NATIONAL HEMOPHILIA FOUNDATION
for all bleeding disorders

MASAC Document #278
(Replaces Document #221)

MASAC RECOMMENDATIONS ON ADMINISTRATION OF VACCINES TO INDIVIDUALS WITH BLEEDING DISORDERS

The following recommendation was approved by the Medical and Scientific Advisory Council (MASAC) on April 21, 2023, and endorsed by the NHF Board of Directors on May 2, 2023.

There has been considerable discussion in the hemophilia community regarding the optimal protocol for the administration of vaccines to individuals with bleeding disorders. Speculation that vaccines may induce the development of inhibitors to factor concentrates are not substantiated[1]. The MASAC Vaccine Working Group has reviewed the available literature, online and in print, and has developed the following recommendations.

1. **Centers for Disease Control and Prevention (CDC) Guidelines**
   It is highly recommended (See MASAC Recommendation #218, page 5, Section G.1 and G.2)[1] that patients with bleeding disorders continue to follow the American Academy of Pediatrics' and CDC's vaccine recommendation route and schedule for their age. These recommendations can be found on the CDC website as follows:
   A. Infant Schedule Age (0-6yrs):
      http://www.cdc.gov/vaccines/parents/downloads/parent-ver-sch-0-6yrs.pdf
   B. Child Schedule Age (7-18 yrs):
      http://www.cdc.gov/vaccines/who/teens/downloads/parent-version-schedule-7-18yrs.pdf
   C. Adult Schedule Age (19 yrs and older):
      http://www.cdc.gov/vaccines/schedules/downloads/adult/adult-schedule-easy-read.pdf
      http://www.cdc.gov/vaccines/schedules/downloads/adult/adult-schedule-easy-read-bw.pdf
   D. Travel Recommendations:
      http://wwwnc.cdc.gov/travel/page/vaccinations.htm
   E. Special Groups:
      http://www.cdc.gov/vaccines/spec-grps/default.htm

2. **Protocol for Administration of Vaccines**
   MASAC recommends that when giving immunizations, the following procedures may be considered:
   A. A fine-gauge needle (23 gauge or smaller caliber) be used.[2]
   B. Firm pressure should be applied to the site for at least 2 minutes without rubbing.[2]
   C. The patient and/or caregiver should be informed that there is risk of hematoma development at the injection site.[2] Patients with hemophilia depending on their factor

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level, may consider use of therapy to prevent hematoma formation, in consultation with their hemophilia treatment center.

D. Anticipatory guidance should be given regarding when to call the physician or HTC regarding any adverse reactions such as hematoma, fever, warmth, redness.[2]
E. For pain/fever relief [2], avoid aspirin and NSAIDS (such as ibuprofen, naproxen sodium) because of the potential risk of bleeding. Acetaminophen is a safe alternative, but should be used with caution, especially in individuals at risk for liver disease.
F. If the patient is receiving prophylaxis treatment for hemophilia, vaccination may be administered within 24 hours of Standard or Extended half-life FVIII or Standard half-life FIX concentrate and within 48 hours of administration of Extended half-life FIX concentrate, to decrease the risk of developing a hematoma.[3-4] For patients with a basal FVIII or FIX level above 10%, no hemostatic precautions may be required.[5]
a. Patients on Emicizumab prophylaxis may not require additional treatment prior to vaccinations.[3-5]
G. Patients with Type 1 or 2 Willebrand disease (VWD), depending on their baseline von Willebrand factor (VWF) activity levels, may consider use of therapy to prevent hematoma formation, in consultation with their hemophilia treatment center. Patients with Type 3 VWD should consider a VWF-containing infusion prior to vaccination.[5]
H. All rare bleeding disorder patients (including those with thrombocytopenia and/or platelet function disorders) should be vaccinated with the above general precautions.
I. Patients on Vitamin K antagonists should have prothrombin time testing performed within 72 hours prior to injection to determine international normalized ratio (INR); if results are stable and within the therapeutic range, they can be vaccinated intramuscularly. No data are available in patients on DOACs/NOACs.[6]

3. Vaccines that can be given subcutaneously

There is considerable variation regarding vaccine route of administration (IM vs SQ) among HTC providers (reference CDC data). Many vaccines have not undergone rigorous investigation to demonstrate that SQ administration is as effective as IM administration. Whether or not the potential reduction in intramuscular hematomas from SQ administration outweighs any potential reduction in vaccine efficacy is not known. The vaccines (single vaccines, not in combination with other vaccines) that have been tested and demonstrated to be effective when administered either IM or SQ include:

A. Pneumococcal polysaccharide (PPSV)[7]
B. Polio, inactivated (IPV)[7]
C. Hepatitis A[8]
D. Hepatitis B[9-11]

4. The safety, efficacy, and optimal protocols for administration of other existing, and existing and emerging vaccines will be evaluated by MASAC on an ongoing basis.

5. Live vaccines should not be administered in patients receiving high dose steroid or immune-modulating drugs as a part of immune tolerance therapies or gene therapy protocols.[12]

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