COVID in the Nursing Homes: The US Experience

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Abstract

The death toll in nursing homes accounted for almost 30% of total COVID-19 deaths in the U.S. We examine the course of the pandemic in nursing homes focusing especially on where policy failed or might have been improved. Could nursing homes have been better isolated, protecting the elderly while lifting restrictions on the young? Could nursing home residents have been vaccinated earlier? We evaluate the evidence of successful shielding of nursing homes, including the relationship between traditional quality measures and COVID-19 outcomes. Results suggest it was always going to be difficult to protect vulnerable nursing home residents from SARS COV-2. However, policy failures from the CDC and FDA made things worse causing severe shortages and extended wait times for COVID-19 tests, which hampered attempts to isolate infectious residents and allowed outbreaks to grow larger and deadlier. Earlier vaccinations could have saved tens of thousands of lives and is likely the single most important policy that could have been pursued.

Introduction

Nursing homes were the epicenter of the pandemic. In the United States there were approximately 60 COVID cases - mostly connected to the Diamond Princess cruise ship - when a 73 year old woman, hospitalized in the Seattle area, tested positive on February 28, 2020. The woman had no history of travel or known exposure, but the nursing home she was admitted from had experienced a cluster of respiratory illness starting in mid-February, prompting a full investigation by the Center for Disease Control and Prevention (CDC) and the Seattle & King County Public Health authority. By March 9th a major outbreak was undeniable; 111 cases were identified including 81 of the facility's 130 residents (62%), 17 staff, and 13 visitors. Just as concerning was the damage the virus inflicted. Of the 81 residents infected, 46 were hospitalized (57%) and 22 (27%) died (McMichael et al., 2020).

The outbreak at Life Care Center in King County was the first glimpse of the risks posed by the virus to the country's 15,436 nursing homes and their 1.3 million residents.[1] Nursing homes were like tinder boxes for communicable disease because close contact between staff and residents is unavoidable when nearly 90% of residents need daily help with activities like eating and getting out of bed.[2] In addition to an average age of 78, the typical nursing home resident also had multiple risk factors and preexisting comorbidities; 77% of residents had diagnosed high blood pressure, 29% were obese, and 23% had congestive heart failure, all factors associated with higher risk for severe illness and death.[3]

Few nursing homes were able to avoid the virus. Between Jan 1, 2020 and Jan 3, 2021, around the time the first vaccinations started having an effect, 92% of nursing homes had experienced at least one resident case and 75% had one or more deaths. 553,660 residents had tested positive, as well as 474,195 of the roughly 1.5 million staff members.[4] Overall there were 107,413 confirmed COVID deaths in nursing homes and recent research shows substantial underreporting in the first half of 2020, bringing the estimated death count in nursing homes during closer to 124,000, almost a third of all COVID deaths (380,272) in 2020.[5]

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[1] This is not quite right. As Carter Mecher had pointed out in a Feb. 20 "Red Dawn" email the passengers on the Diamond Princess cruise ship, although mobile and in relatively good health, were quite elderly and not dissimilar from many nursing home and resident care residents. For the Red Dawn emails see Lipton, Eric. 2020. "The 'Red Dawn' Emails: 8 Key Exchanges on the Faltering Response to the Coronavirus." *The New York Times*, April 11, 2020, sec. U.S. https://www.nytimes.com/2020/04/11/us/politics/coronavirus-red-dawn-emails-trump.html.

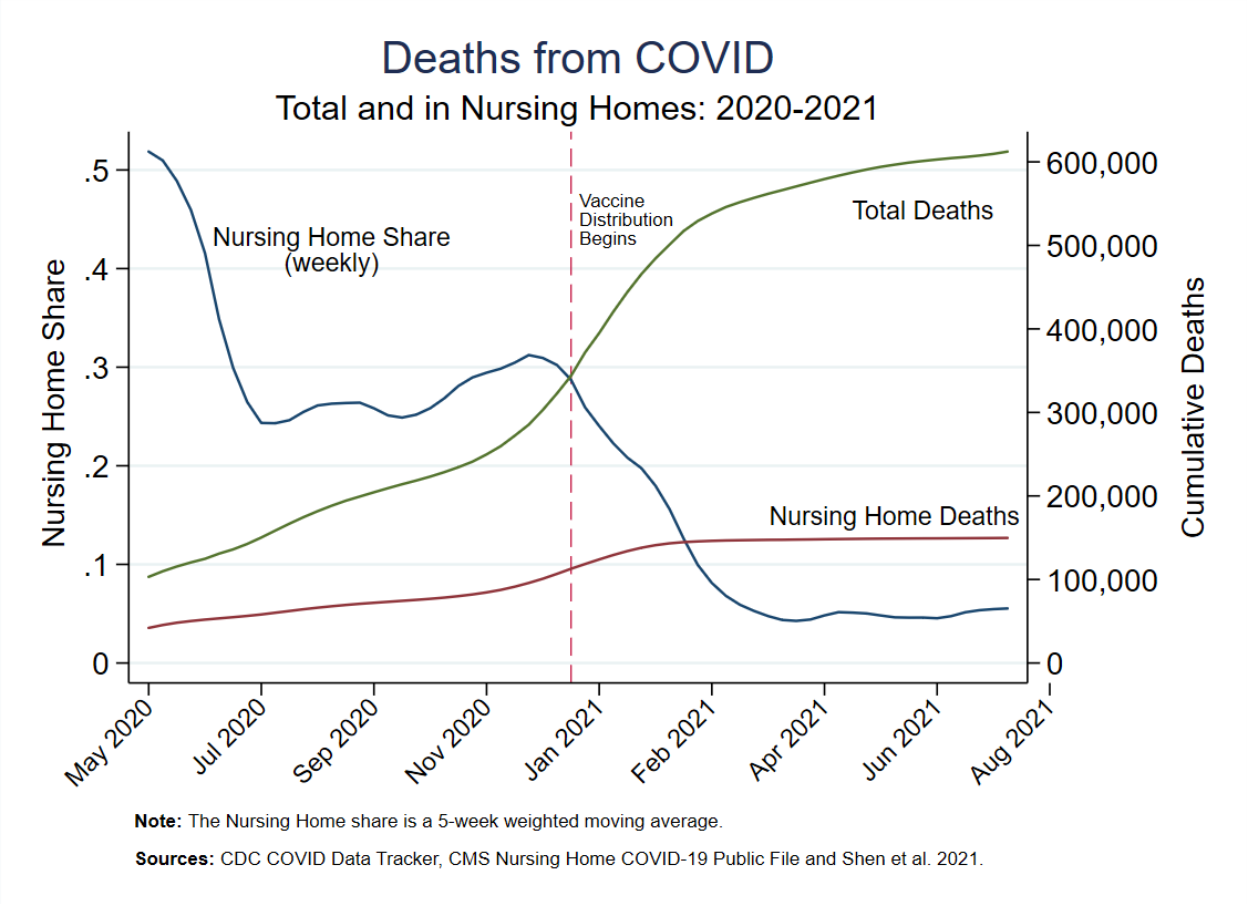
[2] LTCFocus Public Use Data from the National Institute on Aging (P01 AG027296) and Brown University School of Public Health. Available at www.ltcfocus.org.

[3] See CDC List of Underlying Medical Conditions Associated with Higher Risk for Severe COVID-19, available at https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/underlying-evidence-table.html

[4] U.S. Bureau of Labor Statistics (BLS), Division of Occupational Employment Statistics. May 2020 National Industry-Specific Occupational Employment and Wage Estimates. Available at https://www.bls.gov/oes/current/naics4_623100.htm.

[5] On confirmed nursing home deaths see CMS Nursing Home COVID-19 Public File, https://data.cms.gov/covid-19/covid-19-nursing-home-data. Note that the nursing home resident population turns over in a year so the total population moving through nursing homes is larger than the average population. See

Figure One shows total deaths and nursing home deaths and the weekly share of nursing home deaths from May 2020 to August 2021. Until vaccine distribution began, nursing home deaths were 25-30% of total deaths. Vaccine distribution began in mid-December with priority given to nursing homes. The vaccines reduced nursing home deaths dramatically along with nursing home deaths as a share of total deaths which fell from about 30% in mid-December to approximately 5% by March of 2021.



