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Information from the American College of Rheumatology Regarding Vaccination Against SARS-CoV-2

Background

As of this writing, more than 165 vaccines against SARS-CoV-2 are under development worldwide with dozens already in human trials. One pharmaceutical company has announced its intention to produce 100 million doses before the end of 2020. It is likely that numerous vaccines will eventually be approved by the FDA for use in the US, but limited supplies in the early stages may lead to the need for strategies to allocate these finite resources.

This document will address vaccine development, allocation and patient education.

Support for vaccine development and testing

The American College of Rheumatology (ACR) supports rigorous testing of efficacy and safety of all vaccines prior to their approval and widespread use in the US via pathways established by the FDA. The ACR appreciates and supports guidance published by the FDA to assist sponsors in the development and licensure of vaccines against SARS-CoV-2. Inappropriately rushed release of unsafe or ineffective vaccines and/or a lack of transparency will only jeopardize public confidence, exacerbate skepticism about vaccines, reduce the uptake of vaccines against SARS-CoV-2, and hinder this and future vaccination efforts.

In particular, the ACR agrees that early-phase studies to assess safety and immunogenicity should enroll smaller numbers of healthy adults, whereas late-phase clinical trials must be of adequate size and represent diverse populations to ensure safety and efficacy. It will be particularly important to evaluate vaccine safety and efficacy in patient populations at elevated risk of contracting SARS-CoV-2 and complications related to COVID-19. Therefore, vaccine trials should include racial and ethnic minorities, elderly individuals, and those with medical comorbidities that increase the risk of severe COVID-19. Vaccine trials should also include rheumatology patients, a population of patients who routinely take medicines that blunt vaccine responses. In addition to monitoring subjects for adverse events in the days immediately following vaccination, vaccine evaluation must accommodate long-term pharmacovigilance to monitor for delayed adverse events.

Considerations for vaccine allocation

Approval of the first SARS-CoV-2 vaccine(s) in the US will likely take place before enough doses have been manufactured to vaccinate all vaccine candidates in the US.

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Therefore, the ACR supports the development of a fully transparent, apolitical process to allocate early vaccine supplies based on scientific analyses of the risks and benefits of early vaccination in specific populations. Initial vaccination allocation should prioritize populations at high risk of exposure (e.g., healthcare and other frontline workers) as well as populations at risk of severe disease, including elderly patients, and those with comorbidities which increase the risk of severe COVID-19. While data assessing the risk of severe COVID-19 in rheumatology patients are limited, the Global Rheumatology Alliance has published a case series of rheumatology patients with COVID-19 indicating that the use of prednisone at 10 mg per day or higher may be associated with an elevated risk of hospitalization. Such patients should be considered for priority vaccination against SARS-CoV-2. As additional data become available regarding outcomes of COVID-19 in rheumatology patients, further allocation recommendations may be appropriate.

How to talk to patients about a SARS-CoV-2 vaccine

The risk of COVID-19 vs. the risk of a vaccine

Comprehensive safety checks are required as part of the process leading to FDA approval of a new vaccine. As with all vaccines that have passed rigorous testing and licensure procedures, the benefits of vaccination (preventing or reducing the severity of infection) are expected to far outweigh any risk from the vaccine. For some individuals, live-attenuated (weakened) vaccines could be an exception. In general, patients taking immunosuppressive medicines, especially chronic prednisone at 10 mg/d or higher, and possibly patients taking biologics, should avoid live-attenuated vaccines until and unless those vaccines have been demonstrated to be safe in those populations. Otherwise, we anticipate recommending all patients, including rheumatology patients, receive an approved COVID-19 vaccine.

Partial vs. absolute protection

Most vaccines offer incomplete protection against infection and this is likely to be the case with SARS-CoV-2 vaccines as well. However, even partial protection will be of benefit both to patients and the general public. Partial protection may mean that most but not all persons develop immunity, or that some recipients develop weak immunity that makes the consequences of infection less severe than they would have been otherwise.

Durability of protection

Seroconversion (development of antibodies) following natural infection with SARS-CoV-2 takes place between 5-14d after onset of symptoms. Antibody titers appear to correlate with clinical severity but their appearance does not clearly correlate with an abrupt decline in viral load. Also, in some cases, IgM/IgG antibody levels decline rapidly. There is wide variability in the quality of commercially available kits used to

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measure antibody responses against SARS-CoV-2. Thus, it remains unclear how long protection against re-infection lasts following natural infection with SARS-CoV-2. The same questions apply to durability of protection against SARS-CoV-2 following vaccination. All individuals (including rheumatology patients and staff members engaged in their care) receiving vaccines against SARS-CoV-2, or recovering from COVID-19 infection, should be counseled that the durability of protection remains to be determined, and that prior infection and measurable IgM and IgG antibody responses may not confer reliable or durable protection from reinfection.

Herd immunity

When a large portion (estimated to necessarily be as high as ~70% in the case of SARS-CoV-2) of the individuals in a population are immune to a virus, it becomes difficult for that virus to spread within that population. This phenomenon, known as herd immunity, helps protect individuals who are not immunized, even though they are not immune. This is especially important to members of a population who are poor candidates for vaccines, and to patients who are at risk of severe disease should they contract the virus. Therefore, we highly encourage all employees of rheumatology practices to receive vaccination for the protection of their patients. Some providers and organizations may consider vaccination of employees, and/or other measures to mitigate viral spread, a requirement for (continued) employment.

9 Sept 2020