National Psoriasis Foundation COVID-19 Task Force guidance for management of psoriatic disease during the pandemic: Version 2—Advances in psoriatic disease management, COVID-19 vaccines, and COVID-19 treatments

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Objective: To update guidance regarding the management of psoriatic disease during the COVID-19 pandemic.

Study Design: The task force (TF) includes 18 physician voting members with expertise in dermatology, rheumatology, epidemiology, infectious diseases, and critical care. The TF was supplemented by nonvoting members, which included fellows and National Psoriasis Foundation staff. Clinical questions relevant to the psoriatic disease community were informed by inquiries received by the National Psoriasis Foundation. A Delphi process was conducted.

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Results: The TF updated evidence for the original 22 statements and added 5 new recommendations. The average of the votes was within the category of agreement for all statements, 13 with high consensus and 14 with moderate consensus.

Limitations: The evidence behind many guidance statements is variable in quality and/or quantity.

Conclusions: These statements provide guidance for the treatment of patients with psoriatic disease on topics including how the disease and its treatments affect COVID-19 risk, how medical care can be optimized during the pandemic, what patients should do to lower their risk of getting infected with severe acute respiratory syndrome coronavirus 2 (including novel vaccination), and what they should do if they develop COVID-19. The guidance is a living document that is continuously updated by the TF as data emerge. (J Am Acad Dermatol 2021;84:1254-68.)

Key words: biologics; COVID-19; psoriasis; psoriatic arthritis; SARS-CoV-2; vaccines.

CAPSULE SUMMARY

- The National Psoriasis Foundation COVID-19 Task Force produced 27 guidance statements to promote optimal management of psoriatic disease during the pandemic.
- Shared decision making, adherence to evidence-based treatment, and the urgent use of novel COVID-19 vaccination are recommended. The guidance statements will be updated in accordance with the rapidly evolving science of COVID-19.

The COVID-19 pandemic has substantially worsened since the publication of Version 1 of the National Psoriasis Foundation (NPF) COVID-19 Task Force (TF) recommendations on September 4, 2020.[1] In just the ensuing 15 weeks alone, there have been more than an additional 11,100,000 cases and 125,000 COVID-19 deaths in the United States and an additional nearly 50,000,000 cases and more than 800,000 deaths worldwide.[2] Similar to the exponential growth of COVID-19 cases, basic biological and epidemiologic knowledge related to this pandemic have expanded dramatically. In just a few months since our initial recommendations, there have been major advances in the understanding of how to prevent and treat COVID-19 as well as a substantial increase in data to inform management decisions for patients with psoriatic disease during the pandemic. Therefore, this TF is providing updated scientifically based guidance to promote optimal management of psoriatic disease during the pandemic.

METHODS

The methods have been described in detail previously.[1] Briefly, the COVID-19 TF includes physicians, fellows, and senior NPF staff with a variety of expertise relevant to decision making in the pandemic. The TF reviews COVID-19 literature weekly in relation to psoriatic disease and meets every 2 to 4 weeks to address 5 core questions related to the pandemic. Existing recommendations were updated based on evolving science and were approved by unanimous consent. New recommendations were generated by using a modified Delphi process based on the RAND appropriateness method, including 2 rounds of voting with discussion in between.[3] (Only 1 round was used for new recommendations that achieved high consensus on the first round.) Panel consensus was determined to be low when 5 or more votes fell into the 1-to-3 rating range with 5 or more votes concurrently falling into the 7-to-9 rating range. Consensus was interpreted as high if all 18 votes fell within a single tertile, with all other combinations considered as moderate levels of consensus. The results were analyzed by the NPF with an independent analysis of the data by a nonvoting member of the TF.

RESULTS

The TF reaffirms the initial 22 guidance statements with updated data and has issued 5 new recommendations (Table I). The median was within the category of agreement for all new statements, with the number of votes outside the range of agreement being only 2 for the 1 new statement for which agreement was not unanimous. All guidance statements were recommended, 13 with high consensus and the 14 with moderate consensus.

Abbreviations used:

CI:	confidence interval
EUA:	Emergency Use Authorization
FDA:	US Food and Drug Administration
IL:	interleukin
mRNA:	messenger RNA
NPF:	National Psoriasis Foundation
OR:	odds ratio
PsA:	psoriatic arthritis
RR:	relative risk
SARS-CoV-2:	severe acute respiratory syndrome coronavirus 2
TF:	Task Force
TNFi:	tumor necrosis factor inhibitors

Category 1: What are the effects of psoriatic disease itself on severe acute respiratory syndrome coronavirus 2 infection and COVID-19 illness?

