

AMERICAN SOCIETY FOR REPRODUCTIVE MEDICINE (ASRM) PATIENT MANAGEMENT AND CLINICAL RECOMMENDATIONS DURING THE CORONAVIRUS (COVID-19) PANDEMIC

UPDATE No. 14 – *March 23, 2021* VACCINATION: COMBATING HESITANCY AND MISINFORMATION

In the current update, the ASRM Coronavirus/COVID-19 Task Force (the "Task Force")¹ continues to support both vaccination with currently available vaccines for all individuals, including women who are either pregnant or contemplating conception (see <u>Update #11</u>), and continued strict adherence to its earlier recommended mitigation strategies for disease prevention, including use of social distancing, and rigorous attention to hand washing, Personal Protective Equipment (PPE), especially masking, and quarantines when appropriate (see <u>Update #3</u>). In addition, the Task Force is issuing this update to assist reproductive care specialists in counseling their patients and their communities regarding vaccination, including vaccination in pregnancy, and to provide considerations for relaxing restrictions.

Since the last update published on February 22, 2021, the Task Force has observed the following:

- In the past month there has been a plateau in case numbers in the United States (U.S.) from the peak in January 2021. Daily new cases remain at 58,000 per day, similar to case numbers in late October 2020 and the July 2020 peak. Causes for the plateau are likely multifactorial and include the increased prevalence of more contagious variant strains, coupled with relaxation of mask requirements in some states and increased travel. Deaths have declined to 1,100 per day but remain at a high level.
- To date, the U.S. Food and Drug Administration (FDA) has issued Emergency Use Authorizations (EUAs) for three SARS-CoV-2 vaccines (Pfizer-BioNTech, Moderna, and Johnson & Johnson). Mass vaccination sites have opened, and vaccination continues at 2.5 million inoculations per day. As of mid-March 2021, in the U.S. 74 million individuals have received one dose (23% of the population) and 29 million are fully vaccinated.
- Emerging evidence suggests that COVID-19 vaccines are not only highly effective in preventing illness and

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¹ This guidance document was developed under the direction of the Coronavirus/COVID-19 Task Force of the American Society for Reproductive Medicine. These recommendations are being provided as a service to its members, other practicing clinicians, and to the patients they care for, during the coronavirus pandemic. While this document reflects the views of members of the Task Force, it is not intended to be the only approved standard of practice or to dictate an exclusive course of treatment. Clinicians should always use their best clinical judgment in determining a course of action and be guided by the needs of the individual patient, available resources, and institutional or clinical practice limitations. The Executive Committee of the American Society for Reproductive Medicine has approved this guidance document.

hospitalization but are also effective for the prevention of viral transmission. If current trends continue, the U.S. is likely to reach herd immunity by late June 2021. Despite vaccinations, some countries have experienced taxing surges leading again to shutdowns.

- While a considerable percentage of older at-risk individuals have been vaccinated, a large portion of younger persons in the U.S. remain at risk for hospitalization and death because other risk factors affect many individuals, such as obesity or pre-existing conditions.
- In the past month, the U.S. Centers for Disease Control and Prevention (CDC) has issued <u>additional guidance for</u> <u>fully vaccinated individuals</u>, including being able to: a) visit with other fully vaccinated people indoors without wearing masks or physically distance; b) visit with unvaccinated people from a single household without wearing masks or physically distance, provided they are at low risk for severe COVID-19 disease indoors; and c) refrain from quarantine and testing following a known exposure if asymptomatic. The Task Force emphasizes strict adherence to CDC guidelines and recommendations, including travel.
- The new SARS-CoV-2 variants identified so far (B.1.1.7, B.1.351, P.1, B.1.427, and B.1.429) are classified as "variants of concern" in the U.S. by the CDC. These are detected by most commonly used tests for the virus. The new variant strains appear more transmissible, but evidence suggests current vaccines remain reasonably effective against the variants. COVID-19 prevention should remain a top priority to reduce the likelihood of the emergence of additional, new SARS-CoV-2 variants. Reproductive care centers should continue to ensure double masking, hand washing, avoidance of crowds, and social distancing.
- Given the known risks and severity of COVID-19 disease during pregnancy, vaccination of pregnant women or women attempting pregnancy is recommended, including by the World Health Organization (WHO), the American College of Obstetricians and Gynecologists (ACOG), the Society for Maternal-Fetal Medicine (SMFM), and the ASRM, <u>as first recommended by this Task Force</u>.

