Our world has been inextricably 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 300,000 people in the United States and 1.6 million people worldwide have died from COVID-19. Sadly, many people with Down syndrome and other intellectual disabilities have been hit even harder by COVID-19 than the general population.

For months, it seemed like there was no end in sight but now we are moving rapidly in a positive direction: COVID-19 vaccines are becoming available. A COVID-19 vaccine developed by Pfizer-BioNTech received an Emergency Use Authorization from the FDA, and a second vaccine will soon be reviewed. 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.” (1).

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 a person with Down syndrome or other intellectual disability. The COVID-19 vaccine is recommended for most people, including people with Down syndrome or another intellectual disability.

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. This is a well-studied vaccine.

However, for this vaccine, like other vaccines and medications, it does not appear that people with Down syndrome or other intellectual disabilities were included in the study population. There was no report in the information released that any of the participants had Down syndrome or an intellectual disability. 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) but most are never systematically tested in people with Down syndrome or another intellectual disability before they are released for general distribution.

The vaccine was not studied in children and at this time, it is not recommended for any children less than 16 years of age.

Are there people who shouldn’t get the vaccine?
There is some concern about those with severe allergies. If the allergy is severe such as anaphylaxis (which includes difficulty breathing, reduced blood pressure, dizziness, and other symptoms) in response to the first dose, the second dose is not recommended. 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. If the injection is given, the CDC recommends observation for 30 minutes after the injection.

**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?**
One of the concerns regarding the vaccine is that it is a messenger RNA vaccine which is a new form of vaccine. 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. No information has been provided from this study 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. There are no reports of increased autoimmunity (although follow-up was on average only two months).

All vaccines trigger the immune system and increased autoimmunity has not been reported in people with Down syndrome with other vaccines. In addition, one of the concerns regarding getting an infection due to COVID-19 is the activation of the immune system causing serious systemic medical complications. The potential risk of developing COVID-19 infection and one of these known serious complications of the disease should be weighed against the theoretical risk of the immune system being negatively triggered by the vaccine.

Although Guillain-Barre syndrome was not reported to have occurred in any of the participants in the Pfizer-BioNTech study, some have expressed concern. Guillain-Barre syndrome, a condition in which the immune system attacks the nervous system has been rarely linked to other vaccines. However, no reports were found that reported this complication in people with Down syndrome in connection to receiving any vaccine. For those with a history of Guillain-Barre, the COVID-19 vaccine may not be appropriate but there isn't adequate information to give a firm recommendation.

As noted above, the COVID-19 vaccine is recommended for most people, including people with Down syndrome or another intellectual disability. The vaccine may not be appropriate for people with severe allergies or a history of Guillain-Barre syndrome. The vaccine is a safe path to which we can reduce symptomatic COVID-19, save lives, and return more rapidly to the many aspects of our lives that have been altered.