The outbreak in King County confirmed the potential for tragedy. On March 18, the CDC warned "Substantial morbidity and mortality might be averted if all long-term care facilities take steps now to prevent exposure of their residents to COVID-19. The underlying health conditions and advanced age of many long-term care facility residents and the shared location of patients in one facility places these persons at risk for severe morbidity and death."(McMichael et al., 2020)

Thus, the risks to nursing home residents were acknowledged at the time and in fact many steps were taken to protect nursing home residents. While mistakes were made, a topic we'll return to, the

(Shen et al., 2021) for information on undercounts, and CDC COVID Data Tracker, https://covid.cdc.gov/covid-data-tracker/ for total deaths.

devastation in nursing homes happened despite the allocation of significant resources, both public and private, to protect nursing home residents.

In what follows we examine in greater detail the course of the pandemic in nursing homes focusing especially on where policy failed or might have been improved. We also ask whether some nursing homes performed better than others and if so what lessons are to be learned. Did quality certification or regulation, for example, predict nursing home success. Could the nursing homes have been better isolated from the pandemic, protecting the elderly while lifting restrictions on the young as some commentators--most notably the Great Barrington Declaration--advocated?

Isolation and Testing

The nursing homes were an ideal place for using testing as a public health (prophylactic) measure but that wouldn't come until much later. In the early months, it was difficult to test anyone. SARS-CoV-II testing was delayed in the United States due to a series of failures and policy actions by the CDC and the FDA. The initial test developed by the CDC was botched by contamination due to a failure of CDC labs to follow standard operating procedures (Gottlieb 2021).

A single failure should not have been critical but instead of encouraging and aiding private test suppliers to enter the market the CDC and the FDA essentially monopolized the market. The CDC, for example, stated that only the CDC could operate its test and they refused to provide virus samples to test manufacturers (Gottlieb 2021). The FDA also issued guidance requiring manufacturers to have SARS-CoV-II tests pre-approved, a new "emergency requirement" that flouted the long-held understanding that laboratory developed tests did not require FDA pre-approval (Gottlieb 2021, Malani and Tabarrok 2021, Clement and Tribe 2015).

As a result, in the entire month of February the CDC managed to test fewer than 4000 samples. During the same time period, German manufacturers had produced and shipped hundreds of thousands of test kits (Gottlieb 2021). The failure to ramp-up testing--which could only be done with the involvement of the large private labs--had cascading consequences.

With so few tests available, the CDC issued stringent guidelines on who could be tested--essentially restricting testing to symptomatics with a close connection to China or a confirmed case at a time when it was already clear that asymptomatic transmission was possible and likely common. The failure to test meant that the spread of the virus was invisible to policy makers, including the CDC itself. Scott Gottlieb (2021, p. 132) writes:

> The [CDC] took deliberate steps to enforce guidelines that would make sure it didn't receive more samples than its single lab could handle. In late March, the CDC went so far as to edit an article that was slated for publication in a science journal, to remove a passage inserted by a Washington State public health official that called for widespread testing at senior assisted-living

> facilities. That statement encouraged more testing than the CDC was prepared to allow or was able to handle at the time.
>
> ...Clinicians and local health officials would later say that they often had to press CDC officials for days to get the agency to accept a sample from a patient that doctors suspected of having COVID.

Limiting tests often meant that by the time a facility had a positive test, the virus had already spread throughout the facility. Recall the King County outbreak mentioned in the introduction. The outbreak started mid-February, with multiple residents getting severely ill, including hospitalizations at least as early as February 24, but COVID tests could not be done until February 27 (as no staff/residents had traveled to Hubei etc.) when the interim guidance for testing changed to include unexplained respiratory illness. Thus, the first positive test of a person with no connection to a previous COVID case or China was on February 28.[6]

Another example of this is Canterbury Health and Rehab, a 190-bed facility outside of Richmond, VA, where a resident was confirmed positive on March 19. Even after the CDC gave symptomatic patients in long term care facilities Priority 2 status for testing on March 24, no residents met the requirements for testing because Virginia also required there to be "no alternative diagnosis", before COVID tests would be approved.[7] Thus, clinicians were required to test for influenza, other respiratory infections, even run x-rays before testing for COVID. Despite a willing test supplier and pleas from medical directors to the state's Governor, two weeks went by from the index case until mass testing was done, at which point 92 of the 160 residents tested positive. Fifty four residents, more than half of the positive cases, were asymptomatic at the time of the test, but symptoms would soon appear as approximately 50 residents died over the next few weeks in what at the time was one of the country's deadliest outbreaks.[8]

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[6] For guidance pre February 27, see https://web.archive.org/web/20200227031026/www.cdc.gov/coronavirus/2019-nCoV/hcp/clinical-criteria.html and for post Feb 27, see https://web.archive.org/web/20200228190044/www.cdc.gov/coronavirus/2019-nCoV/hcp/clinical-criteria.html

[7] Virginia Guidance on Testing as of March 20, 2020. https://www.vdh.virginia.gov/content/uploads/sites/182/2020/03/VDH-Updated-Guidance-on-COVID19-Testing_FINAL.pdf .

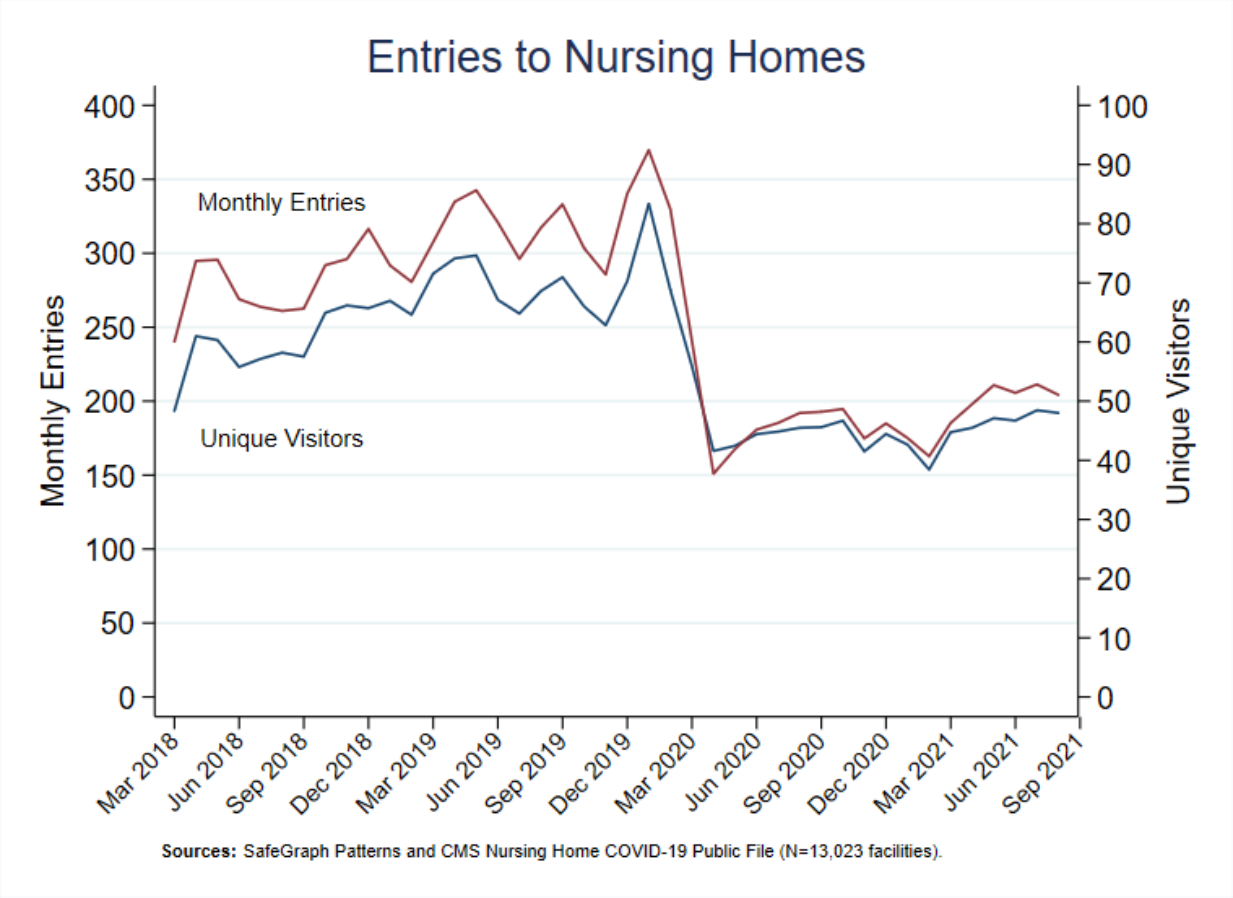
[8] For data on the Canterbury outbreak see the COVID Tracking Project, https://covidtracking.com/, which reports 49 deaths and 154 cases on the first available report, dated July 9, 2020. It is unclear why the facility only reported 2 deaths and 102 cases to CMS as of May 24, 2020, but the figures from the COVID Tracking Project align with media reports from the time, see for instance, AP News "11,000 deaths: Ravaged nursing homes plead for more testing" which reported 49 deaths on April 24, https://apnews.com/e34b42d996968cf9fa0ef85697418b01. For an interview with Jim Wright, Canterbury's Medical Director at the time, see "'Every day I grieve': A deadly COVID outbreak at Canterbury Rehabilitation changed long-term care", by Michael Martz, Richmond Times-Dispatch, March 19, 2021, available at https://richmond.com/news/state-and-regional/govt-and-politics/every-day-i-grieve-a-deadly-covid-outbreak-at-canterbury-rehabilitation-changed-long-term-care/article_3eba6f1d-fb40-5184-9a19-50b75da6f547.html

On March 27, the CDC investigative team released another MMWR report from a neighboring facility of Life Care Center of Kirkland, where an outbreak had developed despite visitor restrictions, twice daily assessments of residents, and fever screening staff before every shift. The report concluded "Symptom-based screening in SNFs could fail to identify approximately half of residents with COVID-19."
Despite this, test availability meant CDC guidelines continued to limit testing for nursing home residents to those with symptoms, even after nursing home residents were made high priority on April 27.[9] While CMS recommended weekly testing of all staff and residents on May 18, supply constraints meant that in practice, testing remained limited to those with symptoms or facilities with known outbreaks (CMS, 2020).

In the absence of testing, isolation became necessary. On March 4, 2020, the Center for Medicare and Medicaid Services (CMS) issued guidance to screen people entering, isolate potentially infectious residents, and suspend non-emergency health inspections. On March 13 the nursing homes were ordered to lock down completely by canceling group activities, communal dining, and prohibit entry from non-essential personnel and visitors, except on a case-by-case basis for end-of-life situations.[10] Cell phone data in Figure Two suggests that entries to nursing homes started falling in February and continued to plummet in March and April as visitation restrictions and stay-at-home orders were imposed.[11]

Figure Two

[9] For CDC Test criteria as of April 27, 2020, see web.archive.org/web/20200428234951/https://www.cdc.gov/coronavirus/2019-nCoV/hcp/clinical-criteria.html.
[10] It is worth noting here that while the CDC didn't recommend face masks for use in public until April 3, CMS recommended them be made "available and accessible" in facility entrances, waiting rooms, patient check-ins of nursing homes on March 4, and required visitors to wear them starting on March 13. For more on this guidance see CMS Memo, Guidance for Infection Control and Prevention Coronavirus Disease 2019 of (COVID-19) in Nursing Homes, QSO-20-14-NH, March 4, and the revised version that includes visitation from March 13, 2020, available at www.cms.gov/files/document/qso-20-14-nh-revised.pdf. For more on the suspension of health inspections see CMS Memo: Suspension of Survey Activities ("QSO-20-12-all.pdf," 2020).
[11] Some of the initial drop reflects fewer post-acute care admissions, as most elective surgeries were put on hold.



It is ironic, given the goal of isolation, that one of the few groups allowed to enter nursing homes during this period were COVID-19 patients who were discharged from hospitals to free up hospital capacity. Nursing home operators were reluctant to admit patients without knowing whether they were still infectious but were often required to admit COVID patients. On March 25, New York controversially required nursing homes to admit medically stable COVID patients, an order that also prohibited homes from requiring a test before admission.[12] New Jersey, Pennsylvania, and Michigan soon followed suit.

It's unknown how many additional COVID cases were created by sending discharged patients to nursing homes. The incubation time of the virus suggests that few patients would still have been infectious, and thus the admissions were mostly resulting from, rather than contributing to the nursing home outbreaks in these states.[13] Nevertheless, admitting anyone, let alone a COVID patient, to the tinderbox of nursing

[12] New York State Department of Health, "Advisory: Hospital Discharges and Admissions to Nursing Homes", March 25, 2020, available at https://dmna.ny.gov/covid19/docs/all/DOH_COVID19%20_NHAdmissionsReadmissions_%20032520.pdf

[13] For analysis of the New York admission requirements see "Factors associated with Nursing Home Infections and Fatalities in New York State During the COVID-19 Global Health Crisis", New York State Department of Health, February 11, 2021, available at www.health.ny.gov/press/releases/2020/docs/nh_factors_report.pdf.

homes carried some risk. It seems likely that more could have done to isolate these patients, either temporarily in facilities like the Javits Center and the USNS Comfort that went largely unused, or in designated "COVID-only" nursing homes, an approach that was attempted in Massachusetts (Dafny and Lee, 2020) and a handful other states (Connecticut, New Mexico, Rhode Island, Utah, and Florida).[14] Hotel occupancy rates in 2020 hit all time lows and many could also have been repurposed during the emergency.[15]

Instead, these patients were spread widely; by May 24, 2020, when CMS first posted the nursing home COVID-19 data, at least 3,518 nursing homes (23% of facilities nationwide) had admitted one or more of the 27,455 previously hospitalized COVID-patients. In New York and New Jersey the same figures are 52 and 66 percent, respectively.[16]

Visitation remained highly restricted. While CMS introduced flexibility based on local conditions in May 2020, about half of states banned visits outright as late as June, and 8 continued through October. When states did allow visits they were limited to outdoor settings, designated areas with strict infection protocols, or to essential caregivers. By late April of 2021, guidance on visitation had been mostly normalized but cell phone data suggest nursing homes remained socially isolated throughout the pandemic.[17]

Isolation likely helped to avoid some infections but would likely have worked much better when combined with testing. Testing, however, continued to be very restricted, allowing even known outbreaks to grow larger and more deadly.

It has been pointed out that the New York Department of Health advisory did not technically require nursing homes to admit COVID-patients, but it is clear from reporting and the language in the advisory that it was interpreted that way. The language stated "No resident shall be denied re-admission or admission to [a nursing home] solely based on a confirmed or suspected diagnosis of COVID-19. [Nursing homes] are prohibited from requiring a hospitalized resident who is determined medically stable to be tested for COVID-19 prior to admission or readmission". For reporting see Kaiser Health News, "Is Cuomo Directive to Blame for Nursing Home COVID Deaths, as US Official Claims?" available at www.khn.org/news/is-cuomo-directive-to-blame-for-nursing-home-covid-deaths-as-us-official-claims/.

[14] For more see National Governors Association, "State Actions Addressing COVID-19 in Long-Term Care Facilities," October 20, 2020, available at www.nga.org/wp-content/uploads/2020/06/State-Actions-Addressing-COVID-19-in-Long-Term-Care-Facilities.pdf .

[15] On hotel occupancy rates see https://www.npr.org/2021/01/27/960384171/2020-was-the-worst-year-ever-for-u-s-hotels-heres-whats-next

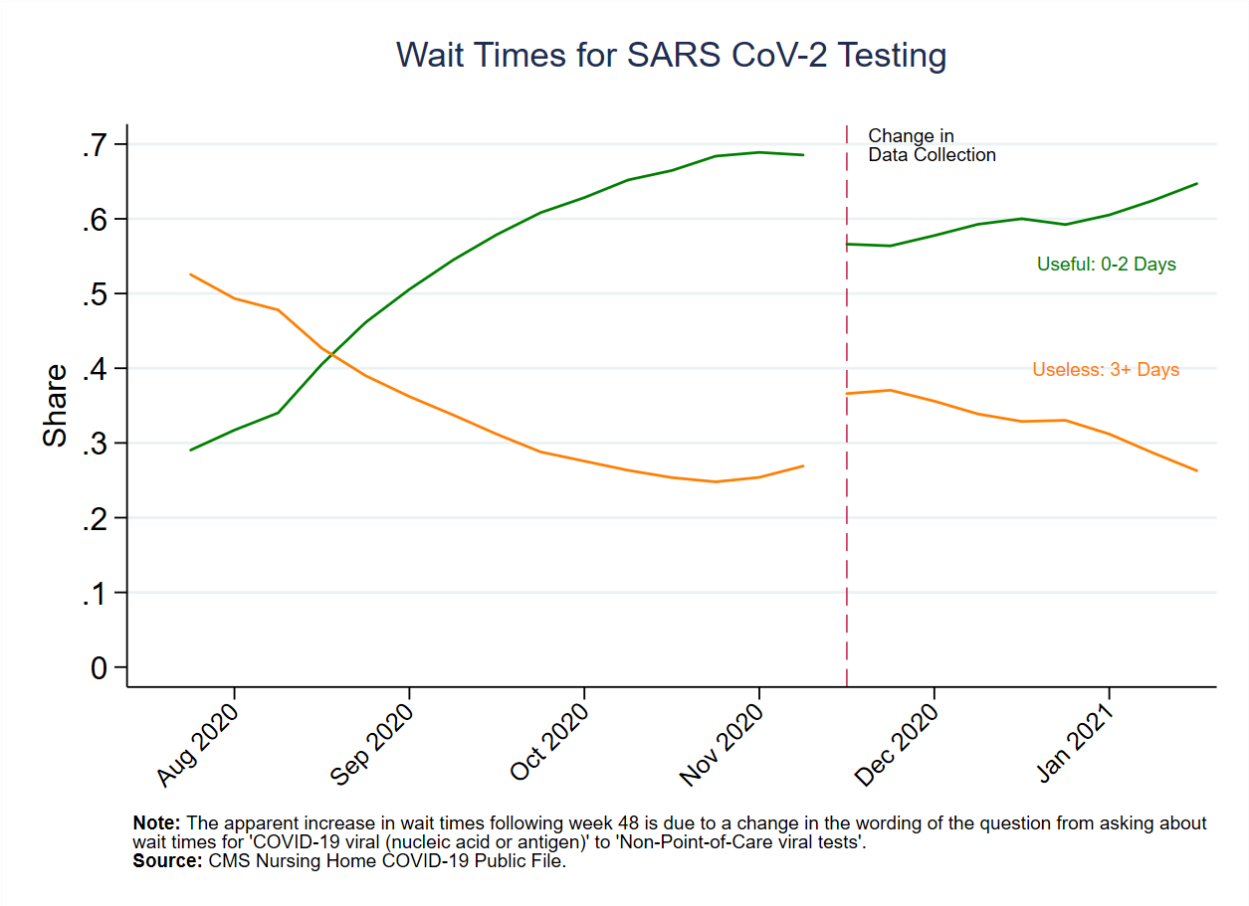
[16] Other notable states include Massachusetts (64%), Connecticut (59%), New York (52%), and the District of Columbia (63%).

[17] For details see CMS Memo's QSO-20-3--NH, QSO-20-39-NH, and QSO-20-39-NH-Revised available at https://www.cms.gov/files/document/qso-20-39-nh-revised.pdf .

The Surprising Failure of Rapid Testing

When testing did happen, its impact was limited by long wait times. As late as the week of August 16 when tests were nominally available, only 3% of facilities reported wait times of less than a day, about a third reported 1-2 days, while more than half said tests took 3 to 7 days, and 10% reported more than 7 days. In effect rendering a large portion of tests virtually useless.[18]

Figure 3.



Note: The apparent increase in wait times following week 48 is due to a change in the wording of the question from asking about wait times for 'COVID-19 viral (nucleic acid or antigen)' to 'Non-Point-of-Care viral tests'.
Source: CMS Nursing Home COVID-19 Public File.

Slow testing was supposed to be fixed by rapid antigen tests which could return results in 15 minutes. In July the Department of Health and Human Services (HHS) started sending Quidel Sofia and BD Veritor point-of-care devices to give every nursing home rapid antigen test capability, and in late August HHS purchased the entire lot of Abbott's 150 million BinaxNOW kits and started shipping these to states, including about 8 million that went directly to nursing homes and assisted living facilities.

[18] From the CMS Covid-19 Public File for the week ending August 16, the first time this question was included. 403 facilities responded less than 1 day, 4,069 facilities 1-2 days, 8,406 facilities 3-7 days, and 1,363 facilities reported average wait-times of more than 7 days.

On August 25, 2020, CMS required facilities to test all staff and residents immediately in the event of a positive case, and retest every 3-7 days until no new cases were identified. CMS also required staff (but not residents) to be tested routinely based on the county's positivity rate, which in effect required most facilities to test their staff at least weekly.[19]

Unfortunately, the requirements and point-of-care tests did not quickly turn the tide on testing, even though two thirds of nursing homes had test capability by the middle of September. Figure 4 shows weekly test volumes in nursing homes by recipient (staff or resident), and also breaks out the volume of point-of-care tests for staff and residents separately. Unfortunately we don't have data on lab tests prior to late November, but we do know that by December nursing homes reported weekly totals of nearly 3 million tests, enough to test all staff and residents weekly.

It took until late November-December before nursing homes were running a million weekly antigen tests, and even then, they ran more of the slower, more expensive lab tests. Why weren't the rapid antigen tests used much more frequently? The explanation is not entirely clear, though we can list some possibilities.[20]

The initial impact of the rapid antigen test rollout was confusion as major states including California, New York, and Pennsylvania already required health care workers to be tested regularly using PCR tests, required certain antigen results be confirmed with PCR, or did not have data collection procedures for antigen tests which added administrative burden.[21]

The difference between rapid antigen tests as public health tests and PCR tests for diagnostic purposes wasn't properly understood early on. Nevada, for example, briefly halted the use of RATs all-together on October 2nd, after PCR testing confirmed just 16 of 39 positive antigen tests, suggesting a false-positive (23/39) rate of nearly 60%.[22] It was less remarked on, however, that Nevada has run 3,725 antigen tests with 3665 coming back negative–thus of potentially considerable information value. Gans et al. (2022) find that the rate of false positives from antigen tests is very low when measured (as it should be) against the number of people screened.

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[19] Cite: QSO-20-38-NH. The minimum frequency required was once a month at a positivity rate below 5%, once a week at a positivity rate between 5-10%, and twice a week if the positivity rate was above 10%.

[20] The CMS COVID-19 data does ask facilities for reasons for not testing. The responses essentially rule out reasons such as lack of personnel, supplies, PPE, uncertainty about reimbursement, and access to a laboratory.

[21] Other states were New Jersey, Connecticut and Massachusetts. For more on California's requirement see Coronavirus Disease 2019 (COVID-19) Mitigation Plan Recommendations for Testing of Health Care Personnel (HCP) and Residents at Skilled Nursing Facilities (SNF), California Department of Public Health, May 22, 2020, available at https://web.archive.org/web/20200629003518/https://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/AFL-20-53.aspx.

[22] "REMOVAL OF DIRECTIVE to Discontinue the Use of Antigen Testing in Skilled Nursing Facilities Until Further Notice", Nevada Department of Health and Human Services, October 9.

Another problem that slowed the use of RATs was that it wasn't understood that rapid antigen tests were tests of infectiousness rather than infection (Tabarrok 2020, Mina 2020). Thus some thought that the lower sensitivity of antigen relative to PCR tests would allow too many false-negative individuals to enter facilities undetected but these concerns were likely misplaced if these individuals were past the point of infectiousness.