This update will address issues related to available COVID-19 vaccine efficacy and effectiveness; COVID-19 vaccination and pregnancy; vaccination disparities; vaccination hesitancy and potential strategies to avoid vaccine hesitancy; vaccine misinformation; the critical role of health providers, including reproductive care specialists, in advocating for and educating patients and the public regarding COVID vaccination; clinic policies regarding partners or support persons; learning to live with COVID-19; and managing the continuing negative impact of the pandemic on mental health.

COVID-19 VACCINE EFFICACY VS. EFFECTIVENESS

<u>Much confusion</u> exists regarding the efficacy of the COVID-19 vaccines currently being approved for use. <u>Vaccine efficacy</u> is the percentage reduction in a disease in a group of people who received a vaccination in a clinical trial. It differs from <u>vaccine effectiveness</u>, which measures how well a vaccine works when given to people in the community outside of clinical trials. <u>Vaccine efficacy assesses the vaccine under optimum (clinical trial) conditions while vaccine effectiveness assesses the vaccine under optimum (clinical trial) conditions while vaccine effectiveness assesses the vaccine under optimum (clinical trial) conditions while vaccine effectiveness assesses the vaccine under optimum (clinical trial) conditions while vaccine effectiveness assesses the vaccine under optimum (clinical trial) conditions while vaccine effectiveness assesses the vaccine under optimum (clinical trial) conditions while vaccine effectiveness assesses the vaccine under optimum (clinical trial) conditions while vaccine effectiveness assesses the vaccine under optimum (clinical trial) conditions while vaccine effectiveness assesses the vaccine under optimum (clinical trial) conditions while vaccine effectiveness assesses the vaccine under optimum (clinical trial) conditions while vaccine effectiveness assesses the vaccine under optimum (clinical trial) conditions while vaccine effectiveness assesses the vaccine under optimum (clinical trial) conditions while vaccine effectiveness assesses the vaccine under optimum (clinical trial) conditions while vaccine effectiveness assesses the vaccine under optimum (clinical trial) conditions while vaccine effectiveness assesses the vaccine under optimum (clinical trial) conditions while vaccine effectiveness assesses the vaccine under optimum (clinical trial) conditions while vaccine effectiveness assesses the vaccine under optimum (clinical trial) conditions while vaccine effectiveness assesses the vaccine under optimum (clinical trial) conditions while vaccine under optimum (clinica</u>

In the real-world, very few vaccines are 100% effective, although many routine vaccines have very high levels of effectiveness. For example, the <u>MMR vaccine</u> is up to 97% effective against measles, 88% effective against mumps, and about 97% effective against rubella. Alternatively, the annual flu shot has an effectiveness of <u>40–60%</u>, but is able to prevent millions of illnesses and thousands of deaths in the U.S. alone. While it is too early to fully assess the effectiveness of the COVID-19 vaccines, the rapid decrease in U.S. cases from their peak in January, starting soon after vaccinations began to be administered, suggests that vaccines are highly effective in real-world conditions.

Alternatively, data regarding vaccine efficacy are being published in authoritative sources and peer-reviewed journals. **Table 1** describes the features of many currently available vaccines. Most important is the efficacy of the vaccine in preventing severe life-threatening disease. <u>Coronavirus vaccine tracker</u> provides up to date information on the status of vaccines in development and in use.

Vaccine	How it works	Efficacy	Phase	Status	Things to
		rate			know
Pfizer-BioNTech	mRNA	95%	2/3	• Emergency use in US, EU,	2 doses 3
"Comirnaty" (3, 4)				other countries.	weeks apart
				 Approved in several 	
				countries	
Moderna "mRNA -1273" (5)	mRNA	94.1%	3	• Emergency use in US, UK,	2 doses 4
				EU, other countries	weeks apart
				 Approved in Switzerland 	
Johnson & Johnson	Adenovirus with	72%	3	• Emergency use in US, EU,	Single dose
"Ad26.COV2.S" (6)	double stranded DNA			and Bahrain	
Oxford-AstraZeneca	Adenovirus with	82.4%	2/3	• Emergency use in US, EU,	2 doses 12
"ADZ1222 or Covishield" (1)	double stranded DNA			and other countries	weeks apart
Gamaleya "Sputnik V" (2)	Adenovirus with	91.6%	3	Early use in Russia	2 doses 3
	double stranded DNA			 Emergency use in other 	weeks apart
				countries	
CanSino "Convidecia" (7)	Adenovirus with	65.3%	3	 Approved in China 	Single dose
	double stranded DNA			 Emergency use in Mexico, 	
				Pakistan	
Vector Institute	Protein	Not	3	 Early use in Russia 	2 doses 3
"EpiVacCorona"		published			weeks apart
Novavax "NVX-CoV2373"	Protein	55-96%	3	 Not yet approved 	2 doses 3
					weeks apart
Sinopharm "BBIBP-CorV"	Inactivated	79.3%	3	 Approved in China, UAE, 	2 doses 3
	coronavirus			Bahrain	weeks apart
				 Emergency use in other 	
				countries	
Sinovac "Coronavac"	Inactivated	50.3-80.5%	3	 Approved in China 	2 doses 2
	coronavirus			 Emergency use in other 	weeks apart
				countries	
Bharat Biotech	Inactivated	80.6%	3	 Emergency use in India, 	2 doses 4
	coronavirus			Iran, and Zimbabwe	weeks apart

