

COVID-19: VACCINE UPDATE

DR. MARK DONALDSON BSP, RPH, PHARMD, FASHP, FACHE

DRMARKDONALDSON@GMAIL.COM

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COVID-19 Tracker Canada Menu

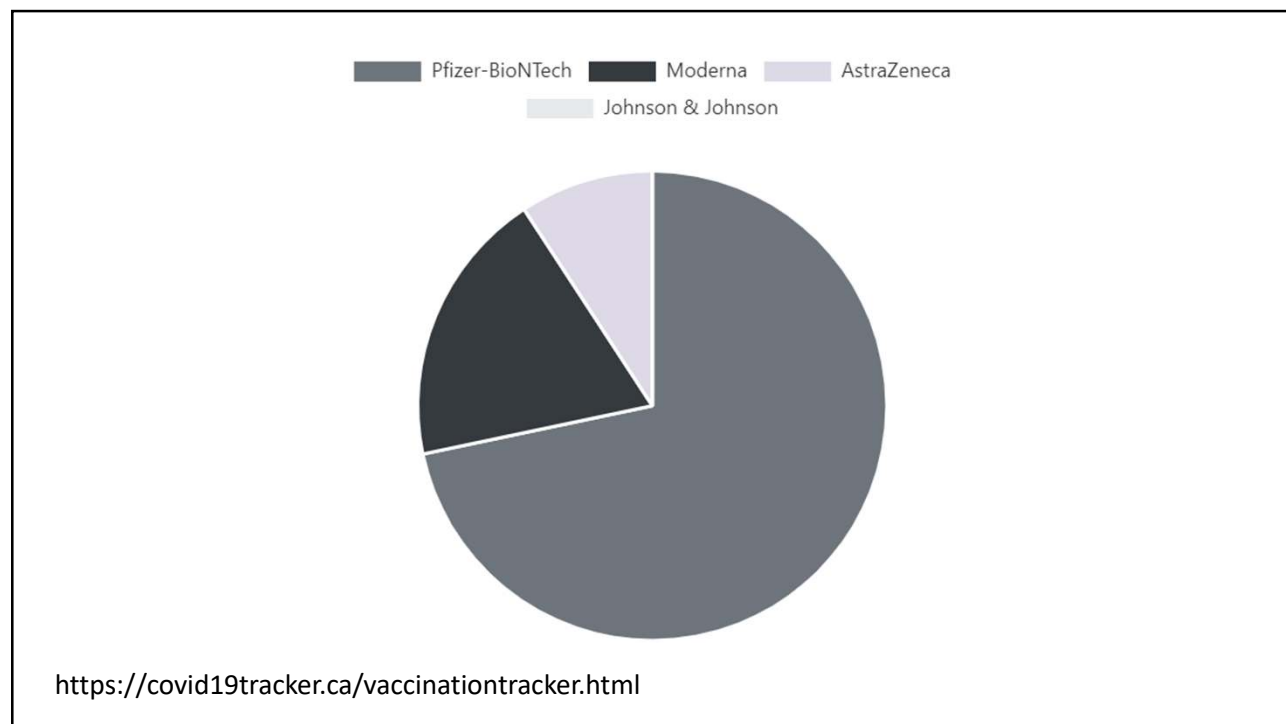
COVID-19 Vaccination Tracker

29,795,637 doses administered (+324891 today) <small>People ? <input type="checkbox"/></small>	32,926,064 doses delivered <small>90.5% of doses delivered have been administered ?</small>	64.853% <small>of the Canadian population has received at least one dose</small> <small>Eligible ? <input type="checkbox"/></small>	13.540% <small>of the Canadian population is fully vaccinated</small> <small>Eligible ? <input type="checkbox"/></small>
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After lagging behind other countries in the early months of vaccination, **Canada is now among the leaders** when it comes to the percentage of the population vaccinated against COVID-19 with at least one dose (#9).