There was also some ambiguity as to whether the tests, which were granted Emergency Use Authorization "to test specimens from individuals who are suspected of COVID-19" could (legally) be used outside the tests authorization on asymptomatic individuals. This prompted CMS to notify facilities that it would exercise enforcement discretion and not penalize facilities for this on December 7, 2020.[23]

Another part of the answer of why rapid tests were not used more frequently is likely reimbursement policy, as Medicare (and sometimes Medicaid) would reimburse diagnostic tests for residents, including asymptomatic residents if the facility had an outbreak, but did not reimburse surveillance tests, or staff tests, even though these were those the most aggressively mandated by states and CMS.[24] HHS paid and sent point-of-care rapid test devices to every nursing home, but didn't fund (or subsidize) their use (beyond one round which was included with the devices). This was a missed opportunity and a likely consequence of a lack of unified decision making.

Similarly, health insurers were required to pay for diagnostic tests of (insured) workers who were symptomatic or had known exposure, but not surveillance tests. In late May, a stand-off erupted between New York's health department, who issued a directive stating the tests were "medically necessary" and thus should be covered by insurance without cost-sharing, and insurers who claimed surveillance tests were akin to health-screenings like physicals and drug tests that employers routinely pay for.[25] Ultimately the homes themselves would often be responsible to pay for much of this testing, though states like Maryland and Minnesota paid for some, and about a dozen states deployed teams to help administer tests, sometimes involving the national guard.

As a result of these and other issues, the point-of-care devices were underutilized.[26] The BinaxNOW initiative, however, was an even greater failure. As of February 2021, at least 32 of the 150 million kits were collecting dust in state warehouses, approaching their expiration dates. Making matters worse, the

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[23] For more on this, see www.cms.gov/files/document/clia-sars-cov-2-point-care-test-enforcement-discretion.pdf .

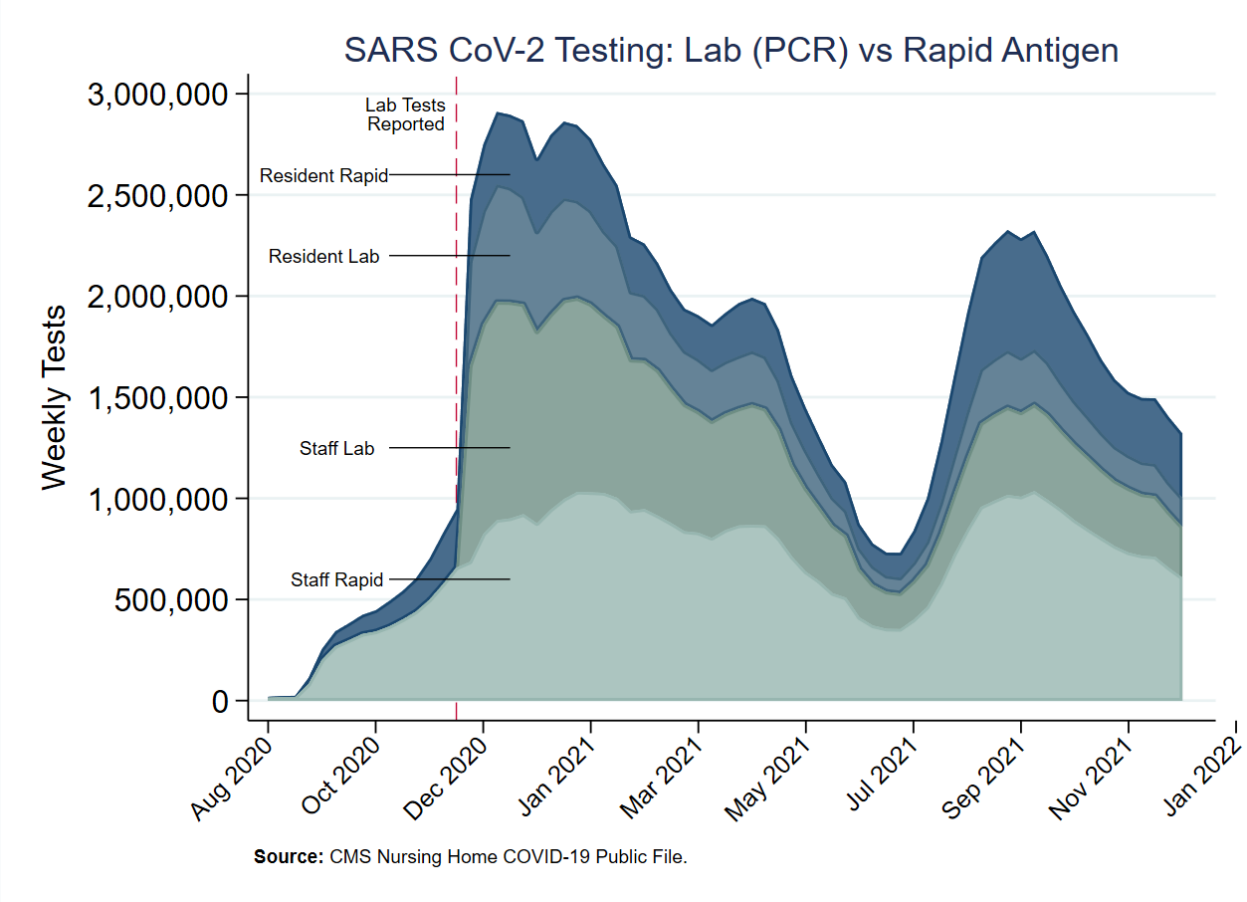
[24] For tests covered by Medicare, Medicaid, and some other sources see www.cms.gov/files/document/covid-medicare-payment-covid-19-viral-testing-flow-chart.pdf .

[25] For more on the conflict over who would pay for surveillance tests including some state policies see "Testing Nursing Home Workers Can Help Stop Coronavirus. But Who Should Pay?" New York Times, June 9, 2020, available at www.nytimes.com/2020/06/09/health/testing-coronavirus-nursing-homes-workers.html , and also New York State Department of Health, "Directive: COVID 19 Testing of Nursing Home and Adult Care Facility Personnel Deemed Medically Necessary", May 19, 2020, available at https://coronavirus.health.ny.gov/system/files/documents/2020/05/medicalnecessitydirective.pdf .

[26] For more see "Many Nursing Homes Shun Free COVID Testing Equipment", Wall Street Journal, Nov 7, 2020, available at www.wsj.com/articles/many-nursing-homes-shun-free-covid-19-testing-equipment-11604769383 .

actual figure is likely much larger, as only about half of states had submitted data.[27] Countries like Germany did pursue far more ambitious antigen strategies, aiming to supply facilities with enough rapid tests for every resident to be tested 20 times per month. While it is unclear how much these initiatives contributed to the lower fatality rates experienced among German nursing home residents, evidence from 382,017 tests run exclusively on asymptomatic individuals in Bavarian long term care facilities did identify 1,058 cases, leading Tischer et al., (2021) to speculate "that a number of infection outbreaks in Bavarian healthcare institutions may have been prevented based on the relatively inexpensive and fast antigen tests."

Figure 4.



5-Star Ratings and Quality Measures

[27] For more on the unused BinaxNOW kits, see "The U.S. Bought Rapid Covid-19 Tests to Help Control the Virus. Now Many Are Unused." Wall Street Journal, February 15, 2021, available at www.wsj.com/articles/the-u-s-bought-rapid-covid-19-tests-to-help-control-the-virus-now-many-are-unused-11613397601. The HHS announcement is available at www.hhs.gov/about/news/2020/07/14/trump-administration-announces-initiative-more-faster-covid-19-testing-nursing-homes.html

If it was feasible to shield nursing homes from the virus, we would expect to see better outcomes among higher quality nursing homes. A natural place to look is therefore the CMS Five-Star Rating system, which rates facilities from 1 to 5 stars relative to facilities in the same state and is based on comprehensive data from annual health inspections, staff payrolls, and clinical quality measures from quarterly Minimum Data Set assessments. The rating system has been validated against other measures of quality such as mortality and hospital readmissions, and thus serves our purposes as we are primarily interested in clinical outcomes (Cornell et al., 2019; Konetzka et al., 2020).[28] So, did higher quality homes have better COVID-19 outcomes?

Researchers rushed to answer this question in the early months of the pandemic. Konetzka et al. (2021), reviewed 16 studies that examined the relationship between the overall Five-Star Rating and facility-level COVID-19 outcomes, and surprisingly concluded "no practically meaningful or statistically significant relationship was found between the overall 5-star rating and COVID-19 outcomes."[29] However, they also noted important limitations including that most studies were conducted prior to the November-December surge, thereby missing a large portion of the cases and deaths. Many studies also failed to control for local disease prevalence and facility size, the most consistent predictors in the literature, and almost all studies used cross-sectional data, leading the authors to conclude "More work is needed to establish causal connections and assess temporal trends." We revisit this question with data on the universe of U.S. nursing homes and a year of additional data, relative to the most recent study reviewed by Konetzka et al.

Before analyzing this data we note that CMS required nursing homes to report weekly data on cases and deaths from May 24, 2020, but allowed voluntary reporting for the period prior to this. We also note that the testing requirements that were imposed in late August of 2020, and the vaccine distribution starting in December 2020 would all significantly impact the data generation process.

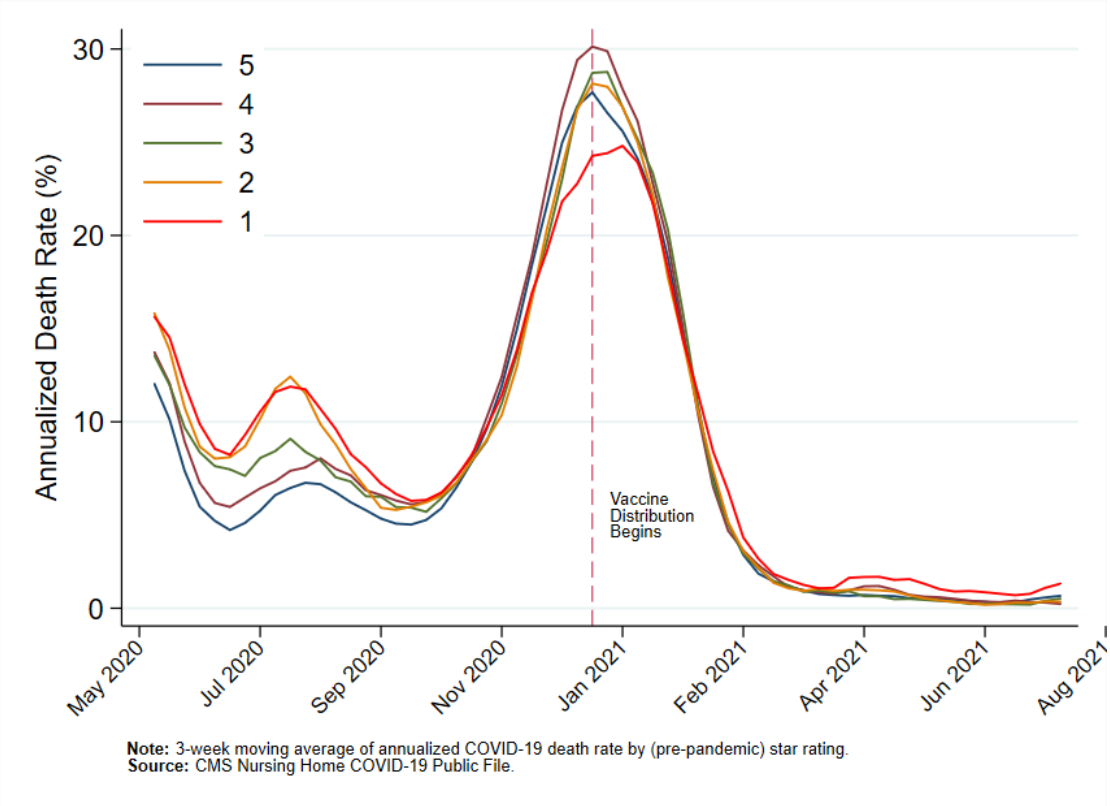
To explore this more we start by plotting unadjusted COVID-19 death rates by pre-pandemic star rating in Figure 5. These seem to paint a slightly different picture; unadjusted death rates followed ratings during the spring and summer of 2020, but seem mostly indistinguishable from the fall and winter of

[28] The rating system has been criticized, among other things for overemphasizing clinical outcomes, relative to measures of subjective wellbeing/customer satisfaction, and for relying on facility-reported staff data. The first is less of a concern for us as we are primarily interested in clinical outcomes, and the second is no longer a concern after the staff measure was updated in 2018 with data based on auditable payrolls.

[29] The study with the most recent data ended in January 2021 (Williams et al.) 2021, did find a modest negative (and statistically significant) relationship, however, Konetzka et al. point to several potential flaws with that particular study. First, the ratings used were from January 2021, which meant that performance during COVID could predict ratings, rather than the other way around. Second, the study "used an unusual denominator for their outcome measures: cumulative resident incidence and mortality" where "[t]he denominator for the cumulative measures was the resident census as of January 2021 rather than the typical baseline measure, with an offset term to account for average resident census starting only in May 2020." In effect, this meant that the outcomes would be inflated in facilities who experienced large drops in occupancy from deaths or drops in admissions prior to NHSN data collection which began May 2020. For more see p.4-5 of Konetzka et al., (2021).

2020, except perhaps for facilities with 1-star ratings, which surprisingly had the lowest death rates during the December-January peak.

Figure 5.



We therefore split our data into four separate time periods; prior to May 24, when reporting was voluntary, between May 24 and August 30, 2020, when reporting was mandatory but testing had yet to be required, from August 30, to December 27, when testing was mandated, and from December 28, 2020, when the vaccine deployment began, until December 5, 2021.

COVID-19 cases and deaths are counts that we find are overdispersed (i.e. have a variance greater than its mean) and tend to have excess zeros relative to negative binomial or poisson distributions.[30] We note that positive counts and zeros are potentially different data generating processes, for instance, it may be that higher quality homes employ more staff, which raises the probability of introducing the virus to a facility, but that the higher quality staff follow infection protocols more closely, which reduces the chance it will spread within the facility. To model this, we run Zero-Inflated Negative Binomial models, which allow these processes to be different (Deb et al., 2017).

[30] For cases we observe between 10,012 (period 1) and 1,826 (period 4) facilities with zero cases, and for deaths we observe between 10,939 (period 1) and 5,892 (period 4) facilities with zero deaths. Our samples range from 14,008-14,860 facilities. We confirm the counts are overdispersed by noting that our models produce estimates of the negative binomial overdispersion parameter, alpha, ranging from 1.10-3.04 for cases, and 1.72-2.15 for deaths (values of alpha greater than 1 indicate overdispersion).

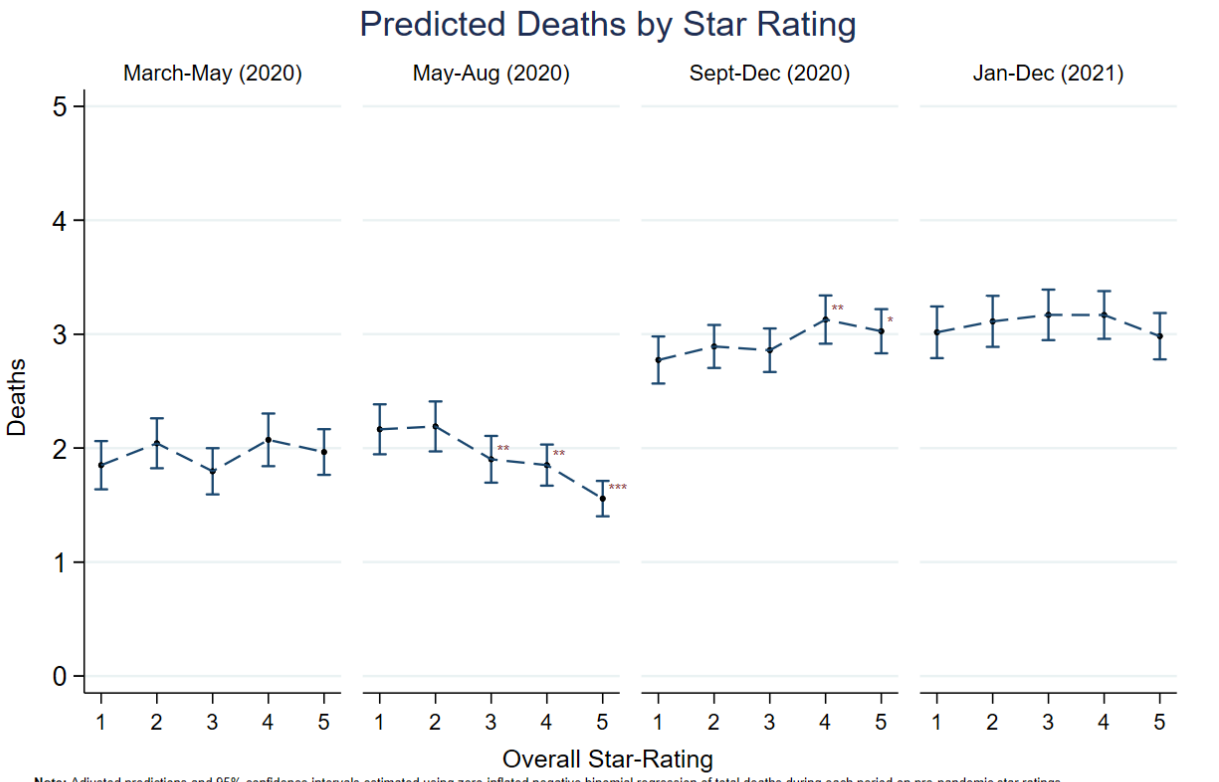
Our variable of interest is the overall pre-pandemic Five-Star rating, which, unlike other consumer ratings that might have bimodal distributions, come in five categories of similar proportions.[31] We control for factors outside the facility's control including the disease prevalence during each period (measured as the number of positive tests as a share of the county population), natural immunity prior to the period (measured as cumulative cases as a share of population), the county's Urban-Rural classification from the National Center for Health Statistics (six categories), socioeconomic factors using the county's Area Deprivation Index, and the facility's size (log number of beds). The model for 2021 also controls for the county's average vaccination rate during the period. Finally, the count portion includes an exposure term that is the log of the number of resident-weeks in the facility during each period, while the zero-portion is a logit model with the same control variables.[32]

Detailed results of the count models are shown in Table 2 in the appendix, but for convenience in Figure 6 we plot predicted counts of deaths in each period by overall star rating. We also test whether deaths were different in facilities rated 2, 3, 4 and 5 star relative to those rated 1-star attach significance stars in the graph. We also conduct the same analysis for cases, which find similar results to that of deaths, and is included in the appendix.

Figure 6.

[31] 17% of facilities were rated 1 star, 20% rated 2 star, 18% rated 3 star, 21% rated 4 star, and 24% rated 5 star.

[32] We excluded approximately 1.5% of facilities for failing to meet the CMS data quality check 10% of weeks or more.



Note: Adjusted predictions and 95% confidence intervals estimated using zero-inflated negative binomial regression of total deaths during each period on pre-pandemic star ratings. Significance stars show estimate is statistically different to homes rated 1-Stars, at 1% (***), 5% (**), and 10% (*) percent levels. Standard Errors clustered by county. Estimates adjusted for the log bedcount, NCHS Urban-Rural classification (six categories), local immunity prior to the period (measured as cumulative COVID-19 cases as a share of the county population), local disease prevalence (measured as cases as a share of the county population during the period), and local socioeconomic factors using the county's Area Deprivation Index. The estimates from 2021 also control for the county's average vaccination rate during the period. The count portion include an offset term for the log number of resident-weeks. The zero-portion is a logit model with the same control variables.

On balance, we find star ratings were not predictive of future deaths. In some periods deaths in five stars and 1-star facilities were similar, in others they were lower in 5-star facilities, in others higher. Even when we consider the most generous hypothetical; a customer choosing between a 1- and a 5-star rated facility, we find no effect prior to May 24, 2020 or from December 28, 2020 to December 5, 2021.

We find modest evidence of fewer deaths when we compare facilities rated 1- vs 3- to 5 star, in the May-August "mandatory-reporting, optional test" period. Our estimated differences (standard errors) for this period are -0.26 (.126) deaths for facilities rated 3-star, -0.31 (.138) for facilities rated 4-star, to -0.61 (.134) for facilities rated 5-star, relative to 1-star facilities (see Table 2, Appendix). The estimates are statistically significant at the 5% level for 3 and 4-star facilities, and at the 1% level for 5-star facilities.

Importantly, these differences were short lived. Our estimates for September-December (2020) finds that homes rated 4 and 5 stars actually had modestly *higher death counts* relative to those rated 1-star. Our estimates range from 0.35 (.154) additional deaths for facilities rated 4-stars, to 0.25 (.146) additional deaths for facilities rated 5 stars, relative to 1-star facilities during this period (again for more see Table 2, in Appendix). These estimates are statistically significant at the 5% level for 4-star facilities and at the 10% level for 5-star facilities.

One possible explanation that could mask a real underlying relationship is that some of the worst performing facilities are not assigned ratings. We rule out this possibility by assigning facilities enrolled in the Special Focus Facility program 1-star ratings and find the results are qualitatively the same.[33]

The lower death counts for higher rated facilities from May-August (2020), roughly cancel out the somewhat higher death counts from September to December. Considering we found no evidence of a relationship in the other two periods, we therefore conclude that, on balance, higher quality homes (as measured by star ratings) did not provide consumers a reliable prediction of lower death counts from COVID-19. Our findings are therefore in line with the earlier conclusions by Konetzka et al.

The question then becomes whether the lack of relationship between ratings and COVID-19 outcomes is because it is so hard to shield a nursing home from COVID-19 that we don't observe much variation in COVID-19 outcomes at all, or whether star-ratings are simply measuring the wrong thing?

It is possible that gains from better routines, compliance with care standards, and more available staff might simply be too small to measure, or offset one another (i.e. better practices are offset by the additional risk of more staff entering the facility (McGarry et al., 2021a), leading to no net gains.

Another possibility is that star ratings don't measure quality well, at least not as it pertains to COVID-19, or even strategic responses to the rating system, a possibility that has some support in non-covid literature (Han et al., 2018; Ody-Brasier and Sharkey, 2019) and receives regular attention in the media.[34] However, the evidence we find does not suggest this; for instance we note in Figure 7-8 that higher rated facilities consistently invested in more testing. On average, facilities with 5- star ratings ran 0.93 Point-of-Care (antigen) tests per resident-week, compared to 0.76 for facilities rated 1-star. The difference is even greater for lab tests where 5-star rated facilities ran 0.94 tests per resident-week vs 0.57 for facilities rated 1-star.

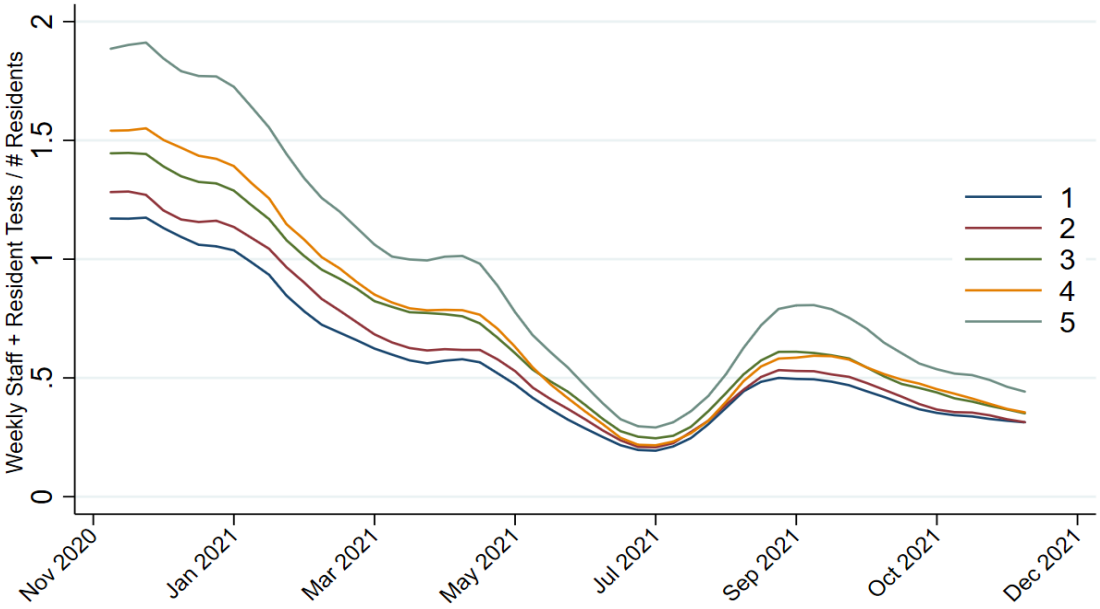
Since quality ratings do not reliably predict COVID-19 outcomes we ask if any nursing homes were able to insulate residents from COVID-19, and what, if anything, can be learned from these facilities?

