



Coronavirus (COVID-19) Vaccine recommendations March 18, 2021

The Coronavirus (COVID-19) pandemic continues to pose a significant risk to the population worldwide with new variants of SARS-CoV-2 virus are emerging. There has also been reports on non-genetic heterotopic ossification developing in NON-FOP patients with COVID-19 infections. The ICC recommends that people living with FOP to continue to follow strict precautionary measures to **prevent infection from SARS-CoV-2, the virus that causes the COVID-19 illness**. The ICC is providing this update to the prior statement in Dec 2020. This document focuses on COVID-19 vaccination recommendations.

The recommendations are changing rapidly, are country specific and based on COVID-19 vaccine availability:

- **New!** At this time, ICC is **unable to recommend for or against** the COVID vaccine for patients with FOP.
- **New!** The decision to take a vaccine is a **personal one** and based on the balance of risks and benefits, and this should be discussed with your medical team.
- **New!** Most common side effects of the vaccine in non-FOP patients has been fever, chills, muscle aches and pains, and fatigue. There are rare reports of other side effects such as allergic reactions or anaphylaxis. However, there are quite a number of people that tolerate the vaccines well too.
- **New!** For patients with FOP, the major consideration is the risk of intramuscular (IM) injection and flare ups. **The ICC currently does not recommend subcutaneous COVID19 vaccination** because there is no data for safety or efficacy using this route. IM injection of some vaccines (non-COVID) has been associated with an increased risk of FOP flare activity and heterotopic bone. For example, the DPT vaccine is associated with HO in 27% of FOP children (Lanchoney et al., 1995). The specific mechanisms and incidence are still unknown.
- **New!** Because very little is known about COVID in patients with FOP, please consider being part of the observational clinical study for patients who have been exposed or diagnosed with COVID, or who are considering the COVID vaccine. This study is led by Dr Edward Hsiao at UCSF. Please contact him at edward.hsiao@ucsf.edu if you are interested in learning more.

New! If you decide to take the COVID vaccine, we recommend

- **Discuss your plans with your doctor.** Review any potential allergies or prior reactions like anaphylaxis that you should consider before taking the vaccine.
- **Take the vaccine via the recommended route and dose** (ie **intramuscular** for the currently available vaccines). Safety and efficacy of taking an IM vaccine through the subcutaneous route is not known, and could cause a more exaggerated inflammatory response and is currently not recommended.
- If possible, take the vaccine in a **location that is already fused**, as the vaccines all appear to induce some local site reaction (arm pain and swelling). For example, if your left hip or right shoulder are fused, you should use the muscle around those sites.
- You should be **flare free for at least 2 weeks** prior to receiving the vaccine.
- Have the injection done by an experienced nurse or physician or pharmacist.
- Use the **shortest needle available** (this varies with site). The clinician should be aware that patients with FOP may have hidden HO and thinned muscle at the site of the injection. Avoid injecting directly next to existing HO bone if possible.
- Prior to the vaccination, **have ibuprofen or acetaminophen available**. Also, have a course of prednisone for flares available.
- Make sure your physician is familiar with the ICC Treatment guidelines, specifically on vaccinations and flare management. [Guidelines - International Clinical Council \(ICC\) on Fibrodysplasia Ossificans Progressiva \(FOP\) \(iccfop.org\)](https://www.iccfop.org). Notify your physician you plan to do the vaccine, and when.
- On the day of the injection:
 - Your local team may not allow you to take ibuprofen or acetaminophen prior to the injection (this is because they may screen for COVID symptoms first).
 - After you receive your injection, there may be a brief observation period.
 - After that is completed, take ibuprofen (2 to 3 times/day) or acetaminophen (2-3 times/day) following the label instructions, for the next 48 hrs, regardless of your symptoms.
 - Rest and stay hydrated.
 - In the event of a flare, contact your physician for guidance. You may need to do a short course of prednisone, but this needs to be balanced with the immunosuppressive effects of steroids. The usual flare dosing is prednisone 2 mg/kg/day up to 100 mg, for 4 days; your physician may recommend starting at a lower dose, depending on your symptoms.
 - Even if you take the vaccine, you still need to continue physical distancing, wearing masks, and appropriate hand washing
- **The ICC can't guarantee that these steps will "work" to prevent complications. All medications and treatments have risk, so it is important to discuss your specific situation with your doctor as you decide whether to take the vaccine or not.**
- Make sure that you complete the full immunization regimen recommended (ie do both doses if the vaccine recommends 2 doses)
- Discuss with your physician if you should do a booster if that is needed, such as to cover local variants. This is an area of active investigation so will need to be updated.

New! How does the development of a vaccine change things?

- Recent developments of a vaccine provide long term hope. However, the impact of the vaccine on the pandemic will take quite some time to manifest. Many types of vaccines are being tested and new variants of SARS-CoV-2 virus are emerging and so this is a rapidly changing field.
- **Vaccines to date are not approved in children or with subcutaneous delivery.** This is actively being studied, and will be added to the guidelines once available.
- The duration of immunity conferred by the vaccines is unknown
- At this time, the ICC does **not recommend vaccination for children** due to the lack of safety and efficacy data.
- At this time, **ICC can not recommend for or against vaccination in FOP adults.** The specific risks and benefits should be discussed with your physician.
- The ICC recommends that **FOP family members and caregivers get vaccinated for COVID-19** if safely available for them.
- Vaccinations can take 2+ weeks to show any efficacy, so there is no protection immediately after vaccination. In addition, vaccines do not confer absolute immunity to the SARS-CoV-2 virus, and may not have activity against all forms of the SARS-CoV-2 virus. **Anyone who receives a vaccine should still continue with masking, hand hygiene, and physical distancing.**
- This information is rapidly evolving. Please discuss with your local care providers regarding benefits and risk of any locally approved vaccines.
- It's very important to maintain social distancing and wearing a mask when around members outside your household
- Additional updates will be shared as new information becomes available.