<https://covid19tracker.ca/vaccinationtracker.html>

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	Vaccine candidates				
	mRNA vaccines		Replication-defective vector vaccines	Attenuated vaccines	Protein subunit
	mRNA-1273 (Moderna)	mRNA-BNT162b2 (BioNTech/Pfizer)	AZD1222 (AstraZeneca/Vaxzevria)	JNJ-78436735 (J&J)	NVX-CoV2373 (Novavax)
Manufacturer	Moderna/NIAID	Pfizer Inc/BioNTech SE	AstraZeneca	Janssen	Novavax
FDA status (if authorized, indication)	EUA – For active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals aged ≥ 18 y. Submission for EUA ≥ 12 y likely to occur in June.	EUA – For active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals aged ≥ 12 y	Investigational	EUA – For active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals aged ≥ 18 y	Investigational – EUA expected to be submitted in September
Vaccine platform technology	LNP-encapsulated, nucleoside-modified mRNA vaccine	LNP formulated, nucleoside-modified mRNA vaccine	Recombinant, replication-defective simian adenovirus vector	Recombinant, replication-defective adenovirus type 26 vector leveraging AdVac technology	Recombinant nanoparticle vaccine technology, leveraging Sf9/BV insect cell platform and Matrix-M™ adjuvant technology
Pharmacology	<ul style="list-style-type: none"> mRNA encoding for the SARS-CoV-2 spike glycoprotein is delivered to cells in a lipid capsule Using mRNA, cells manufacture the spike protein (antigen) Spike protein stimulates the body's immune response and production of antibodies against SARS-CoV-2 		DNA sequence for SARS-CoV-2 spike glycoprotein (antigen) is encoded into a human or non-human adenovirus. Upon delivery to the host cell, host cells manufacture the spike protein (antigen), which stimulates the body's immune response. AZD1222 uses a simian adenovirus and JNJ-78436735 uses a human adenovirus with low prevalence in humans. Due to genetic alterations, adenovirus vectors are unable to replicate (replication-defective) once in the host cell.	<p>CoV-2 spike glycoprotein (antigen) is encoded into a human or non-human adenovirus. Upon delivery to the host cell, host cells manufacture the spike protein (antigen), which stimulates the body's immune response. AZD1222 uses a simian adenovirus and JNJ-78436735 uses a human adenovirus with low prevalence in humans. Due to genetic alterations, adenovirus vectors are unable to replicate (replication-defective) once in the host cell.</p> <p>Genetic sequence encoding the antigen (spike protein) is cloned into baculovirus and inserted into Sf9 insect cells, where the antigen is produced and subsequently isolated/extracted. Matrix-M adjuvant boosts immune response and enables vaccine dose-sparing by stimulating entry of antigen-presenting cells into the injection site and enhancing B- and T-cell responses.</p>	

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CDC, FDA to Resume J&J COVID-19 Vaccination Following Pause Over Rare Clots

Total of 15 cases of clots have been identified in J&J vaccine recipients, all in women. Nearly 10 potential cases are still under review. Among the data presented:

- The rate of clots estimated to be about 1.9 per million people vaccinated with the J&J vaccine
- Women aged 18 to 49 years, the clot rate is higher, at 7.0 per million. Women in their 30s had the highest rate
- Consideration from this vaccine:
 - Men
 - Women over the age of 50

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Phase 3 efficacy results for late-stage COVID-19 vaccines

	Vaccine candidates				
	mRNA vaccines		Replication-defective vectored vaccines		Protein subunit
	mRNA-1273 (Moderna)	mRNA-BNT162b2 (BioNTech/Pfizer)	AZD1222 (AstraZeneca)	JNJ-78436735 (J&J)	NVX-CoV2373 (Novavax)
Phase 3 trial characteristics	<ul style="list-style-type: none"> • Enrollment: July 27 to Oct. 23, 2020 • U.S.-based phase 3 trial (>99 trial sites in the U.S.) • Final analysis (data cutoff, Nov. 21, 2020) 	<ul style="list-style-type: none"> • Enrollment: July 27 to Nov. 14, 2020 • International phase 1/2/3 trial (85% sites in U.S.) • Final analysis (data cutoff, Nov. 14, 2020) 	<ul style="list-style-type: none"> • Enrollment: April 23 to Nov. 4, 2020 • International phase 3 trial: U.S., Peru, Chile • Interim analysis (data cutoff, Feb. 2021) 	<ul style="list-style-type: none"> • Enrollment: Sept. 7 to Dec. 18, 2020 • International phase 3 trial (46.7% of participants in U.S.) • Interim analysis (data cutoff, Jan. 22, 2021) 	<ul style="list-style-type: none"> • UK phase 3 trial • Final analysis
No. of patients	Enrolled: 30,351	Enrolled: 43,448	Enrolled: 32,449	Enrolled: 43,783	Enrolled: 15,000
No. of vaccine doses	2 doses, 28 d apart	2 doses, 21 d apart	2 doses, 4 wk apart	1 dose	2 doses, 21 d apart
Outcomes					
Symptomatic (mild to severe) COVID-19 (without previous SARS-CoV-2 infection)	<ul style="list-style-type: none"> • Primary endpoint, measured 14 d after dose 2 • 185 cases in placebo group vs. 11 cases in vaccine group • VE: 94.1% (95% CI, 89.3-96.8) 	<ul style="list-style-type: none"> • Primary endpoint, measured 7 d after dose 2 • 162 cases in placebo group vs. 8 cases in vaccine group • VE: 95% (95% CI, 90.3-97.6) 	<ul style="list-style-type: none"> • Primary endpoint, measured ≥ 15 d after dose 2 • VE: 76% (95% CI, 68-82) 	<ul style="list-style-type: none"> • Secondary endpoint, measured 14 d and 28 d after vaccine • 14 d: 351 cases in placebo group vs. 117 cases in vaccine group; VE of 66.9% (95% CI, 59.1-73.4) • 28 d: 195 cases in placebo group vs. 66 cases in vaccine group; VE of 66.5% (95% CI, 55.5-75.1) 	<ul style="list-style-type: none"> • Primary endpoint, measured ≥ 7 d after dose 2 • 96 cases in placebo group vs. 10 cases in vaccine group • Overall VE: 89.7% (95% CI, 75.2-95.4) • VE, original strain: 96.4% (95% CI, 73.8-99.5) • VE, UK variant strain: 86.3% (95% CI, 71.3-93.5)

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Symptomatic COVID-19 (with or without previous SARS-CoV-2 infection)	<ul style="list-style-type: none"> Subgroup analysis, measured 14 d after dose 2 187 cases in placebo group vs. 12 cases in vaccine group VE: 93.6% (95% CI, 88.6-96.5) 	<ul style="list-style-type: none"> Primary endpoint, measured 7 d after dose 2 169 cases in placebo group vs. 9 cases in the vaccine group VE: 94.6% (95% CI, 89.9-97.3) 	Not reported	<ul style="list-style-type: none"> Secondary endpoint, measured 14 d and 28 d after vaccine 14 d: VE of 66.1% (95% CI, 59.7-71.6) 28 d: VE of 65.5% (57.2-72.4) 	Not reported
Moderate or severe COVID-19	<ul style="list-style-type: none"> Secondary endpoint, severe COVID-19 30 cases observed in placebo group vs. 0 cases in vaccine group (note: 1 vaccine recipient met definition for severe disease, but negative SARS-CoV-2 at hospital, but previously positive) VE: 100% (95% CI, not estimated) 	<ul style="list-style-type: none"> Secondary endpoint, severe COVID-19 After dose 1: 9 cases in placebo group vs. 1 case in vaccine group After dose 2: 4 cases in placebo group vs. 1 case in vaccine group VE, after dose 2: 75% (95% CI, -152.6-99.5) 	<ul style="list-style-type: none"> Secondary endpoint, severe or critical COVID-19 and hospitalization 8 cases observed in placebo group vs. 0 cases in vaccine group VE: 100% 	<ul style="list-style-type: none"> Primary endpoint, moderate to severe/critical COVID-19, measured 14 d and 28 d after vaccine 14 d: 348 cases in placebo group vs. 116 cases in vaccine group; VE of 66.9% (95% CI, 59-73.4) 28 d: 193 cases in placebo group vs. 66 cases in vaccine group; VE of 66.1% (95% CI, 55-74.8) U.S. only: VE of 72% (95% CI, 58.2-81.7) 	<ul style="list-style-type: none"> 5 severe cases (including hospitalization/death) in placebo group vs. 0 cases in vaccine group (4 of 5 severe cases were caused by UK variant) VE: 100%

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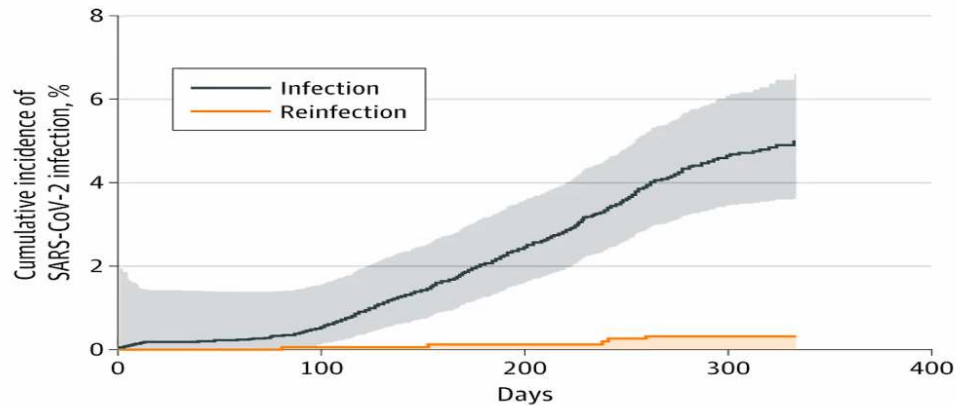


CDC
breakthrough
data

- CDC keeping track of [breakthrough infections](#) in U.S
- Out of >95 million Americans who are fully vaccinated against COVID-19
 - 6025 symptomatic breakthroughs (0.007%)
 - Only 0.0006% hospitalizations for COVID-19
 - Deaths 0.0001% for COVID-19
- Not a single breakthrough infection has been reported to have transmitted

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Assessment of SARS-CoV-2 Reinfection 1 Year After Primary Infection in a Population in Lombardy, Italy



No. days at risk				
RT-PCR positive	10 988	137 085	325 798	496 586
RT-PCR negative	31 742	491 579	2 040 576	3 499 503

JAMA Intern Med. Published online May 28, 2021. doi:10.1001/jamainternmed.2021.2959

Date of download: 6/6/2021

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Pfizer-BioNTech efficacy at 6 months

91.3% efficacy against symptomatic illness diagnosed from 1 week to 6 months after the second dose of vaccine

- 850 confirmed COVID-19 cases in the placebo group versus 77 in the vaccine group out of some 46,000 trial participants
- 100% efficacy against CDC-defined severe disease (32 cases with placebo, none with the vaccine)
- 12K vaccine recipients revealed no serious safety concerns
- South Africa, where 800 participants were enrolled, the vaccine was 100% efficacious against symptomatic illness: Of the nine cases in the placebo group, six were found to be caused by the B.1.351 variant, suggesting that the vaccine is efficacious against this lineage

Pfizer

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COVID-19 Vaccines: Real-World Effectiveness

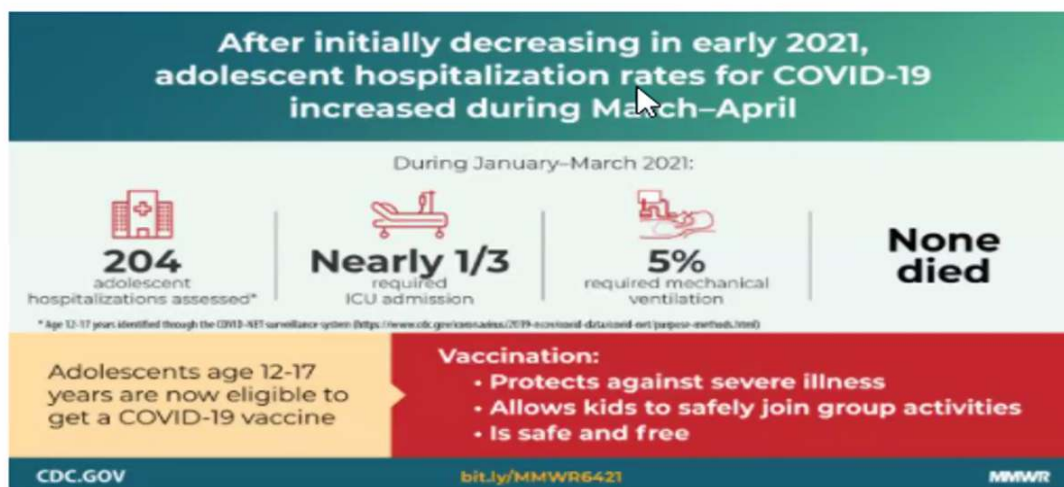
In the United States, the real-world effectiveness of the COVID-19 mRNA vaccines is 90%, CDC researchers reported in *MMWR*

- 4K* from eight U.S. locations self-collected nasal swabs PCR testing each week, regardless of symptoms, between mid-December and mid-March. Those with prior evidence of SARS-CoV-2 infection were excluded.
- 63% received two doses of mRNA vaccine, and 12% received one dose, during the study period
- Incidence rate of infection was 1.38 per 1000 person-days in unvaccinated people, 0.19 per 1000 in partially vaccinated people (≥ 14 days after the first dose and before the second), and 0.04 per 1000 in fully vaccinated people (≥ 14 days after second dose)
- This translated to an effectiveness of 80% for partial vaccination and 90% for full vaccination.

*healthcare workers, first responders, and other essential or frontline workers

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Increase in Younger Teens



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Pfizer: Vaccine Shown 100% Effective in Kids 12-15 in Phase III

- 2,260 adolescents ages 12-15
- No infections were reported in the group given the vaccine
- Placebo group reported 18 cases of COVID-19
- The vaccinated children showed a strong antibody response with no serious side effects

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New names for coronavirus variants will end stigma for countries

NEW NAMES FOR COVID-19 VARIANTS

Variants of concern



WHO label	Pango lineage	Earliest documented samples
Alpha	B.1.1.7	United Kingdom Sep 2020
Beta	B.1.351	South Africa May 2020
Gamma	P.1	Brazil Nov 2020
Delta	B.1.617.2	India Oct 2020

Infographic: Rafa Estrada

Source: World Health Organization, May 31, 2021



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Moderna Variant Trail

A version of Moderna's vaccine designed to protect against the B.1.351 variant has begun testing in a phase 1 trial sponsored by the National Institute of Allergy and Infectious Diseases

- The trial will enroll 210 volunteers, some of whom have previously received the original Moderna vaccine, and will test the candidate vaccine (known as mRNA-1273.351) alone or in various combinations with the original vaccine
- The trial's aim is to assess the candidate vaccine's safety, reactogenicity, and ability to induce an immune response

National Institutes of Health

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Pfizer-BioNTech vaccine doesn't need to be adapted for variants, drugmaker says

There is no evidence supporting the need to adapt the COVID-19 vaccine it developed with Pfizer to be more effective against coronavirus variants

- BioNTech said it "has developed a comprehensive strategy to address these variants should the need arise in the future." For example, the FDA has approved plans made by BioNTech and Pfizer to study the effectiveness of a third vaccine dose for prolonged immunity and protection against variants

11 Becker's Hospital Review

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Heterologous Vaccination

- This is not a new concept. In the past, different vaccine products have been used to complete a vaccine series for influenza, hepatitis A, and others to complete a vaccine series for influenza, hepatitis A, and others.
- Basically, all vaccines work by showing people's immune systems something that looks like an invading virus but really isn't. If the real virus ever comes along, their immune systems will recognize it and be prepared to fight it off.
- **Using two different vaccines is a bit like giving the immune system two pictures of the virus, maybe one face-on and one in profile.**

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Share Who Report Receiving A COVID-19 Vaccine Continues To Increase, With Few Remaining Eager To Get A Vaccine As Soon As Possible

Have you personally received at least one dose of the COVID-19 vaccine, or not? As you may know, an FDA-authorized vaccine for COVID-19 is now available for free to all adults in the U.S. Do you think you will...?



NOTE: December 2020 survey did not have an option for respondents to indicate they had already been vaccinated. December 2020-April 2021 question wording: "When an FDA authorized vaccine for COVID-19 is available to you for free, do you think you will...?" See topline for full question wording.

SOURCE: KFF COVID-19 Vaccine Monitor • [Download PNG](#)

KFF COVID-19
Vaccine Monitor

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Pfizer, Moderna COVID-19 vaccines effective in pregnant, lactating women

The Pfizer/BioNTech and Moderna [COVID-19] vaccines are effective in pregnant and lactating women, who can pass protective antibodies to newborns

- Study researchers looked at 131 women who received either the Pfizer/BioNTech or Moderna [COVID-19] vaccine
- Vaccine-induced antibody levels were equivalent in pregnant and lactating women, compared to non-pregnant women
- Antibody levels were strikingly higher than those resulting from coronavirus infection during pregnancy

the American Journal of Obstetrics and Gynecology

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Safety of vaccine in pregnancy

Early results indicate that COVID-19 vaccination appears to be safe in the third trimester of pregnancy, according to a CDC study in the New England Journal of Medicine:

- Post-vaccine local and systemic events seem to be similar between pregnant and nonpregnant individuals
- Spontaneous abortion was 12.6% among vaccinated compared to 10% to 26%
- Completed pregnancy, the rates of adverse pregnancy and neonatal outcomes appear to be similar to prepandemic rates
- Among the pregnancies that ended in a live birth, 98% received their first vaccine dose in the third trimester

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Facial paralysis

- The COVID-19 mRNA vaccines do not appear to pose any higher risk for facial paralysis than other viral vaccines, according to an analysis in JAMA Internal Medicine:
- 135K adverse drug reactions linked to the mRNA vaccines reported to the WHO's pharmacovigilance database, 0.6% were facial paralysis-related events (e.g., paralysis, paresis, spasms)
- The majority of these were linked to the Pfizer-BioNTech vaccine, and the median time to onset was 2 days
- For comparison, facial paralysis events accounted for 0.5% of adverse reactions to other viral vaccines and 0.7% of reactions to influenza vaccines

Autoimmune phenomenon or virus that affects nerves – VERY rare

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Symptomatic Acute Myocarditis in Seven Adolescents Following Pfizer-BioNTech COVID- 19 Vaccination

Seven cases of acute myocarditis or myopericarditis in healthy male adolescents who presented with chest pain all within four days after the second dose of Pfizer-BioNTech COVID-19 vaccination

- **Five patients had fever around the time of presentation**
- **Acute COVID-19 was ruled out in all 7 cases & none had prior infections**
- **None of the patients met criteria for multi-system inflammatory syndrome in children (MIS-C)**
- **All 7 patients resolved their symptoms rapidly**
- **Three patients were treated with non-steroidal anti-inflammatory drugs (NSAIDs) only and 4 received intravenous immune globulin (IVIG) and corticosteroids**

3 American Academy of Pediatrics

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FDA official says myocarditis is rare among adolescents, young adults who receive COVID-19 vaccines, connection to shot remains unclear

VaST concluded that there are relatively few reports of myocarditis to date and that these cases seem to occur:

- **Predominantly in adolescents and young adults**
- **More often in males than females**
- **More often following dose 2 than dose 1**
- **Typically, within 4 days after vaccination**

Most cases appear to be mild, and follow-up of cases is ongoing.

The Advisory Committee on Immunization Practices (ACIP) COVID-19 Vaccine Safety Technical (VaST) Work Group
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The CDC guidance on cleaning and disinfection

- The laundry of a COVID-19 patient can be washed and dried with laundry from healthy people in the household. People should wash their hands after handling dirty laundry
- High-touch metal and plastic outdoor surfaces (such as playground equipment and railings) should be cleaned regularly
- In terms of what not to do, fogging, fumigation, and electrostatic spraying generally are not recommended for surface disinfection and carry several safety risks. In addition, ultrasonic waves, high-intensity UV radiation, and LED blue light do not have proven effectiveness against SARS-CoV-2

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Lessons from COVID-19 Vaccination Programs in Healthcare Workers

- Israel, weekly incidence of COVID-19 among vaccinated HCWs began to fall starting about 2 weeks after the first dose of the Pfizer vaccine then continued to decline and remained low after the second dose. This reduction occurred even as the B.1.1.7 variant became the dominant lineage in Israel
- University of Texas Southwestern between December 15, 2020, and January 28, 2021, infections occurred in 2.61% of nonvaccinated employees, 1.82% of partially vaccinated employees, and only 0.05% of fully vaccinated employees; the infection rate was >50-fold lower in the fully vaccinated group than in nonvaccinated HCW, coinciding with a >90% decrease in the number of HCWs in quarantine

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Lessons from COVID-19 Vaccination Programs in Healthcare Workers

- 36,659 HCWs in California who received at least one dose of an mRNA vaccine, about 1% subsequently had a positive test; however, 71% of these infections were detected within 2 weeks of the first dose. Of 28,184 employees who received two doses, only 0.05% tested positive ≥8 days after the second vaccination
- Three weeks after receiving the first dose of BNT162b2, HCWs in Kansas with recent SARS-CoV-2 infection (or positive antibody responses at baseline) had higher levels of anti-SARS-CoV-2 antibodies than HCWs without any history of infection

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Final Thoughts

- For the India variant (Delta) mRNA is still very protective 60-65% versus our 90+%
- The rising India variant, is increasing, roughly 10% of cases and more so in the southern states. Studies show it is more contagious, more severe symptoms and increased hospitalizations. For those who may not want to vaccinate their children (for lack of data on long term effects)
- Vaccinated individuals cannot be carriers of the virus based on current data
- Complacency is NOT a solution and should NOT be an option
- **Separate flu and COVID vaccines by 2 weeks**

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