COVID-19

Statistics, Therapies, Impact, and the Future

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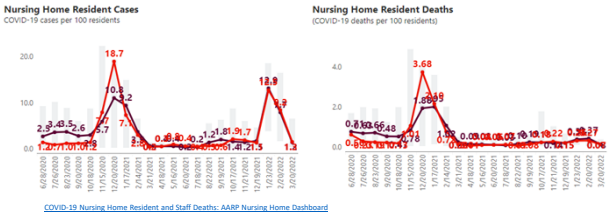
COVID statistics

- U.S. Total Cases-80,998,091
- U.S. Deaths-990,367
- CO Total Cases-1,382,091
- CO Deaths-13,201



COVID-19 Nursing Home Resident and Staff Deaths: AARP Nursing Home Dashboard

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Deaths from COVID-19 in the U.S. are broken down as follows by age as of January 2022: (CDC)

Ages 0–4: 0% of total deaths
Ages 5–11: 0%
12–15: 0%
16–17: 0%
18–29: 0.8%
30–39: 1.8%
40–49: 4%
50–64: 17.6%
65–74: 22.1%
75–84: 26%
85+: 27.7%

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Therapeutics

Brief Overview

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NOT IN THE HOSPITAL

Symptoms for 5 days or less

- **Paxlovid™:** This medication is taken by mouth (as a pill) to treat mild to moderate symptoms of COVID-19. It must be given within 5 days after the first symptoms of COVID-19 appear. Paxlovid is for adults and children who are 12 years of age and older, weighing at least 88 pounds. Paxlovid may interfere with hormonal contraceptives (such as pills, an implant, an intrauterine device [IUD], injections, vaginal rings, and skin patches), so other contraceptive methods are advised. Paxlovid is not recommended for people with serious kidney or liver disease.
- **Lagevrio (molnupiravir):** This medication is taken by mouth (as a pill) to treat mild to moderate symptoms of COVID-19. It must be given within 5 days after the first symptoms of COVID-19 appear. Lagevrio is for adults 18 years and older. Lagevrio is not recommended during pregnancy or when breastfeeding. Also, additional contraceptive methods are required for a short while after the last dose.

Symptoms for 7 days or less

- **Bebtelovimab:** This is a mAb for adults and children 12 years or older (weighing at least 88 pounds) who have tested positive for COVID-19, have mild to moderate symptoms, are not in the hospital, and are at high risk for serious COVID-19. Bebtelovimab must be given within 7 days after the first symptoms of COVID-19 appear.
- **Remdesivir:** This antiviral treatment is also known as Veklury®. It is for patients staying in the hospital and patients who are not in the hospital. Patients who are not in the hospital must go to an IV infusion center to receive this treatment. Remdesivir must be given within 7 days after first symptoms of COVID-19 appear.

IN THE HOSPITAL

- **COVID-19 convalescent plasma:** Convalescent plasma is blood plasma taken from people who have recovered from COVID-19. It contains antibodies that treat SARS-CoV-2, the virus that causes COVID-19; it also contains other components that may improve a person's immune response to the virus. Convalescent plasma is for patients staying in the hospital and who have a weakened immune system.
- **Baricitinib (Olumiant®):** This mAb treatment is for patients 2 years of age or older who require supplemental oxygen, invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO) to treat COVID-19.
- **Tolcilizumab (Actemra®):** This is a mAb treatment for adults and pediatric patients (2 years of age and older) who are receiving corticosteroids and who require supplemental oxygen, a ventilator, or ECMO. Actemra may decrease the risk of death for patients in the hospital with COVID-19.
- **Remdesivir:** This antiviral treatment is also known as Veklury. It is for patients staying in the hospital and patients who are not in the hospital. Remdesivir must be given within 7 days after first symptoms of COVID-19 appear.

The U.S. Food and Drug Administration (FDA) has authorized these treatments for emergency use. Learn more about remdesivir, Actemra, bebtelovimab, Paxlovid, and Lagevrio.

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Remdesivir

- Remdesivir should be given as a 200 mg intravenous infusion on Day 1, followed by remdesivir 100 mg intravenously on Days 2 and 3. Infusion should occur over 30 to 120 minutes.
- Treatment should be initiated as soon as possible and within 7 days of symptom onset in all patients.
- Perform hepatic laboratory and prothrombin time testing in all patients before starting remdesivir and during treatment as clinically appropriate.
- The PINETREE trial showed that 3 consecutive days of IV remdesivir resulted in an 87% relative reduction in the risk of hospitalization or death compared to placebo

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Paxlovid

- Paxlovid is composed of two distinct agents; nirmatrelvir an inhibitor of coronavirus protease and ritonavir, an inhibitor of CYP3A (ritonavir is also an HIV-1 protease, not related to its action against SARS-CoV-2). Ritonavir is needed to slow the metabolism of nirmatrelvir.
- A normal Paxlovid dose consists of 300 mg nirmatrelvir (two 150 mg tablets) AND 100 mg of ritonavir (one 100 mg tablet). These three tablets will be packaged together and all three taken together as a single dose.
- Paxlovid is taken orally with or without food.
- Paxlovid is taken twice daily for 5 days for a complete a course. As noted above each dose consists of three tablets.
- Paxlovid has been shown to reduce severe disease or death by 88%.

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Molnupiravir

- MOV is an oral prodrug with activity against SARS-CoV-2. After intracellular metabolism, the MOV metabolic byproduct is incorporated into viral RNA causing lethal viral mutagenesis and inhibition of viral replication.
- A normal MOV adult dose is 800 mg (four 200 mg tablets) taken orally every 12 hours for 5 days.
- MOV is taken orally with or without food.
- Molnupiravir has been shown to reduce severe disease or death by 30%.

- MOV may cause fetal harm in pregnancy.
  - MOV is not recommended for use in pregnancy.
  - Advise women of childbearing potential of the potential risk to a fetus during treatment with molnupiravir and for 4 days after the final dose.
  - Advise sexually active males with partners of childbearing potential of risks during treatment and for at least 3 months after the last dose of molnupiravir.
  - Breastfeeding is not recommended during treatment with MOV and for 4 days after the final dose.

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Monoclonal Antibodies

- Bebtelovimab is an investigational neutralizing immunoglobulin G1 (IgG1) mAb that binds to the SARS-CoV-2 spike protein.
- Laboratory testing showed that bebtelovimab retains activity against both the omicron variant and the BA.2 omicron subvariant.
  - Clinical trials did NOT include persons at high-risk for severe COVID-19.
  - Clinical trials did NOT show a reduction in death or progression to severe disease.
  - Clinical trials did NOT involve any patient infected with Omicron.
  - EUA was authorized solely based on laboratory efficacy vs Omicron.
- Bebtelovimab is administered as a single 175 mg intravenous dose over at least 30 seconds.
- 5. Bebtelovimab should be administered as soon as possible after a positive test for symptomatic COVID-19 and within 7 days of symptom onset.
- Other Monoclonals are not effective against BA.2 variant
- Evusheld does retain activity, but is not for treatment, only pre-exposure prophylaxis

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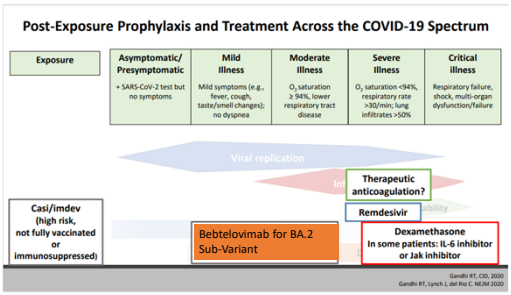

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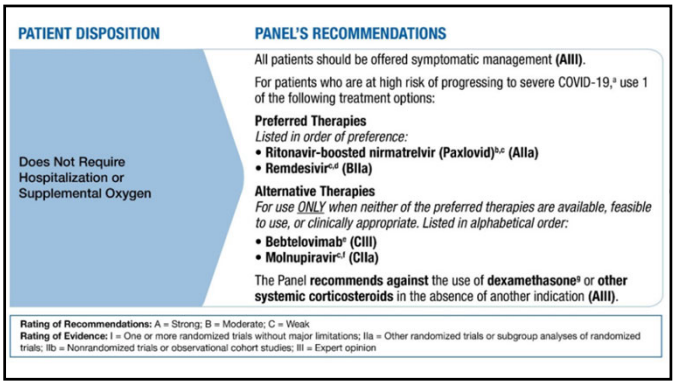

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COVID-19 and Vitamin D

- Evidence to show that Vitamin D deficiency does correlate with greater risk of severe disease
- Patients with vitamin D deficiency (<20 ng/mL) were 14 times more likely to have severe or critical disease than patients with 25(OH)D ≥40 ng/mL
- Vitamin D is a known regulatory component of the innate immune system and adaptive response to viral infections.
- Other studies demonstrated NO benefit to treatment with Vitamin D

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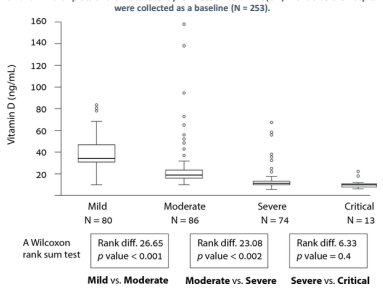
Fig 2. Box-and-whisker plots of the most recent pre-infection serum 25(OH)D levels before hospitalization were collected as a baseline (N = 253).



A Wilcoxon rank sum test	Rank diff. 26.65, *p* value < 0.001	Rank diff. 23.08, *p* value < 0.002	Rank diff. 6.33, *p* value = 0.4
	Mild vs. **Moderate**	**Moderate** vs. **Severe**	**Severe** vs. **Critical**

Dror AA, Morozov N, Daoud A, Namir Y, Yakir O, et al. (2022) Pre-infection 25-hydroxyvitamin D3 levels and association with severity of COVID-19 illness. PLOS ONE 17(2): e0263069. https://doi.org/10.1371/journal.pone.0263069
https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0263069

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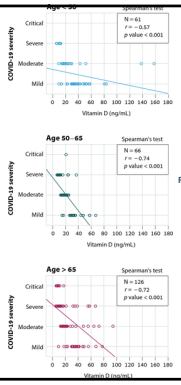

Fig 3. Correlation between pre-infection vitamin D deficiency status and COVID-19 disease severity stratified by three different groups of age (<50, 50–64, ≥65).

Dror AA, Morozov N, Daoud A, Namir Y, Yakir O, et al. (2022) Pre-infection 25-hydroxyvitamin D3 levels and association with severity of COVID-19 illness. PLOS ONE 17(2): e0263069. https://doi.org/10.1371/journal.pone.0263069
https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0263069

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Infection Control

Renewed Focus

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— C. S. Lewis

- "Of all tyrannies, a tyranny sincerely exercised for the good of its victims may be the most oppressive. It would be better to live under robber barons than under omnipotent moral busybodies. The robber baron's cruelty may sometimes sleep, his cupidity may at some point be satiated; but those who torment us for our own good will torment us without end for they do so with the approval of their own conscience."

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FACT SHEET: Protecting Seniors by Improving Safety and Quality of Care in the Nation's Nursing Homes, Feb.2022

- A set of reforms from HHS through CMS
- Improve quality and safety of nursing home care
- Hold nursing homes accountable
- Make the quality of care and facility ownership more transparent
  - "resident outcomes are significantly worse at private equity-owned nursing homes"
  - "Another study found that private equity-backed nursing homes' COVID-19 infection rate and death rate were 30% and 40% above statewide averages, respectively."
  - "despite depriving residents of quality care, private equity-owned nursing homes actually led to an uptick in Medicare costs"

- FACT SHEET: Protecting Seniors by Improving Safety and Quality of Care in the Nation's Nursing Homes | The White House

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White House Statement Quotes

The pandemic has highlighted the tragic impact of substandard conditions at nursing homes,

failure to comply with Federal guidelines at nursing homes is widespread

82% of all inspected nursing homes had an infection prevention and control deficiency, including a lack of regular handwashing,

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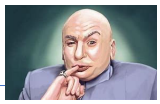
White House action points



- Minimum Staffing requirements
- Single occupancy rooms
- SNF-VBP-payment changes based on staffing and staff retention, resident experience
- Reinforce Safeguards against unnecessary meds
- $500 million for increased inspections
- Increased scrutiny of poor performers (more frequent inspections)
- Change 1-time fines to daily until issue corrected and increase max penalty from $21K to $1 million dollars

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White House Statement Continued

- Initiatives around increasing transparency
- Initiatives for workforce sustainability including Unionization
- Pandemic preparedness-
  - COVID testing and vaccinations
  - Increase requirements for on-site IP
  - Enhanced Pandemic Preparedness
  - Integrate Pandemic Lessons into Nursing Home requirements

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Is Medicare Running Out of Money?

- Medicare may be in trouble, but it is not going bankrupt. According to a 2021 report by the Biden administration, the Medicare Hospital Insurance (HI) trust fund will be depleted if healthcare expenses continue to exceed money flowing in. Without new legislation, it's estimated that by 2026, Medicare Part A may only be able to pay for 91% of the costs it covers today.

Is Medicare Going to Run Out of Money? (verywellhealth.com)

Centers for Medicare & Medicaid Services. Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds.

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AMDA Response

- AMDA Response to SOTU Final.pdf (paltc.org)
- "We welcome some of the proposed initiatives the President has outlined, including reduced occupancy or single-occupancy resident rooms, full-time infection preventionists, launching a Nursing Home Career pathway and greater ownership transparency in our setting. Unfortunately, some of the proposed policies appear to double down on the same punitive measures that for the last three decades have not materially improved the patient or resident experience in PALTC."
- The Society has embraced this bold vision and strategy in a special issue of our medical journal, JAMDA
- (https://www.jamda.com/issue/S1525-8610(21)X0011-4)

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"Do, or it will be done to you!"

~Clay Watson, MD

- Many of these proposals require congressional approval
- You have an advocate in AMDA, use them, get involved, fund them, use other effective Organizations
- Though CMS is running low on dough, there are other sources. Seek out grants from Federal, State and private entities to fund IP/IC initiatives.
- Mandate IP networking, collaboration,
- Find the "easy wins" in IC, take them and become the expert
- Reach out to partners who understand the space, other operators, researchers, Optum (payors). We have an IP program ready and willing to assist.

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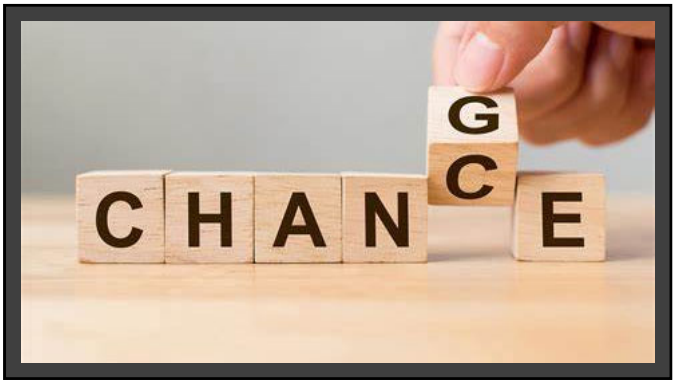

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