Patients with psoriasis are more prone to thrombosis and comorbidities that portend worse COVID-19 outcomes and may be more susceptible to infection, which raised concerns that they could be at increased risk for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection and worse COVID-19 outcomes.[4-8] Nevertheless, patients with psoriatic disease appear to have similar rates of infection with SARS-CoV-2 and COVID-19 outcomes as the general population, with multiple new studies from Italy, which primarily focused on patients with psoriasis receiving oral or biologic treatment, supporting our initial recommendation (guidance 1.1).[9-11] Additional new studies of patients with psoriatic arthritis (PsA) nested within cohorts of patients with rheumatic disease also suggest that they have similar rates of infection with SARS-CoV-2 and COVID-19 outcomes as the general population.[12-14] However, the risk of COVID-19 in autoimmune diseases was higher than in control patients (odds ratio [OR], 2.19; 95% confidence interval [CI], 1.05-4.58) in a meta-analysis of 7 case-control studies.[15]

The severity of COVID-19 continues to be primarily driven by risk factors such as current smoking, male sex, older age, and underlying comorbidities (guidance 1.2).[16-19] New data confirm that age, male sex, and pre-existing comorbidities are also important drivers of poor COVID-19 outcomes in patients with psoriasis.[20]

Category 2: What are the effects of psoriasis or PsA treatment on SARS-CoV-2 infection and COVID-19 illness?

The evolving literature reaffirms the TF conclusion that treatments for psoriasis and/or PsA do not appear to meaningfully alter the risk of acquiring SARS-CoV-2 infection or having worse COVID-19 outcomes; therefore, patients who are not infected with SARS-CoV-2 should continue their biologic or oral therapies for psoriasis and/or PsA in most cases (guidance 2.1 and 2.2). COVID-19 hospitalization was more frequent in patients using nonbiologic systemic therapy than in those using biologics (OR, 2.8; 95% CI, 1.3-6.2) in a registry of 374 patients with psoriasis from 25 countries.[20] A cohort of 6501 patients with psoriasis on biologics at northern Italian centers showed that the standardized incidence ratio of hospitalization and death in patients with psoriasis compared with those in the general population was 0.94 (95% CI, 0.57-1.45) and 0.42 (95% CI, 0.07-1.38), respectively.[11] In a study of 12,807 patients with psoriasis on biologics from 33 Italian dermatology centers, 26 (0.25%) had confirmed SARS-COV-2 infection (similar to general population in Italy [0.31%]).[21] In a study of patients with psoriasis (100 on topical treatment, 80 on biologics) from a single Italian dermatology center, COVID-19 symptoms were more common, but not statistically significant, in the biologic group (OR, 1.22; 95% CI, 0.58-2.58).[22] A cohort of 2329 patients with psoriasis on systemic therapy in Spain yielded standardized incidence ratios of 1.58 (95% CI, 0.98-2.41), 1.55 (95% CI, 0.67-3.06), and 1.38 (95% CI, 0.03-7.66) for COVID-19 cases, hospitalizations, and deaths, respectively.[23] Finally, a study of a global electronic medical record database that includes information on approximately 53 million people identified no evidence for increased COVID-19 hospitalization for patients prescribed tumor necrosis factor inhibitors (TNFi) (relative risk [RR], 0.73; 95% CI, 0.47-1.14), methotrexate (RR, 0.87; 95% CI, 0.62-1.23), or the combination of TNFi/methotrexate (RR, 0.91; 95% CI, 0.68-1.22) within 1 year of developing COVID-19.[24]

Similarly, the use of immunosuppressive/immunomodulating therapy was not associated with an increased risk for COVID-19 in a cohort of 5302 patients with inflammatory bowel disease.[25] This finding was supported by the Surveillance Epidemiology of Coronavirus Under Research Exclusion (SECURE-IBD) registry, which showed no increase in severe outcomes in patients on TNFi or anti−interleukin (IL) 12/23 monotherapy.[26] Patients with rheumatic disease do not appear to be at higher risk of contracting SARS-CoV-2 infection or of developing severe COVID-19 when on anti-TNF therapy.[15,27,28]

Nevertheless, uncertainty remains based on the quality of the existing data and lack of detailed analysis of patients at high risk because of age and/or

Table I. NPF COVID-19 TF guidance for management of psoriatic disease during the pandemic: Version 2

Guidance number	Guidance statement	Level of consensus
1.1	It is not known with certainty if having psoriatic disease meaningfully alters the risks of contracting SARS-CoV-2 (the virus that causes COVID-19 illness) or having a worse course of COVID-19 illness. Existing data, with some exceptions, generally suggest that patients with psoriasis and/or psoriatic arthritis have similar rates of SARS-CoV-2 infection and COVID-19 outcomes as the general population.	Moderate
1.2	The likelihood of poor outcomes from COVID-19 is driven by risk factors such as older age and comorbidities such as chronic heart, lung, or kidney disease and metabolic disorders such as diabetes and obesity. Patients with psoriatic disease are more prone to these comorbidities, particularly in those with more severe disease.	High
2.1	It is not known with certainty if treatments for psoriasis and/or psoriatic arthritis meaningfully alter the risks of contracting SARS-CoV-2 (the virus that causes COVID-19 illness) or having a worse course of COVID-19 illness. Existing data generally suggest that treatments for psoriasis and/or psoriatic arthritis do not meaningfully alter the risk of acquiring SARS-CoV-2 infection or having worse COVID-19 outcomes.	Moderate
2.2	It is recommended that patients who are not infected with SARS-CoV-2 continue their biologic or oral therapies for psoriasis and/or psoriatic arthritis in most cases. Shared decision making between clinician and patient is recommended to guide discussions about use of systemic therapies during the pandemic. (See guidance 2.5 for definition of *shared decision making*.)	High
2.3	Chronic systemic corticosteroids should be avoided if possible for the management of psoriatic arthritis. If patients require chronic systemic corticosteroids for the management of psoriatic arthritis, the dose should be tapered to the lowest dose necessary to achieve the desired therapeutic effect. Chronic systemic corticosteroid use for the treatment of psoriatic disease at the time of acute infection with SARS-CoV-2 may be associated with worse outcomes from COVID-19 illness. It is important to note, however, that corticosteroids may improve outcomes for COVID-19 when initiated in hospitalized patients requiring oxygen treatment.	High
2.4	Individuals newly diagnosed with psoriasis and/or psoriatic arthritis or who are currently not receiving treatment should be aware that untreated psoriatic disease is associated with serious impact on physical and emotional health and, in the case of psoriatic arthritis, can lead to permanent joint damage and disability. Shared decision making between clinician and patient is recommended to guide discussions about use of systemic therapies during the pandemic. (See guidance 2.5 for definition of *shared decision making*.)	High
2.5	Providers recommend shared decision making with patients. Shared decision making between clinician and patient should be guided by several factors, including the potential benefits of treatment, the activity of skin and/or joint disease and response to previous therapies, as well as the patient's underlying risk for poor COVID-19 outcomes and ability to maintain measures to prevent infection with SARS-CoV-2 such as hand hygiene, wearing of masks, and physical distancing as required by pandemic conditions. A review of known benefits of treatment accompanied by acknowledgment of the uncertainty related to the COVID-19 pandemic and a discussion of a patient's individual circumstances and preferences should guide decision making.	Moderate
3.1	Telemedicine should be offered to manage patients wherever possible when local restrictions or pandemic conditions limit the ability for in-person visits. The following patients can be managed with telemedicine: Patients who are clinically stable and previously started on psoriatic disease treatment. Patients requiring a follow-up visit and refills for medication. New patients without timely access to in-person visits. Patients diagnosed with COVID-19 who are experiencing a significant flare. If telemedicine visits become inadequate to monitor patients' disease progress or manage new or evolving symptoms or signs of skin and joint disease, clinicians and patients should consider in-person visits.	Moderate

Continued

Table I. Cont'd

Guidance number	Guidance statement	Level of consensus
3.2	The following patients should be considered for in-person care if pandemic conditions allow (ie, the clinical practice is open to see patients in person) and standard operating procedures are observed (ie, social distancing, hand washing, and masking): Patients at risk for melanoma and nonmelanoma skin cancer should be seen in person at a frequency consistent with the standard of care for a full skin examination. New patients establishing care. Patients experiencing unstable psoriatic disease/flares. Patients requiring a thorough skin/or joint examination and a full physical examination for rheumatology patients.	Moderate
3.3	Providers recommend the recent guidelines published by Lim et al[35] on how to optimize safety of office phototherapy for the patients and staff in the setting of the pandemic. See Supplemental Table V for details.	High
4.1	Patients should be advised to follow measures that prevent infection with SARS-CoV-2. These preventative measures include the following: to practice good hand hygiene, to maintain physical distancing from nonhousehold members, and to wear a face covering of the nose and mouth when indoors (except in their own home) and when outdoors but unable to maintain physical distancing. Face coverings should not be used in children under 2 years old due to risk of suffocation. See Supplemental Table VI for details.	High
4.2	Patients with psoriatic disease should follow measures to prevent infection with SARS-CoV-2 in the workplace. If the workplace environment does not allow for the maintenance of prevention measures, a shared decision-making process between the patient and his/her clinician is recommended to determine if specific accommodations are medically necessary, especially for individuals who, due to age or underlying health conditions, are at especially high risk for poor COVID-19 outcomes.	Moderate
4.3	Youth with psoriatic disease should follow measures to prevent infection with SARS-CoV-2 while at school. These measures include maintaining 6 feet of physical distancing, consistently wearing masks if over the age of 2 years, and washing hands frequently. If the school environment is unable to ensure these prevention measures or families believe their child may not be able to adhere to these practices, we encourage discussion with the patient, caregivers, and his/her clinician to collectively develop a learning plan in the best interest and safety of the child.	High
4.4.	Patients with psoriatic disease should receive the seasonal inactivated (eg, killed) influenza vaccine. While this vaccine will not protect against SARS-CoV-2, influenza vaccine lowers the risk of infection from seasonal influenza, which is of special importance to individual and public health during the COVID-19 pandemic. Patients taking systemic medications for psoriasis or psoriatic arthritis should discuss the timing of influenza vaccination with respect to their systemic psoriatic medications with their health care provider in order to optimize the response to the influenza vaccine.	High
4.5	Patients with psoriatic disease who do not have contraindications to vaccination should receive an mRNA-based COVID-19 vaccine as soon as it becomes available to them based on federal, state, and local guidance. Systemic medications for psoriasis or psoriatic arthritis are not a contraindication to the mRNA-based COVID-19 vaccine. If vaccine supply is limited, the TF recommends following the CDC's prioritization guidelines for early vaccination for selected groups based on their comorbidities and work setting (https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations-process.html).	High
4.6	It is recommended that patients who are to receive an mRNA-based COVID-19 vaccine continue their biologic or oral therapies for psoriasis and/or psoriatic arthritis in most cases. Shared decision making between clinician and patient is recommended to guide discussions about use of systemic therapies during the pandemic. (See guidance 2.5 for definition of *shared decision making*.)	High
4.7	For patients with psoriatic disease deciding whether or not to participate in a COVID-19 therapeutic or vaccine clinical trial, the TF recommends that the decision should be made on a case-by-case basis with shared decision making among the patient, researcher, and provider.	High
5.1	Patients with psoriatic disease who become infected with SARS-CoV-2 should monitor their symptoms and discuss the management of their treatments with their health care providers.	Moderate

Continued

Table I. Cont'd

Guidance number	Guidance statement	Level of consensus
5.2	Patients with psoriatic disease who become infected with SARS-CoV-2 should be prescribed and adhere to evidence-based COVID-19 therapies. Evidence-based therapies* currently include supportive care for all patients and the following: For outpatients: • Bamlanivimab for patients meeting specific criteria and who are at high risk for progressing to severe COVID-19 and/or hospitalization • Casirivimab and imdevimab to be administered together for patients meeting specific criteria and who are at high risk for progressing to severe COVID-19 and/or hospitalization For hospitalized patients: • Dexamethasone (systemic steroids) for patients meeting specific criteria • Remdesivir treatment for patients meeting specific criteria • Baricitinib, in combination with remdesivir, for patients meeting specific criteria The care of the hospitalized patient should include consultation with rheumatologists, dermatologists, and/or infectious disease specialists as medically necessary. *Evidence-based therapies are those that have been tested in well-conducted randomized controlled clinical trials and have proven benefit on clinically relevant COVID-19 outcomes.	Moderate
5.3	Systemic corticosteroids for the management of COVID-19 in patients with psoriatic disease are not contraindicated and should not be withheld due to the concern of potentially flaring psoriasis upon withdrawal of corticosteroids when evidence demonstrates the effectiveness for treating COVID-19 illness.	Moderate
5.4.1	Hydroxychloroquine or chloroquine are not recommended for the prevention or treatment of COVID-19 in patients with psoriatic disease outside of a clinical trial. Cases of psoriasis flare have been reported in patients on antimalarial medications, but the clinical significance is not well understood.	High
5.4.2	At this time, due to insufficient data to recommend for or against the use of convalescent plasma for the treatment of COVID-19 in patients with psoriatic disease, the TF recommends convalescent plasma to primarily be used in the setting of a clinical trial. Outside of a clinical trial, its use may be considered on a case-by-case basis with shared decision making between the patient and provider.	Moderate
5.4.3	Ivermectin is not recommended for the prevention or treatment of COVID-19 in patients with psoriatic disease outside of a clinical trial.	High
5.5	Resumption of psoriasis and/or psoriatic arthritis treatments held during SARS-CoV-2 infection should be decided on a case-by-case basis. Most patients can restart psoriasis and/or psoriatic arthritis treatments after complete resolution of COVID-19 symptoms. In those who have had a severe hospital course, shared decision making made on a case-by-case basis is recommended.	Moderate
5.6	Patients with psoriatic disease should be aware that infection with SARS-CoV-2 may result in a flare of psoriasis based on case reports. The clinical significance of the risk of COVID-19 flaring psoriasis is not known.	Moderate
5.7	Patients with psoriatic disease who become infected with SARS-CoV-2 should follow CDC guidance on home isolation and discuss with their health care providers when they can end home isolation. We recommend waiting a minimum of 10 days after COVID-19 symptom onset, along with fever resolution for 24 hours without antipyretics and improvement in other symptoms, before ending home isolation and returning to work, as patients are unlikely to be infectious after this point. In patients with severe cases of COVID-19 or when psoriasis patients are on medications with immunosuppressive effects, we recommend a case-by-case approach to determining the length of home isolation.	Moderate
5.8	Patients with close contact to someone with SARS-CoV-2 infection should quarantine themselves for 14 days after the last contact and discuss the management of their psoriatic disease treatment with their medical provider(s).	Moderate

CDC, Centers for Disease Control and Prevention; *mRNA,* messenger RNA; *NPF,* National Psoriasis Foundation; *SARS-CoV-2,* severe acute respiratory syndrome coronavirus 2; *TF,* Task Force.

comorbidity; therefore, shared decision making between the clinician and patient is recommended (guidance 2.2, 2.4, and 2.5). Chronic systemic corticosteroids should be avoided, if possible, for the management of PsA, because additional research confirms that their use is associated with worse COVID-19 outcomes (guidance 2.3).[15,29]

Category 3: How should medical care be delivered to patients with psoriatic disease to lower their risk of infection with SARS-CoV-2 while still ensuring quality of care?

Telemedicine remains a critical option for treating patients with psoriatic disease during the pandemic for appropriate patients (guidance 3.1 and 3.2). The evolving literature suggests that a short interruption of in-person patient-rheumatologist interactions had no major detrimental impact on the disease course of PsA as assessed by patient-reported outcomes.[30] Nevertheless, reductions in in-person care during the pandemic may be associated with a delay in diagnosis and treatment of malignancies, including melanoma.[31,32]

Universal masking for staff, clinicians, and patients; restrictions on visitation; and liberal reverse transcription polymerase chain reaction testing of symptomatic and asymptomatic patients are very effective in limiting SARS-CoV-2 spread, with nosocomial transmission exceptionally rare.[33,34] Therefore, patients should be informed that in-person medical care, including phototherapy (guidance 3.3), can be delivered safely with minimal risk of COVID-19 transmission in the clinical setting when safeguards are maintained.[35,36] Outbreaks in the clinical setting that have occurred have been due to lack of masking in patient care areas and a lack of distancing among staff while eating unmasked.[33] Thus, the TF updated guidance 3.2, emphasizing that standard operating procedures for social distancing, hand washing, and masking be observed in clinical settings.

Category 4: What should patients with psoriatic disease do to protect themselves from becoming infected with SARS-CoV-2?

Patients should follow recommended measures to prevent infection with SARS-CoV-2 (guidance 4.1, 4.2, and 4.3).[37] In cases where measures to prevent the transmission of SARS-CoV-2 at work or school cannot be maintained, shared decision making is recommended to determine if specific accommodations are medically necessary (guidance 4.2 and 4.3). In the United States, adherence rates with methods to prevent COVID-19 were lowest among adults aged 18 to 29 years (73%) and highest among those aged older than 60 years (86%).[38] An international survey of patients with psoriasis found that rates of COVID-19 prevention measures were slightly higher in those receiving biologics for psoriasis than in those receiving nonbiologic systemic therapies.[20]

Since our first recommendations, the major advance in protection from COVID-19 is the advent of highly effective vaccines using messenger RNA (mRNA) technology, which results in temporary expression of the SARS-CoV-2 spike protein in human cells after injection, triggering an immune response (Table II). The regimen of 2 doses, 21 days apart, for BNT162b2 (manufactured by Pfizer and BioNTech) conferred 95% protection against COVID-19, with an excellent safety profile similar to that of other viral vaccines, and was granted Emergency Use Authorization (EUA) on December 11, 2020, by the US Food and Drug Administration (FDA).[39,40] Similarly, the regimen of 2 doses, 28 days apart, for mRNA-1273 (manufactured by Moderna) conferred 94.5% protection against COVID-19 (FDA EUA pending).[41] Therefore, the TF recommends that patients with psoriatic disease who do not have contraindications to vaccination should receive an mRNA-based COVID-19 vaccine as soon as it becomes available to them (guidance 4.5). Additional vaccine platforms are undergoing testing (Table II).[42]

The effect of psoriasis treatment on the efficacy of COVID-19 vaccines is unknown. Based on a review of the literature, methotrexate treatment with doses commonly used in patients with psoriatic disease lowers the humoral response to seasonal influenza and pneumococcal vaccines, and temporary discontinuation of methotrexate for 2 weeks after influenza immunization improves the immunogenicity of the seasonal influenza vaccine.[43,44] TNFi and tofacitinib do not significantly affect the humoral immune response to influenza vaccination but have been reported to result in both reduced and sufficient immune responses to the pneumococcal vaccine.[44-48] Abatacept,[49] ustekinumab,[50] and anti—IL-17 treatment[51-53] do not interfere with the immune response to either influenza or pneumococcal vaccination, although large prospective studies of vaccine efficacy are lacking. No data were available at the time of analysis for cyclosporine (as used for psoriasis and other inflammatory diseases), anti—IL-23 biologics, apremilast, or acitretin on the efficacy of any approved vaccine.

Extrapolating from this literature and based on current available evidence, the TF recommends that patients who are to receive an mRNA-based COVID-19 vaccine continue their biologic or oral therapies for psoriasis and/or PsA during the vaccination period (guidance 4.6). Many trials of COVID-19 treatment and vaccines have excluded

Table II. Vaccine candidates for COVID-19 and available data on vaccination schedule, efficacy, and safety

Vaccine candidate	Vaccination schedule	Approximate number of individuals in phase 3	Efficacy	Safety	Status
Pfizer/BioNTech BNT162b2 (mRNA)[39,40]	IM injection on days 0 and 21	44,000	95% efficacy in preventing COVID-19 (162 cases in placebo group, 8 in BNT162b2 group) Severe COVID-19: 9 cases in placebo group, 1 in BNT162b2 group	• Most common solicited adverse reactions: injection site reactions (84.1%), fatigue (62.9%), headache (55.1%), muscle pain (38.3%), chills (31.9%), joint pain (23.6%), and fever (14.2%) • Severe adverse reactions occurred in 0.0% to 4.6% of participants, were more frequent after dose 2 than after dose 1, and were generally less frequent in participants ≥55 years. • The incidence of serious adverse events was similar in the vaccine and placebo groups (0.6% and 0.5%, respectively). • Four cases of Bell palsy in the vaccine group compared with no cases in the placebo group, consistent with the expected rate	FDA EUA granted December 11, 2020 Safety monitoring will continue for 2 years after administration of the second dose of the vaccine.

Continued

Table II. Cont'd

Vaccine candidate	Vaccination schedule	Approximate number of individuals in phase 3	Efficacy	Safety	Status

Moderna mRNA-1273 (mRNA)[41]	IM injection on days 0 and 28	30,400	94.5% efficacy in preventing COVID-19 (90 cases in placebo group, 5 in mRNA-1273 group)
			Severe COVID-19: 11 cases in placebo group, 0 in mRNA-1273 group
				• Most common solicited adverse reactions: injection site pain (91.6%), fatigue (68.5%), headache (63.0%), muscle pain (59.6%), joint pain (44.8%), and chills (43.4%).
				• Severe adverse reactions occurred in 0.2% to 9.7% of participants, were more frequent after dose 2 than after dose 1, and were generally less frequent in participants ≥65 years.
				• Unsolicited adverse events possibly related to vaccine:
				  • Local lymphadenopathy: 1.1% in the vaccine group and 0.63% in the placebo group
				  • Hypersensitivity: 1.5% in the vaccine group vs 1.1% placebo group
				• Frequency of serious adverse events was similar in vaccine and placebo groups (1.0% for both).
				• Four cases of Bell palsy in the vaccine group compared with 1 case in the placebo group
					FDA EUA pending
					Safety evaluation until day 759 after administration of second dose

AstraZeneca/Oxford AZD1222 (replication-deficient chimpanzee adenoviral vector ChAdOx1, containing the SARS-CoV-2 structural surface glycoprotein antigen)[42]	2-dose regimen, interval to be determined	40,000 Interim data reported on 11,600	62.1% (2 standard doses); 90% (low dose followed by standard dose); overall, 70.4% Severe COVID-19: 10 cases in placebo group, 0 in AZD1222 group	• Serious adverse events: 79 in treatment and 89 in control group • Adverse events: vaccine (n = 12,021) vs control (n = 11,724) • Anaphylactic reaction: 1 (vaccine) vs 0 (control)	Recruiting
Johnson & Johnson JNJ-78436735 (nonreplicating viral vector)	1 dose IM injection; 5×10^{10} viral particles (Ad26.COV2.S)	Up to 60,000 planned (30,000 per group)	TBD	TBD	Recruiting
Novavax NVX-CoV2373 (nanoparticle vaccine)	2 doses of 5 μg SARS-CoV-2 rS + 50 μg Matrix-M1 adjuvant (coformulated), 1 dose each on days 0 and 21	Up to 30,000	TBD	TBD	Recruiting
Inovio Pharmaceuticals INO-4800(DNA vaccine plasmid)	Participants will receive either 1 or 2 1.0-mg ID injections of INO-4800 based on results from phase 2 segment, followed by EP using the CELLECTRA 2000 device on day 0 and day 28	6578 participants	TBD	TBD	Recruiting
Medicago; GlaxoSmithKline; Dynavax VIR-7831 (plant-based adjuvant vaccine)	VIR-7831 given by intravenous infusion	1360 participants	TBD	TBD	Recruiting

EP, Electroporation; *EUA,* Emergency Use Authorization; *FDA,* US Food and Drug Administration; *ID,* intradermal; *IM,* intramuscular; *mRNA,* messenger RNA; *rS*, recombinant spike; *TBD,* to be determined.

patients with immune-mediated diseases or patients taking immune-modulating therapy. The TF encourages the inclusion of patients with psoriatic disease, including those on systemic treatments, in future studies of COVID-19 vaccines and treatments and recommends that patients participate in such experiments based on shared decision making among the patient, researcher, and provider (guidance 4.7).

Category 5: What should patients with psoriatic disease do if they become infected with SARS-CoV-2?

Major advances have occurred in the management of SARS-CoV-2 since Version 1 of the TF recommendations. For outpatients meeting specific criteria and at high risk for progressing to severe COVID-19, the use of monoclonal antibodies specifically directed against the spike protein of SARS-CoV-2 are recommended (guidance 5.2).[54-58] For hospitalized patients meeting specific criteria, in addition to remdesivir and dexamethasone, baricitinib in combination with remdesivir is an option as because reduces recovery time and new infections in hospitalized patients with COVID-19 compared to remdesivir alone.[59] However, baricitinib had no mortality benefit, can be prothrombotic, and is recommended only when corticosteroids cannot be used.[59,60] Furthermore, the remdesivir efficacy is modest, and international trials did not find mortality benefit.[61,62]

Additional evidence suggests that hydroxychloroquine is not effective for the prevention or treatment of COVID-19; therefore, the TF emphasizes that its use be restricted to clinical trials (guidance 5.4.1).[63-67] The evidence that convalescent plasma is effective for COVID-19 is limited despite the FDA EUA; therefore, the TF recommends that it be used primarily in clinical trials (guidance 5.4.2).[68,69] Ivermectin has in vitro activity against SARS-CoV-2; however, doses up to 100 times higher than those approved for use in humans would be required to achieve antiviral effects against COVID-19, raising safety concerns even if therapeutic levels could feasibly be achieved.[70-73] Therefore, the TF recommends ivermectin be used only in the setting of a clinical trial (guidance 5.4.3).

Based on limited available data and to be consistent with prescribing information, it may be prudent to hold treatments that target the immune system in the setting of suspected or confirmed SARS-CoV-2 infection, but the ultimate decision should be made case by case. Patients with psoriatic disease should be aware that infection with SARS-CoV-2 may result in a flare of psoriasis, including pustular flares (guidance 5.6).[74-81]

Patients with psoriatic disease who become infected with SARS-CoV-2 should follow Centers for Disease Control and Prevention guidance on home isolation and discuss with their health care providers when they can end home isolation (guidance 5.7; Version 1, Supplemental Table IX available via Mendeley at https://doi.org/10.17632/w5m8jf94m8.2).[1,82-84] In the event that someone with psoriatic disease has close contact (Version 1, Supplemental Table X) with an individual with suspected or confirmed SARS-CoV-2 infection, he or she should follow local public health authority guidance for the recommended duration of quarantine.[1] The Centers for Disease Control and Prevention recommends a quarantine period of 14 days after last contact with a person who has COVID-19, assuming one remains asymptomatic, but offers an option to shorten quarantine to end after day 10 from last contact or day 7 with appropriately timed diagnostic testing (guidance 5.8).[85] Individuals who have had COVID-19 within the past 3 months do not need to quarantine after close contact with someone who is infected, as long as they do not develop symptoms again.[86] The decision regarding continuing or holding psoriasis treatments during a period of quarantine should be individualized on a case-by-case basis between patient and provider.

Resumption of psoriasis and/or PsA treatments held during SARS-CoV-2 infection should be decided on a case-by-case basis (guidance 5.5). The persistence of 1 or more symptoms of COVID-19, such as fatigue or joint pain, beyond the acute phase of the illness can occur[87] and may complicate the decision to restart psoriasis or PsA medications. Therefore, shared decision making between the patient and provider(s) is recommended (guidance 2.5).

DISCUSSION

The NPF COVID-19 TF guidance statements serve to promote optimal management of psoriatic disease during the pandemic. Several limitations are acknowledged. First, the TF did not formally grade the strength of our recommendations.[88] With the exception of guidance statements 4.4, 4.5, 5.2, 5.4.1, and 5.4.2, which are based on large-scale randomized controlled trials, the evidence behind many guidance statements is limited in quality or quantity. Large-scale, longer-term, population-based studies of patients with psoriatic disease (particularly those with increased COVID-19 risk due to age and/or comorbidity), with appropriate comparator groups, adjustment for relevant confounding variables, and complete ascertainment of clinically important COVID-19 outcomes are urgently needed.[89] Second, the guidance is intended

to be neither proscriptive nor comprehensive. The ultimate judgment regarding how these recommendations should be followed is best left with the treating clinician and the patient in light of the circumstances presented by the individual patient and the variability and biological behavior of the disease and therapeutics.

The recommendations are a living document that will be updated and amended when necessary by the rapidly evolving science of COVID-19. Readers are encouraged to visit https://www.psoriasis.org/covid-19-resource-center regularly for the latest guidance from the TF to promote optimal care and outcomes for patients with psoriatic disease during the pandemic.

Conflicts of interest

Dr Gelfand has served as a consultant for Bristol Myers Squibb, Boehringer Ingelheim, GlaxoSmithKline, Janssen Biologics, Novartis Corp, Regeneron, UCB (Data Safety and Monitoring Board), Sanofi, and Pfizer, receiving honoraria; has received research grants (to the Trustees of the University of Pennsylvania) from AbbVie, Janssen, Novartis Corp, Sanofi, Celgene, OrthoDermatologics, and Pfizer; has received payment for continuing medical education work related to psoriasis that was supported indirectly by Eli Lilly and Company and Ortho Dermatologics; is a copatent holder of resiquimod for treatment of cutaneous T-cell lymphoma; and is a deputy editor for the *Journal of Investigative Dermatology*, receiving honoraria from the Society for Investigative Dermatology. Dr Armstrong has served as a research investigator and/or scientific advisor to Leo, AbbVie, UCB, Incyte, Janssen, Lilly, Novartis, Ortho Dermatologics, Sun, Dermavant, Bristol Myers Squibb, Sanofi, Regeneron, Dermira, and Modmed. Dr Bell is an employee of the National Psoriasis Foundation. Dr Anesi is supported by the Agency for Healthcare Research and Quality (K12HS026372) and has received fees from *UpToDate* for authoring COVID-19 clinical reference material. Dr Blauvelt has served as a scientific advisor and/or clinical study investigator for AbbVie, Almirall, Arena, Athenex, Boehringer Ingelheim, Bristol Myers Squibb, Dermavant, Eli Lilly and Company, Evommune, Forte, Galderma, Incyte, Janssen, Leo, Novartis, Pfizer, Rapt, Regeneron, Sanofi Genzyme, Sun Pharma, and UCB Pharma. Dr Calabrese is a speaker for Sanofi-Regeneron and consultant for AbbVie. Dr Feldman has received research, speaking, and/or consulting support from Galderma, GlaxoSmithKline/Stiefel, Almirall, Alvotech, Leo Pharma, Bristol Myers Squibb, Boehringer Ingelheim, Mylan, Celgene, Pfizer, Ortho Dermatology, AbbVie, Samsung, Janssen, Lilly, Menlo, Merck, Novartis, Regeneron, Sanofi, Novan, Qurient, National Biological Corporation, Caremark, Advance Medical, Sun Pharma, Suncare Research, Informa, *UpToDate*, and National Psoriasis Foundation; has consulted for others through Guidepoint Global, Gerson Lehrman, and other consulting organizations; is the founder and majority owner of www.DrScore.com; and is a founder and part owner of Causa Research, a company dedicated to enhancing patients' adherence to treatment. Dr Gladman is a consultant for AbbVie, Amgen, Bristol Myers Squibb, Galapagos, Gilead, Eli Lilly, Janssen, Novartis, Pfizer, and UCB and has received grants from AbbVie, Amgen, Eli Lilly, Janssen, Novartis, Pfizer, and UCB. Dr Kircik has served either as an investigator, consultant, or speaker for AbbVie, Almirall, Amgen, Arcutis, Bausch Health Canada, Bristol Myers Squibb, Boehringer Ingelheim, Cellceutix, Celgene, Coherus, Dermavant, Dermira, Eli Lilly, Leo, MC2, Maruho, Novartis, Ortho Dermatologics, Pfizer, Dr Reddy's Laboratories, Sun Pharma, UCB, Taro, and Xenoport. Dr Lebwohl is an employee of Mount Sinai; receives research funds from AbbVie, Amgen, Arcutis, Boehringer Ingelheim, Dermavant, Eli Lilly, Incyte, Janssen Research and Development, Leo Pharmaceuticals, Ortho Dermatologics, Pfizer, and UCB; and is a consultant for Aditum Bio, Allergan, Almirall, Arcutis, Avotres Therapeutics, BirchBioMed, BMD Skincare, Boehringer Ingelheim, Bristol Myers Squibb, Cara Therapeutics, Castle Biosciences, Corrona, Dermavant Sciences, Evelo, Facilitate International Dermatologic Education, Foundation for Research and Education in Dermatology, Inozyme Pharma, Kyowa Kirin, LEO Pharma, Meiji Seika Pharma, Menlo, Mitsubishi, Neuroderm, Pfizer, Promius/Dr Reddy's Laboratories, Serono, Theravance, and Verrica. Dr Martin is a consultant for Almirall, Athenex, Bristol Meyers Squibb, Celgene, Eli Lilly, LEO, Ortho Dermatologic, Pfizer, and UCB and a scientific advisor for Almirall, Athenex, Bristol Meyers Squibb, Celgene, Eli Lilly, Janssen, LEO, Ortho Dermatologic, Pfizer, and UCB. Dr Merola is a consultant and/or investigator for Bristol Myers Squibb, AbbVie, Dermavant, Eli Lilly, Novartis, Janssen, UCB, Sun Pharma, Pfizer, and EMD Serono. Dr Scher is a consultant for UCB, Janssen, AbbVie, Pfizer, Novartis, Bristol Myers Squibb, and Sanofi and is supported in part by the Riley Family Foundation and the Beatrice Snyder Foundation. Dr Schwartzman is a speaker for AbbVie, Genentech, Janssen, Lilly, Novartis, Pfizer, and UCB; owns stock in Amgen, Boston Scientific, Gilead, Medtronic, and Pfizer; is a consultant for AbbVie, Myriad, Janssen, Gilead, Lilly, Novartis, and UCB; is a scientific advisory board member for Myriad; and is a board member of the National Psoriasis Foundation. Dr Van Voorhees has been an investigator for Celgene, Lilly, and AbbVie and an advisor/consultant for AbbVie, Allergan, AstraZeneca, Celgene, Dermira, Merck, Novartis, Pfizer, UCB, and Valeant. Dr Syed is supported by a grant from Pfizer. Authors Gondo, Heydon, and Koons are employees of the National Psoriasis Foundation. Dr Ritchlin reports personal fees from AbbVie, Amgen, Janssen, Novartis, UCB, and Boehringer Ingelheim, as well as grants from Amgen, UCB, and AbbVie outside the submitted work. Drs Dommasch, Lo Re, Treat, Ellebrecht, Fenner, Ocon, and Weinstein have no conflicts of interest to declare.

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