Table 1. Summary of currently available vaccines

Following, we list the efficacy against severe disease of some of the vaccines currently available:

- Pfizer/BioNTech: Efficacy against all COVID disease was 94.6%.
- Moderna: Efficacy against severe disease was 100%.
- J&J: Efficacy against severe/critical disease (which includes death) 28 days after a single dose was 85.4%.
- Astra Zeneca: 100% <u>efficacy</u> against severe disease, hospitalization, and death (1).
- **Sputnik V Vaccine**: 100% efficacy against moderate or severe disease (2).

COVID-19 VACCINATION AND PREGNANCY

- While pregnant women were not included in the initial COVID-19 vaccine trials, there is growing data involving pregnant individuals who have received the Pfizer-BioNTech or Moderna vaccines. As stated in <u>Task Force Update</u> <u>#13</u>, there is convincing evidence that pregnant individuals are at increased risk of more severe complications from COVID19. As such, the *theoretical* risk of COVID-19 vaccination to periconception and pregnant women is significantly less than the *real* risk of acquiring COVID-19.
- <u>V-safe</u> is a smartphone-based tool that collects voluntary data using text messaging and web surveys from individuals who have received the COVID-19 vaccine. V-safe includes a Pregnancy Registry that collects additional information from individuals that report vaccination in the periconception period or during pregnancy.
- For those interested in contributing to the data surrounding COVID-19 and pregnancy, enrollment in the V-safe registry is highly encouraged. Individuals are eligible to participate in the study if COVID-19 vaccination occurred in the periconception period (within 30 days before the last menstrual period) or during pregnancy. More information regarding the V-safe Pregnancy Registry and enrollment can be found <u>here</u> and the full V-safe protocol can be found <u>here</u>.
- As of March 8, 2021, more than 44,000 V-safe participants had indicated they were pregnant at the time they
 received their COVID-19 vaccination. The CDC presented <u>preliminary data</u> at the Advisory Committee of
 Immunization Practices (ACIP) meeting on March 1st, 2021 and intends to share more data regarding COVID-19
 vaccination and pregnancy as it becomes available. That data indicated that:
 - As of February 16, 2021, a total of 30,494 patients with pregnancies had been reported to V-safe, of which 16,039 and 14,455 had received the Pfizer-BioNTech and Moderna vaccines, respectively.
 - For both the Pfizer-BioNTech and Moderna vaccines, there were no concerning differences between pregnant and non-pregnant women in the incidence of reported local reactions (such as pain, swelling, redness, or itching) or systemic reactions (fatigue, headache, myalgia, chills, nausea, fever) after both doses of the Pfizer-BioNTech and after the first dose of the Moderna vaccine.
 - The V-safe Pregnancy Registry outcomes of interest include miscarriage and still birth, pregnancy complications, maternal ICU admission, adverse birth outcomes, neonatal death, infant hospitalizations, and birth defects. As of February 19, 2021, the V-safe Pregnancy Registry included 1,815 enrolled participants of which 275 had completed pregnancies resulting in 232 live births. The rates of miscarriage, still birth, gestational diabetes, preeclampsia or gestational hypertension, eclampsia, and intrauterine growth restriction were lower in the V-safe pregnancy registry compared to background rates.

VACCINATION DISPARITIES

Racial and ethnic health disparities in the U.S. are well documented and a focus of the recent <u>ASRM Diversity, Equity, and</u> <u>Inclusion Task Force statement</u>. To date, <u>thirty-eight states</u> have shared race and ethnicity data for vaccinated people with early data suggesting that people of color are getting vaccinated at a rate well below their representation in the population. While apprehension and lack of access to trustworthy information has been reported as part of the reason, people of color continue to be more reluctant to get the vaccine than Whites (8,9). Of those that are hesitant to get the vaccine, over a third focus on information from social media, rather than more reliable sources (8). To this end, the CDC at a recent National Forum on the COVID-19 Vaccine Agenda, highlighted strategies to build trust and confidence in the vaccine (10). The 'Greater Than COVID' organization created <u>an informative video</u> involving Black doctors, nurses and researchers dispelling misinformation and providing real facts. The most trusted spokespeople are medical experts and ASRM continues to encourage our providers to promote the safety and efficacy of the COVID vaccine (see next section). Most experts feel that access is the main reason for the vaccine disparity. Blacks and Hispanics in the United States tend to have less reliable internet service to make online appointments. They also are more likely to have inflexible work schedules, and lack of reliable transportation to vaccine sites, many of which are not accessible by public transportation. Some states have addressed these challenges by partnering with local community and religious leaders, presenting information in different languages and culturally appropriate ways, and bringing the vaccines to community sites that are open at different hours to accommodate work schedules. As vaccine distribution becomes more reliable, it is hoped that this disparity will decrease.

