complications from COVID in adults still far exceeds the risk of any possible risk of GBS by several orders of magnitude.”

COVID19 vaccines are different from flu vaccines. We are not seeing evidence that COVID19 vaccines are more likely to cause GBS, even in individuals who have had GBS brought on by other vaccines. Therefore, we do not see prior GBS as a reason not to get a COVID19 vaccine.” (9,10).
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.
- Children and adults 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 large populations of people with Down syndrome or other intellectual disabilities. This is often the case for other vaccines, medications, and supplements. However, based on data from an international study, the vaccine appears to be safe and effective.
- Previous vaccines that also trigger the immune system (albeit with different technology than the messenger RNA COVID-19 vaccines) 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 children and adults with Down syndrome and other intellectual disabilities, and the safety of the vaccines in the general population, and data available to date for people with Down syndrome, 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).

References

6. https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained