

CURRENT

- **The good news**


- **The vaccines work.** A peer-reviewed study just came out this morning, published in the Lancet. The data, gathered from December 8, 2020, through July 4, 2021, show that of more than 1.2 million adults who received a first dose, fewer than 0.5% reported contracting breakthrough infections two weeks or more after getting the jab. Among those who got both shots, fewer than 0.2% experienced a breakthrough infection a week or more after getting their second shot.

[https://www.thelancet.com/journals/lanmic/article/PIIS2666-5247\(21\)00069-0/fulltext?fbclid=IwAR3cXbFe41uZYKqjESlarmBUoabpw3_w0xT54jRLmnBIRRE9NjrRESExtSQ](https://www.thelancet.com/journals/lanmic/article/PIIS2666-5247(21)00069-0/fulltext?fbclid=IwAR3cXbFe41uZYKqjESlarmBUoabpw3_w0xT54jRLmnBIRRE9NjrRESExtSQ)

And if you don't think vaccines work, go to your local cemetery and count the number of children there before 1950 and after 1950. We have essentially eradicated most childhood disease through vaccination.

- **Kids 5-11 can now be vaccinated!**
- **Masks work.** Another recent study showed that Flu activity, or incidence of flu cases, in November 2020 was approximately 91% lower than in November 2019, according to the data. Flu vaccines were up but we were still under significant masking. Overall we had 1% of the number of hospitalizations for flu nationally in 2020 than in previous years. Yes – masks work.
<https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/about-face-coverings.html>
- **Treatments are being approved.** Merck antiviral product (molnupiravir) and Pfizer (paxlovid) EU approved for use to reduce serious COVID and hospitalizations. Preliminary data says the drug cuts hospitalizations and deaths by 50% in infected individuals. This is **not** a replacement for the vaccine.
- **Now the bad news – becoming dire.**
 - Delta is still raging through the unvaccinated population.
 - 99% of infections in the US are Delta.
 - Delta is still killing more than 1000 people a day in the US.
 - Omicron is beginning to outpace Delta.
 - In South Africa, In October, 80% of all coronavirus samples sequenced in South Africa were from the Delta lineage. Omicron wasn't even part of the mix. In November, 75% of sequenced viruses have been Omicron, with 22% Delta.
 - Omicron has >50 mutations, many of them in the protein spike region, meaning it is not only more infectious, it has a better chance of evading at least some protection from vaccines. Delta had 13 mutations.
 - So far those infected have had mild disease, but most are <40 years of age. It also appears those who had previously been infected with COVID, including Delta, can be re-infected with the Omicron variant.
 - Omicron as of this morning is in 16 states in the US and more than 30 countries, and that is likely under-reported.
 - Variant infection continues predominantly in the unvaccinated
 - Unvaccinated are 43 times more likely to be hospitalized and 5x more likely to die than unvaccinated.

- Deaths from coronavirus jumped 131% from July-August 2021 (CDC)
- 500% increase in hospitalizations among children June-August 2021 (APA)
- 27% of hospitalizations are children
- Maximum exposure time for original virus is only 15 minutes – max exposure time to infection for Delta variant is under 10 seconds. Omicron is likely the same or even worse.

Li B, Deng A, Li K, et al. Viral Infection and Transmission in a Large Well-Traced Outbreak Caused by the Delta SARS-CoV-2 Variant. medRxiv. 2021 Jul 12; <https://doi.org/10.1101/2021.07.07.21260122>

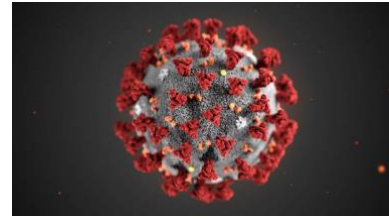
- Breakthrough infections are minimal and generally cause minimal disease, although there have been significant breakthrough cases with hospitalizations and deaths in those who were already medically compromised
- Vaccinated individuals with breakthrough are less likely to transmit disease than unvaccinated, even with the same nasal viral load (antibodies likely “clip” viral mRNA and make it less infectious)
- 97% of infections and 99% of hospitalizations and deaths are in the unvaccinated
 - The CDC studied more than 600,000 COVID cases from April through mid-July, when Delta became dominant, and found that unvaccinated people were about four and a half times more likely to get COVID, over 10 times more likely to be hospitalized and 11 times more likely to die from the disease.
 - A CDC report released in August found that unvaccinated people who previously had COVID-19 were about 2.34 times more likely to get re-infected than vaccinated people who've had it.
 - Viral loads in delta-infected patients are 1000 times more than for the original virus
- 30% of those fully vaccinated who go on to be infected are also asymptomatic; they carry as much virus to transmit as unvaccinated
- Delta variant is 200x more infectious than the original virus and causes more disease in unvaccinated
- US is at about 35,000 new cases and 1,200 deaths per day
- So, for the Love of God:
 - If you aren't vaccinated, get vaccinated. These are ridiculously safe and effective vaccines. The longer we have unvaccinated people running around, not only will we continue to have record number of hospitalizations and deaths, we create conditions for serious additional variants to evolve – and eventually one of those will be able to evade the vaccines altogether and we'll be back where we started.
 - If you are vaccinated, get the booster. Although antibody titers (levels) decline over time, cellular immunity is still robust (see the breakthrough data above) but – get the booster anyway. There are additional boosters back in clinical testing that will be targeted against delta and other variants. Get those too. Hamilton County will start booster shots 9/20.
 - Get you flu shot. Everything you can do to boost your immune system is a good thing.
 - Wear masks, whether you're vaccinated or not, whenever you are indoors in a crowd. The Presbytery office requires them.
 - Whatever precautions you had in place this past January – go back to them. Sigh deeply and shoulder the fights you're going to have. Do it anyway – because you love your community of believers and want them ALL to be safe. Ideally everyone in a sanctuary is masked at all times. For everything. VACCINATE and VENTILATE!!

Status

- The World Health Organization (WHO) has warned that the spread of coronavirus is moving faster than the global vaccine rollout
- Currently WHO reports more than **265.5 million** confirmed cases of COVID-19 globally with more than **5.3 million** reported deaths
 - All countries are involved
 - Current significant spikes in East Asia, South America and Africa
 - In the US, we have more than **50 million** confirmed cases and **808,000** deaths
- Vaccinations
 - 55% of the world population has received at least one dose of a COVID-19 vaccine (39% both doses).
 - 8.1 billion doses have been administered globally, and 34.4 million are now administered each day.
 - Only 6.2% of people in low-income countries have received at least one dose.
 - In the US, 70% have received at least 1 dose and 59% are fully vaccinated (ages 5 and up)

The Virus

- COVID-19 (SARS-CoV) is one of several coronaviruses: 4 are known to cause the common cold, one was SARS (2004) and the other MERS (2012).
 - SARS is considered contained and MERS is restricted to the Arabian Peninsula; neither have a vaccine.
 - They are far less infectious but more fatal (10-50% fatality rate) than the current COVID-19.
- It's called a coronavirus because of the "crown" of protein spikes on the surface
- All coronaviruses are spread through aerosolization and mucus exposure.
- COVID-19 has been shown to last about 4 days on impermeable surfaces and about 2 days on permeable surfaces.
- The virus is a sack of fat with protein spikes on the outside and messenger RNA (mRNA) on the inside.
 - The virus itself is not alive, but the protein spikes attach to the cell it is infecting via the ACE2 (Angiotensin-Converting Enzyme 2) receptor.
 - The ACE2 receptor is a vasodilator that influences blood flow, making it a poor target for treatment or a vaccine.
 - The ACE2 receptor is found all over the body but is prevalent on lung cells lining air sacs, which is why this virus infection can cause pneumonia.
 - Once the virus attaches to the cell via the protein spike, it injects the mRNA into the cell which takes over cellular genetic reproduction, causing the cell to become a virus factory. Eventually the cell bursts and releases additional virus.
 - Variants have been found on the structure of the protein spike which make the virus more infectious (easier to spread) but not to date more virulent (doesn't cause more or more serious disease).
 - Genetic sequence completed 1/11/2020



Infectivity

- COVID-19 is 3 times more infectious than other respiratory viruses.
- The chances of being exposed depend on how many virus particles you are exposed to and the length of time you are exposed.
- All ages can be infected. The severity of the symptomatic response is correlated to age and the presence of other underlying medical conditions, but not exclusively.
- All ages are infectious.
 - **40% of those unvaccinated who are infected are asymptomatic**, but they are still infectious (they just don't know it and neither do you).
 - For those unvaccinated who are infected and will go on to develop symptoms, **they are infectious (more highly infectious) for up to 8 days before symptoms emerge** (so again they don't yet know they are infectious and neither do you- and that could be 2 Sundays).
 - **30% of those fully vaccinated who go on to be infected are also asymptomatic; they carry as much virus to transmit as unvaccinated but the overwhelming majority don't become as ill**
 - A recent study of young children in the US showed that children – who are mostly asymptomatic – have up to **25 times** the amount of virus in the nasal passages than hospitalized adults. They can be significant vectors of community spread. At last count, testing has shown that 40-90% of children in spots are infected.

- “exposure” is multiplicative – if you’ve met with 10 people during the day and they’ve each met with 10 people, you’ve been potentially exposed to 100 people
- **Current: infections increasing in all 50 states due to unvaccinated people becoming infected with delta variant (85-95%)**
 - Delta variant India variant a triple mutation (B.1.617, delta) more highly infectious – WHO has declared a global threat; mRNA vaccines mostly effective to date – may overturn declines in UK, US. Pfizer 88% effective against it in early testing – now in all 50 states and predominant virus spreading
 - is 200% more infectious than the original virus and 60% more infectious than the Alpha variant
 - Whereas the original virus has a maximum time to infection of 15 minutes, the Delta variant has a maximum time to infection of under 10 seconds
 - Hospitalizations and deaths are also increasing; 99% of deaths and hospitalizations are in unvaccinated
 - Over 94,000 children under the age of 12 were diagnosed with COVID last week
 - Vaccinated people are getting infected with the Delta and can transmit the variant
 - Is in 60+ countries as predominant strain
 - Lambda variant (Peru August 2020) also with triple mutation at critical areas of protein spike mRNA, also more infectious and may be more resistant to the current set of vaccines – in 29 countries including US
- Significant variants have emerged (2021) – all are in the US
 - More than 4000 identified, some sequenced; some from US; CDC is warning that too early relaxation of mandates may result in a fourth spike even as vaccines are rolled out
 - Variants “of concern”:
 - **Vietnam variant of concern is a combination of the UK and India variants**
 - Variant from NYC (B.1.526) has a unique set of spike variants, which scientists at Columbia University say "could threaten the efficacy of current antibody therapies and vaccines."
 - **This is to be expected** – viruses make incomplete copies when they replicate so opportunistically variants that are at an advantage for spread will take over
 - Coronaviruses still mutate more slowly than the flu virus
- Breakthrough infection after full vaccination is expected and extremely low, with mild symptoms: Out of 157 million fully vaccinated in the US, there were 4,909 hospitalizations and 988 deaths
- The longer we have a significant portion of the population unvaccinated (in the US and globally), the more variants will emerge

Fatality, Co-Morbidity and Long-Term Sequelae (unvaccinated)

- COVID-19 is **10 times more fatal than the flu** (COVID-19 has an overall 1% fatality rate; the flu is about 0.1%)
- A 1% fatality rate in the US is 3.3 Million people
- Currently in the US 1 person dies about every 70 seconds from COVID; globally it’s about 1 every 17 seconds
- The fatality rate is generally correlated to age and underlying medical conditions
 - Fatality is 30.5/1000 for 85 years of age and above (3%)
 - Fatality is 6/1000 for 65-84, 4/1000 for 50-64, 1/900 18-29, 0.3/1000 5-17

- The virus affects the respiratory system but also the heart, liver, kidneys, GI tract, central nervous system, pancreas (causing diabetes), thyroid (affecting metabolism), and causes significant clotting in small blood vessels
- The **long-term consequences** are far more significant than other viruses: for every 1 fatality there will be:
 - 19 hospitalizations (62 million)
 - 18 who develop permanent heart damage (in one study, 80% of those who recovered showed heart damage by MRI) (59 million)
 - 10 who develop permanent lung scarring and damage (32 million)
 - 3 who develop permanent kidney damage (10 million)
 - 3 strokes (10 million)
 - 2 permanent neurological defects (up to and including psychoses, especially in younger population) (6.5 million)
 - 2 significant cognitive dysfunctions (6.5 million)
 - Long-lasting nerve damage, affecting everything from smell to walking
 - COVID-19 can cause both pulmonary and systemic inflammation, potentially determining multi-organ dysfunction: the virus can get into the pancreas and cause diabetes in those not otherwise predicated; the virus can get into the thyroid and affect the thyroid gland as well as the entire hypothalamic-pituitary-thyroid (HPT) axis; the virus can get into the thymus and disrupt regulation of disruptive immune responses and future predication for chronic diseases including atherosclerosis, hypertension and type 2 diabetes.
 - People younger than 21 account for about one-quarter of the population in the United States, but they make up less than 1 percent of deaths from Covid-19. Still, about 2 percent of children who get Covid-19 require hospital care, and at least 560 children in the United States have died of the disease. Heart issues are the primary reason.

Symptoms

- Early cardinal symptoms include loss of taste and smell, fatigue, shortness of breath, fever, dry cough, joint pain, heaviness in the chest; Progressive symptoms include acute respiratory failure, sepsis, intravascular coagulation (blood clots), and multi-organ failure
- Symptoms are long-lasting – 3 months' post recovery only about 12% are symptom-free, and symptoms can recur after abating
- Stillbirths with infection have been reported to be as high as 80% of pregnancies

Treatments

- There are very few significantly effective treatments for COVID-19
- Normal flu treatments (neuraminidase and endonuclease inhibitors) do not work on COVID-19
- Early in the infection treatment with an anti-viral (Remdesivir) showed some promise; later (smaller studies) have called that into question. Remdesivir just approved by FDA for COVID (10/20); the only approved treatment
- Later in the infection, to stem a hyper-immune response and cytokine storm (causing significant inflammation in the body, the cause of some of the long-term consequences), anti-inflammatory agents (Dexamethasone, a steroid) have been shown to be marginally useful
- Convalescent plasma has also shown some promise but has not been sufficiently tested to demonstrate proof. FDA has not approved convalescent plasma for treatment.
- Some physical manipulation, such as lying the patient on their stomach instead of their back, has provided some relief of lung damage

- Studies with monoclonal antibodies for treatment and potentially prevention are underway (this approach has been shown to be effective for Ebola)
 - In November 2020, the FDA granted emergency use authorization to two monoclonal antibody treatments (bamlanivimab, made by Eli Lilly; and a combination of casirivimab and imdevimab, made by Regeneron). Both treatments have been approved for non-hospitalized adults and children over age 12 with mild to moderate COVID-19 symptoms who are at risk for developing severe COVID-19 or being hospitalized for it. In these patients, the approved treatments can reduce the risk of hospitalization and emergency room visits. These therapies must be given intravenously (by IV) soon after developing symptoms.

Immunity

- The native immune response to COVID-19 has generally been shown to be weak and short-lived
- T-cell response (one of the types of normal immune cells in the body) to the virus may be a more important measure of long-duration immunity than antibody formation and duration, however, tests for antibody are quick and inexpensive, whereas testing for T-cell response is difficult and expensive
- Currently there have been antibodies demonstrated 3-4 months after infection and at least 8 months after vaccination
- Documented re-infections show that native immunity is too specific to cover variants

Vaccines

US

- Full approvals are being sought currently by both Moderna and Pfizer and are expected to be granted by fall.
- Pfizer submits data ages 5-12 in September; Moderna slightly later – vaccines for children ages 5-12 should be approved by the end of the year
- Boosters for the mRNA vaccines will be available beginning September 2021 for use 8 months after second dose. Booster for J&J not yet available.
- 50% US population have received both doses; 58% have received at least one dose. J&J one-dose vaccine is re-established by FDA.
 - “Herd” immunity (80-90% immune) – announced 5/3/21 not likely to be achieved this year as vaccination rates continue to decline and vaccines for children/adolescents not yet approved. Virus is endemic –will become a constant but manageable threat globally for several more years. Variants developing too quickly for herd immunity to be reasonably expected.
 - Vaccines are not as effective in immunocompromised patients

Global

- 32.4% of the world population has received at least one dose of a COVID-19 vaccine, and 24.4% is fully vaccinated.
- 4.93 billion doses have been administered globally, and 34.25 million are now administered each day.
- Only 1.4% of people in low-income countries have received at least one dose.

Vaccine Approval

- In the US, 3 vaccines are approved by FDA for Emergency Use – this **IS AN APPROVAL** – both Moderna and Pfizer have now applied for full approval
 - Two utilize an mRNA technology, using snippets of the coronavirus mRNA that will infect but not cause disease, to prime the immune system into recognizing the virus and providing early immunity (Moderna and Pfizer)
 - **The mRNA of the vaccine does not affect the human DNA or fertility at all!**

- both vaccines have been shown to be highly effective (95%)
- mRNA vaccines had never been commercialized in the US and require extreme transport and storage conditions (up to -70° F), making them difficult to use and requiring some additional safety information for review and approval; Pfizer has completed additional testing and the vaccine can safely be stored in a normal freezer
- both have been approved by FDA and the EU board of health for emergency approval and are rolled out per CDC guidelines (approved only for ages 12 and up)
- initial side effects are generally mild flu-like symptoms; anaphylaxis is rare but under evaluation
- takes 2-4 weeks for immunity to develop – can still be infected during that time and can still pass the virus after immunization
- boosters 3-4 weeks apart to get to full immunity potential
- If you have had COVID wait 90 days before getting the vaccine to avoid competing with natural antibodies
- These manufacturers have made all safety data available to consumers
- Pfizer and Moderna vaccines safely tested in more than 100,000 pregnant women.
- These are showing results similar or better to the antibody and T-cell responses after recovery from the virus (similar to the body's response)
- Vaccine data shows that the vaccine appears as effective in older patients as in younger (not true for all vaccines).
- Testing combinations of vaccine and different booster, as well as testing boosters for key variants
- Pfizer/Moderna vaccines in Phase III clinical trials for children 6 months+
- Approvals in younger children possibly available fall 2021 to 1Q 2022
- Moderna announced that it has shipped doses of its booster vaccine for the South Africa variant to the National Institutes of Health for clinical study.
- Other vaccines are using traditional vaccine manufacture processes, similar to the vaccines on the market today
 - These will be easier to manufacture/transport/store globally – no extreme refrigeration required
 - Emergency Use Approval for Janssen (1 shot) granted in March 2021.
 - Reports of reduced effectiveness for Janssen due to timing of trials (likely included more patients infected with variant): 72% effective in US and 57% effective in SA (but not yet tested on UK and other variants) – single dose; adenovirus carrier
- Manufacturers and scientists are also engaged in an unprecedented open-source data share
- **Only vaccinations will protect – simply having the vaccine and expecting others to be vaccinated will not provide epidemiologic protection sufficient to stop virus spread – will need to stay masked and distanced through fall.**
- Need for booster vaccines and/or annual shots likely but the vaccines are proving to be more long-lasting and robust (against current known variants as well) than anticipated
- mRNA vaccines are about 80% effective against Delta variant with both shots but only 33% effective against the variant if only one shot

What Can I do with a Vaccine?

- A vaccination is not a magic cape
 - Even 95% efficacy means that statistically 19 out of 20 people are effectively covered by the vaccine but 1 in 20 is not

- Vaccines are less effective against variants
- Vaccines are less effective in immunocompromised individuals
- Being vaccinated means it's unlikely YOU will become seriously ill, but there is still a chance you can catch a variant and/or be infectious (be a virus carrier)
- State and CDC regulations are coming back in place. Enclosed spaces remain areas of risk. That includes churches without ventilation.
- Herd immunity is defined as 70-90% of the entire population vaccinated (not just your congregation)
- Globally
 - Canada, Europe, some Middle East, some Caribbean and some others about same rate or higher than US
 - Africa, Central America, Australia/New Zealand, most of South America, most of Eastern Europe and the Baltic/Nordic region, most of Asia is much lower
 - <https://www.cnn.com/interactive/2021/health/global-covid-vaccinations/>
 - international travel is risky right now
- **Breakthrough infection after full vaccination is about 0.01% - miniscule but likely under-reported.**
 - Unvaccinated people who are infected will carry the virus at a much higher level than vaccinated people
 - About 30% of those infected after full vaccination are still asymptomatic
 - More than 50% are in those 60+
 - Variant breakthrough is only one possible reason people can be infected after full vaccination, but it is possible variants will emerge that are not covered by the current vaccines
 - Other reasons – all being investigated at this point:
 - Exposure level to virus/variant
 - Other medications that lessened the vaccine effect
 - Other lifestyle or underlying medical issues
 - If you get symptoms even after full vaccination, insist on a COVID test

BOTTOM LINE – Get Vaccinated!! Continue to distance and wear a mask in a crowd!