VACCINATION HESITANCY

Research has shown how important it is to pay attention to psychological factors such as emotional responses to vaccination, and in particular to negative emotions. For example, Chou et al (11) have outlined evidence-based health communication strategies, including the following recommendations:

- Attend to negative emotions such as fear and anxiety.
- Raise awareness of emotional manipulations by anti-vaccine misinformation efforts.
- Activate positive emotions such as altruism and hope.

Additional key findings from <u>the ongoing February 2021 Kaiser Family Foundation (KFF) poll</u> of Americans document the attitudes, beliefs and changing trends of vaccination behaviors:

- A majority (55%) of U.S. adults now say they have received at least one dose of the vaccine (18%) or that they will get it as soon as they can (37%), up from 47% in January and 34% in December.
 - Most of those who have not yet been vaccinated say the number of doses does not make a difference in their own intentions.

Among those who have not yet been vaccinated:

- People who opt to "wait and see" how the vaccine is working for others before getting vaccinated themselves decreased from 31% in January 2021 to 22% in February 2021.
 - 26% of those in the "wait and see" group say they would be more likely to get a vaccine if only one dose was required.
- One in five respondents stated they will get the vaccine "only if required for work, school, or other activities" (7%), or will "definitely not" get vaccinated (15%).
- While the share that is most enthusiastic to get vaccinated increased across racial and ethnic groups, Black and Hispanic adults continue to be more likely than White adults to say they will "wait and see" before getting vaccinated.
- Vaccine acceptance varies by political affiliation and rurality, with nearly four in 10 Republicans and 3 in 10 rural residents stated they will either "definitely not" get vaccinated or will do so "only if required".
- Likewise, 32% of those who have been deemed essential workers in fields other than health care stated they will either "definitely not" get vaccinated or will do so "only if required".
- Having a close relationship with someone who has been vaccinated is associated with an individual's own intentions to get the COVID-19 vaccine.
 - Seven in 10 of those with a household member who has been vaccinated and about half of those who say
 a close friend or family member has been vaccinated say they want the vaccine "as soon as possible,"
 compared to about a third of those who do not have a close relationship to someone who has received
 the vaccine.
 - Black and Hispanic adults, those with lower incomes, and those without a college degree are less likely

than their counterparts to say someone close to them has received the vaccine.

- The perceived side effects of the vaccine continue to be a top concern for the public, with eight in 10 in the "wait and see" group stating they are concerned they might experience serious side effects if they get vaccinated.
- Large shares of those who want to "wait and see" including majorities of Black and Hispanic adults also state:
 - \circ $\;$ They are concerned that they might get COVID-19 from the vaccine.
 - They might have to miss work if the side effects make them feel sick.
 - They may have to pay an out-of-pocket cost to get vaccinated, despite the vaccine being available for free to everyone.
 - \circ $\,$ Or they will not be able to receive the vaccine from a place they trust.
- Half of Black adults and about one-third of Hispanic adults (35%) state they are not confident that the COVID-19 vaccines have been adequately tested for safety and effectiveness among members of their own racial or ethnic group, and those who are not confident in this type of testing are much less likely to state they have already been vaccinated or want the vaccine as soon as they can get it.

VACCINATION MISINFORMATION

One major obstacle to vaccination utilization, as well as to other safe mitigation practices, is the spread of untruthful information ('misinformation'). One international study (12) investigated how susceptibility to misinformation about the virus affects key self-reported health behaviors. Their findings include:

- While belief in misinformation about COVID-19 is not held by a majority of people in any country that was surveyed, specific misinformation claims are consistently deemed reliable by a substantial segment of the public and pose a potential risk to public health.
- A clear link, replicated internationally, was found between susceptibility to misinformation and vaccine hesitancy and a reduced likelihood of complying with public health guidance.
- Scientists and healthcare providers play a key role as disseminators of factual and reliable information, as well as the potential importance of fostering numeracy and critical thinking skills to reduce susceptibility to misinformation.

A recent study (13) surveyed 1,020 people in the U.S. between the ages of 40 and 80 years about the accuracy of health postings. Although the study did not assess COVID-19 information, the findings have potential implications for addressing misinformation. Findings included:

- People with lower education or health literacy levels, people with a tendency to use alternative medicine, and people who distrust the healthcare system are more likely to believe inaccurate medical postings.
- A person who is susceptible to online misinformation about one health topic may be susceptible to many types of health misinformation.

Key strategies to address misinformation include:

- Debunking.
- Preemptive inoculation.
- Encouragement to assess the accuracy of the material.

For example, van der Linden et al (14) suggested that psychological inoculation or "prebunking" is an effective intervention to combat misinformation. For example, an online <u>game entitled "Go Viral"</u> was developed in collaboration with the UK government and the WHO, where players learn to resist three manipulation techniques commonly used to spread misinformation: fearmongering, the use of fake experts, and conspiracy theories.

THE CRITICAL ROLE OF REPRODUCTIVE CARE SPECIALISTS IN PROMOTING VACCINATION: USING PERSUASION

- A year into the ongoing battle against the COVID pandemic we have the opportunity to transition from hopelessness and despair to purpose and vigor.
- We must find the resilience to resist the urge to complacency, to halting prematurely effective mitigation strategies, and to abandoning scientific recommendations. The price to date of politicization and ignoring scientific guidance has been immense in terms of social economics, long-term morbidity, and lives lost. The need to prevent an imminent resurgence is urgent.
- The conflict currently pits the ongoing vaccine rollout against the emergence and spread of more transmissible and potentially aggressive virus variants.
- The responsibility to lead is urgent. All reproductive care specialists and staff must accept and confront the harsh
 reality that a substantial segment of the current adult US population is hesitant to become vaccinated (see
 section above). This greatly jeopardizes our path to normalcy and enhances the risk of another surge with its
 associated pain, hardship, and death. We must learn from countries that have recently needed to renew lock
 down measures that the outcome of the battle between the covid variant spread and the vaccine rollout is
 uncertain.
- With the increasing availability of vaccines, the priority must shift to persuading those that remain skeptical to vaccination (see section above) to become vaccinated, as that is the most direct and sure way to achieve herd immunity and ultimate control of the pandemic.
- As reproductive care specialists and staff who have a privileged relationship and influence with our patients, we
 must embrace the responsibility and opportunity to serve as vaccine ambassadors and help promote vaccine
 utilization and combat vaccine hesitancy and misinformation, to facilitate the health and safety of our patients,
 our communities, and overall society.

Persuasion is key in combating vaccine hesitancy and misinformation. However, persuasion is not intuitive. As healthcare practitioners our first reaction is to "correct (misconceptions) and convince (with facts)". However, this approach has been shown to be ineffective as a persuasion tool.

- An effective persuasion approach often requires that the persuader demonstrate an understanding of the other's concerns and present the recommendation within a framework that does not require destruction of their view of the world. Thus, we should recognize that individuals who are hesitant or refuse to be vaccinated are simply coming at their point-of-view from a different set of facts.
- To understand the existence of varying points-of-view we must recognize the extreme politicization of the pandemic and its management. To wit, a large segment of the population is focused on individual freedoms while another large segment focuses on achieving collective goals through centralized structure.
- We must understand that persuasion will entail first an acknowledgment that it is very understandable that an individual might be skeptical. For example, to begin to address vaccine hesitancy, it might be appropriate to acknowledge that attempts to handle by "central authorities" and "scientists" have not been flawless or consistent.
 - The CDC, WHO, Dr. Fauci, etc. all advised against restrictions in travel / mobility before they endorsed them. The CDC, surgeon general, and Dr. Fauci all advised against masks for the public explicitly stating

that they may increase transmission through improper use before they ultimately endorsed them. Confusion around airborne and surface transmission also have not helped.

- We might also want to recognize that humans are particularly good at making decisions in complex situations
 without having all the facts. For example, while we should acknowledge that experience backing the COVID-19
 vaccine is still somewhat limited, centuries of experience with vaccination do assure us that the strategy is the
 right one to combat the pandemic and keep all of us safe and healthy. Additionally, we might acknowledge the
 occurrence of vaccination reactions, but also indicate that these appear to be rare and isolated events, much like
 bathtub accidents or getting hit by a car.
- Humans, for the most part, will make the right decision for their communities and their friends and family. Appealing to their desire to make decisions to protect family and friends also will be an effective strategy.

LIVING WITH COVID

- As we mark the one-year anniversary of the declaration of COVID-19 as a global pandemic, it has become abundantly clear that this virus will not disappear soon. However, variation in the global prevalence of the disease may allow a de-escalation from a worldwide pandemic to a continental or regional epidemic. Likely thereafter, COVID will transition to an endemic disease that we will need to learn to live with for the foreseeable future, much as we do with influenza.
- Surveillance strategies will be required to detect and contain local outbreaks all of which depend on disease
 prevalence, morbidity, and mortality. As variants emerge, and when infection rates rise in a given locale,
 mitigation efforts will likely be intermittently required. These will include mask wearing, social distancing,
 and targeted societal restriction of specific activities. It is likely that we will continue to see an undulating
 pattern of disease rise and fall and will need to respond accordingly.
- Approaches to handling COVID-19 will depend on the success of vaccination campaigns and the attainment
 of herd immunity, the effect of variants on disease severity and spread, and the degree to which mitigation
 efforts are proposed and followed. Vaccine boosters may be incorporated into the armamentarium, either
 with currently available formulas or with modifications that anticipate and incorporate the features of the
 most transmissible and lethal forms yet to evolve. Recognizing that boosters may be needed should allow
 government and pharma to plan accordingly and avoid the logistical bottlenecks that hampered deployment
 of the first wave of vaccines.
- Prevention strategies continue to be of utmost importance, not only to prevent death from acute disease, but also to prevent long term complications and ailments that affect a significant percentage of individuals who contract COVID-19.
- While the etiology, risk factors for, and incidence of "long haul" syndrome are not yet known, this disorder can lead to ongoing illness across a wide array of organ systems (15, 16). Symptoms including fatigue, cognitive difficulties, pain, autonomic disturbances, anxiety, and depression have been reported. Experience with other coronaviruses including SARS-Cov-1 (SARS) suggest that COVID-19 is not alone when it comes to follow-on disease in that long-haul syndromes have occurred following other coronavirus outbreaks. Outpatient clinics attending to patients suffering from long-haul COVID-19 are opening in many countries and offer the hope that viewing the individual ailments through a common lens will lead to new insights into the mechanisms underlying their development with an eye towards developing effective therapeutics.

• Early reports of disparate rates of disease along socioeconomic and racial lines have drawn attention to the wider issue of access to care. As has been seen with the initial wave of COVID-19, the ongoing crisis will continue to exacerbate social disparities. To minimize these disparities and increase overall health, healthcare providers should use their position as trusted health experts to make every effort to encourage widespread vaccination and continued adherence to mitigation strategies as the situation dictates.

CLINIC POLICIES REGARDING PARTNERS OR SUPPORT PERSONS

Most clinics and institutions have successfully implemented policies that have reduced the risk of COVID-19 transmission allowing continued provision of reproductive healthcare. As some states relax mask mandates, travel restrictions, etc., patients may question why their clinic continues to adhere strictly to policies and procedures instituted months ago. Furthermore, although the pandemic and associated risks are far from over, the increasing availability of vaccines and declining prevalence in many geographic areas will ultimately lead to easing of restrictions.

One of the risk mitigation strategies that has been most difficult for patients and providers alike has been the discouragement of physically including partners or support persons, despite the fact that a patient's partner is accurately considered a patient in the setting of fertility treatment. This has been a difficult policy to implement, given the well-recognized benefit of emotional support for patients experiencing infertility and undergoing fertility treatments. Additionally, treatment instructions and recommendations are often given verbally at these encounters and having an additional individual present can reduce confusion and increase compliance with the treatment process.

The Task Force does not advise a relaxation of any risk mitigation policy, including the physical presence of partners or support persons, without careful consideration of potential negative impacts. Factors to be considered for allowing partners or support people to be physically present might include:

- The local prevalence of COVID-19.
- Adherence to CDC and local guidelines.
- The availability of clinic resources to screen additional individuals.
- The adequacy of sufficient space to promote social distancing of clinician, staff, and patients for all procedures.
- Vaccination status.

Clinics that are unable to ease restrictions related to the presence of partners or support persons should continue to provide alternative methods of participation, such as by phone or video.

MENTAL HEALTH AND COVID-19

As we pass the one-year anniversary of the COVID-19 pandemic and vaccines are steadily providing a pathway back to normalcy there is cause for both hope and concern. Vaccine utilization has increased, and vaccine hesitancy has decreased; however psychosocial obstacles remain to achieving herd immunity, including, but not limited to, the spread of misinformation (see above). There is increasing evidence of the negative impact of the pandemic on physical and mental health. Research findings around the world have consistently predicted that this pandemic will have a long lasting and profound negative impact on mental health into the future that will affect all areas of society, with a differential impact on more vulnerable groups and individuals. Ongoing international research is consistently finding evidence that supports this prediction. Fertility clinics will benefit from learning about behaviors and attitudes that influence vaccination hesitancy and increase risks to physical and mental health, in order to promote the safety, health, and wellbeing for patients, staff, and providers.

The most recent update of the American Psychological Association (APA) online survey, <u>Stress in America[™] 2020: A</u> <u>National Mental Health Crisis</u> (17) in late February 2021 on 3,013 adults age 18+ who reside in the U.S., revealed concerning results. The prolonged stress caused by the pandemic is directly affecting mental and physical health, including changes to weight, sleep, and alcohol use. It appears that the long-term stressors of the pandemic are overwhelming people's ability to cope in healthy ways. Instead, people may be on unhealthy behaviors such as relying on alcohol. These unhealthy behaviors are likely to lead to higher vulnerability to serious illness from the coronavirus and significant longterm negative impact on individuals, society, and strain on the nation's healthcare system. Furthermore, the results continue to demonstrate that the pandemic is having a disproportionate impact on certain groups, including communities of color, essential workers, and parents. Key findings from the February 2021 <u>Stress in America[™]</u> survey are presented in **Appendix A**, and a series of recommendations that can be shared with patients and staff to change unhealthy behaviors are presented in **Appendix B**.

Regarding the mental and emotional state of patients undergoing reproductive treatment, the Task Force notes the following:

- Generally, the pandemic has increased the number of patients seeking fertility treatment, such that many current patients are experiencing the stress caused by fertility treatment for the first time.
- Patients continue to experience increased levels of isolation due to not having full partner participation in treatments (see section above), not having in-person support networks for events such as a failed in-vitro fertilization (IVF) cycle or a miscarriage, and not being able to engage in their usual daily routines and distractions.
- Patients may be overwhelmed and confused by published information, often incorrect and not clear, about the vaccine as it relates to fertility and pregnancy (see sections above).

Providers should understand that everyone is affected by fears and beliefs about vaccination and by the potential for developing unhealthy coping behaviors, and that patients struggling with infertility/fertility challenges may also be parents struggling with childcare issues. Healthcare providers play a key role in helping patients and others make decisions about vaccination. We recommend they consider the following:

- Fostering discussion around decision-making:
 - Open a discussion about vaccination.
 - Tailor discussions appropriately.
 - Ask, listen, validate when possible (e.g., the concern that the vaccines have been developed too quickly is understandable when remembering how at the beginning of the pandemic experts were warning it would take years to develop a vaccine).
 - Acknowledge fears, anger, and other negative emotions.
 - Activate positive emotions like altruism and hope.
 - Share personal experience and vaccination confidence.
 - Emphasize self-efficacy in being vaccinated.
 - Emphasize stringent safety standards in vaccine development.
 - Framing vaccinations as a beneficial, apolitical decision is helpful.
 - Raise awareness of emotional manipulations by anti-vaccine disinformation efforts.
 - Discuss interventions which aim to improve critical thinking and trust in science are helpful.
 - Emphasize that vaccination is a right and that no one prohibits them from losing that right; these are particularly important messages for the anti-vaxxers, who are often motivated by concerns regarding having their freedom curtailed.
 - Reinforce vaccination confidence.

- When possible, provide paid time off for staff members and providers with:
 - Vaccination appointments.
 - Reactions to vaccinations.
 - Problems with childcare.
- Reinforce accurate information and suggest reliable sources of information about safe mitigation and vaccination.
- Reinforce the importance of mitigation practices and vaccination for the safety of self and others.
- Encourage the importance of maintaining mental health through:
 - Healthy behaviors for sleep, eating, and coping.
 - Use of telemental health and support groups.
 - Provide access to mental health resources, such as the ASRM Mental Health Professional Group to decrease stress, provide support, and promote resilience.
- Encourage providers and staff to:
 - Take breaks to eat healthy meals.
 - Exercise when possible.
 - Provide healthy snacks in break room.
- Inquire carefully about use of alcohol, substances, eating behaviors and make referrals, and, if possible, have referral resources available and visible:
 - Substance Abuse and Mental Health Services Administration (<u>www.samhsa.gov</u>)
 - Alcoholics Anonymous (<u>www.aa.org</u>).
 - Narcotics Anonymous (<u>www.na.org</u>).
 - National Eating Disorders Helpline (<u>www.nationaleatingdisorders.org</u>).

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APPENDIX A – KEY FINDINGS FROM THE APA STRESS IN AMERICA[™] SURVEY

Key findings from the February 2021 APA <u>Stress in America[™]</u> report include:

- A majority of adults (61%) reported experiencing undesired weight changes since the start of the pandemic, with adults reported gaining an average of 29 pounds.
- Two in three Americans (67%) said they are sleeping more or less than they wanted to since the pandemic started.
- Nearly one in four adults (23%) reported drinking more alcohol during the coronavirus pandemic.
- Nearly half of Americans (47%) said they delayed or canceled healthcare services since the pandemic started.
- Slightly more than three in 10 adults (31%) reported their mental health has worsened compared with before the pandemic.
- Nearly half of parents (48%) said the level of stress in their life has increased compared with before the pandemic:
 - More than three in five parents with children who are still home for remote learning (62%) said the same.
 - <u>Parents were more likely than those without children</u> to have received treatment from a mental health professional (32% vs. 12%) and to have been diagnosed with a mental health disorder since the coronavirus pandemic began (24% vs. 9%).
 - More than half of fathers (55%) reported gaining weight, and nearly half (48%) said they are drinking more alcohol to cope with stress.
 - The pandemic has taken a particularly heavy toll on parents of children under 18:
 - Nearly half of mothers who still have children home for remote learning (47%) reported their mental health has worsened, and 30% of fathers who still have children home stated the same.
- The majority of <u>essential workers (54%)</u>, such as health care workers and people who work in law enforcement, said they have relied on a lot of unhealthy habits to get through the pandemic
 - Nearly three in 10 (29%) said their mental health has worsened.
 - Three in four (75%) said they could have used more emotional support than they received since the pandemic began.
 - Essential workers were more than twice as likely as those who are not to have received treatment from a mental health professional (34% vs. 12%) and to have been diagnosed with a mental health disorder since the coronavirus pandemic started (25% vs. 9%).
- People of color reported higher unintended physical changes during the pandemic.
 - Hispanic adults were most likely to report undesired changes since the pandemic began:
 - Sleep (78% Hispanic vs. 76% Black, 63% white and 61% Asian),
 - Physical activity levels (87% Hispanic vs. 84% Black, 81% Asian and 79% white),
 - Weight (71% Hispanic vs. 64% Black, 58% white and 54% Asian).
 - Black Americans were most likely to report feelings of concern about the future.
 - More than half said they do not feel comfortable going back to living life like they used to before the pandemic (54% Black vs. 48% Hispanic, 45% Asian and 44% white).
 - And that they feel uneasy about adjusting to in-person interaction once the pandemic ends (57% Black vs. 51% Asian, 50% Hispanic and 47% white).
- Gen Z adults (46%) were the most likely generation to state that their mental health has worsened compared with before the pandemic, followed by Xers (33%), Millennials (31%), Boomers (28%) and older adults (9%).
- Americans are hesitant about the future, regardless of vaccination status.
 - Nearly half of respondents (49%) stated they feel uneasy about adjusting to in-person interaction once the pandemic ends, with no difference between adults who had or had not received a COVID-19 vaccine (48% vs. 49%, respectively).

APPENDIX B - RECOMMENDATIONS FROM THE APA ON CHANGING UNHEALTHY BEHAVIORS

The <u>Stress in America</u> report (17) provides the following suggestions to identify and address unhealthy habits, change behavior, and manage weight:

Identify unhealthy habits:

- Take note of when you are overeating, making poor food choices, or drinking alcohol.
- What time of the day is it? Did something stressful happen? Are you bored?
- Answering these kinds of questions can help you determine if your habits are not healthy.
- Pay attention to how you feel after a certain activity.
- For instance, drinking might make you feel better in the moment but worse the day after.
- If you notice this is happening, try substituting this behavior with another activity that does not make you feel worse later.

Change behavior:

- Make the goals you set for yourself specific and attainable.
- For instance, if you are trying to drink less during the pandemic, determine a specific number of days and drinks by which you want to limit your alcohol consumption.
- Find an accountability buddy.
- Telling a close friend or family member about your goals can help you stay on track and they can check on your progress.

Manage weight:

- If you are feeling stressed and are gaining weight, instead of trying to lose weight, start by trying to maintain your weight by not overeating and staying active. This can help you develop healthy eating habits.
- To maintain weight or stop yourself from losing weight, establish a routine for eating three meals a day either by setting an alarm to signal mealtimes or blocking off time in your calendar.
- If trying to decide what to eat feels overwhelming, repeating the same breakfast and lunch every day can help build routine.
- If you cannot get outside, go for a walk inside.
- Plan a route through your home that lets you take about 25 steps and take this route while you are in a meeting, catching up with a friend on the phone or taking a five-minute break during your workday._