Figure 7-8.

[33] The Special Focus Facility (SFF) program targets additional oversight toward some of the worst performing facilities in each state and have suppressed ratings on Nursing Home Compare, and were therefore not included in analyses by other authors such as (Williams et al.,). When we run the same analysis including SFF facilities and rate them as 1-star, we find the results are qualitatively the same (results not shown). For more on the SFF program see working paper "Do Patients Benefit from Regulatory Stringency? Evidence from Targeted Nursing Homes,'' Bjoerkheim 2021.

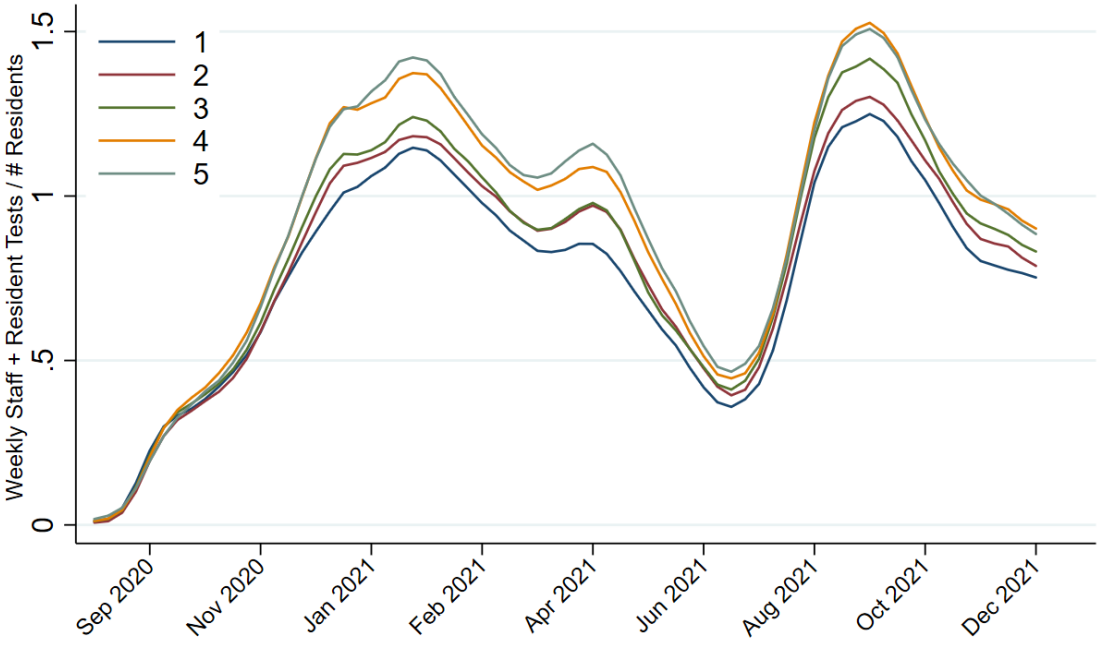
[34] For a recent article on this topic see "Maggots, Rape and Yet Five Stars: How U.S. Ratings of Nursing Homes Mislead the Public." New York Times, March 13, 2021, available at www.nytimes.com/2021/03/13/business/nursing-homes-ratings-medicare-covid.html

Lab Testing by Star Rating



Note: 3-week moving average of total Non-Point-of-Care (lab) tests (both staff and resident) / # residents, by overall-star rating.
Source: CMS Nursing Home COVID-19 Public File.

Point-of-Care (Antigen) Testing by Star Rating



Note: 3-week moving average of total Point-of-Care tests (both staff and resident) / # residents by overall-star rating.
Source: CMS Nursing Home COVID-19 Public File.

Could Focused Protection Work?
Safe Islands in Oceans of Disease

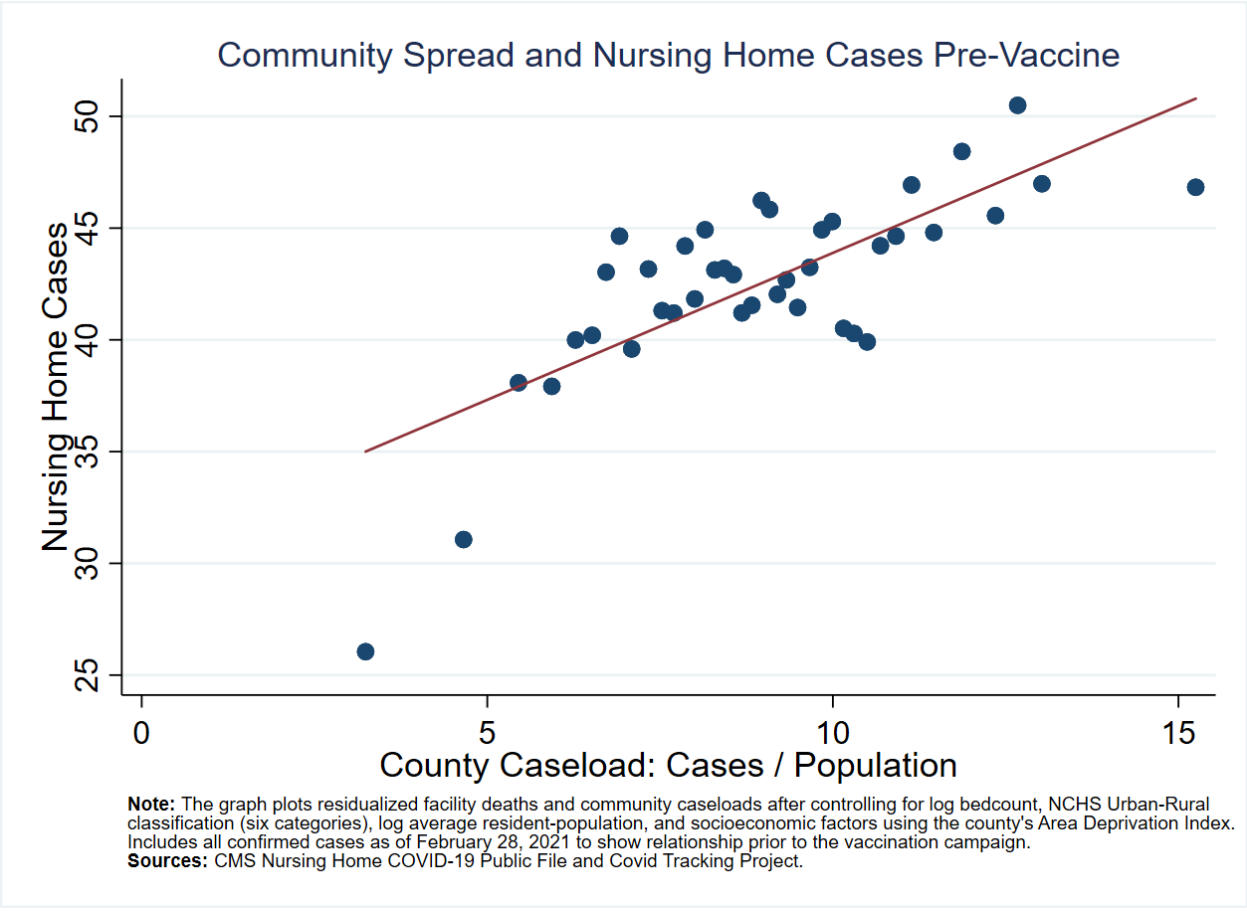
A central premise of the Great Barrington Declaration (Kulldorff et al., 2020) is that protecting the vulnerable would have been possible through Focused Protection, while the virus spread at an inevitably faster rate, in surrounding communities.

> **How do we protect the elderly in nursing homes and other care settings?**
> "A focused protection strategy would include frequent testing of nursing home staff members that are not already immune, testing of visitors, and less staff rotation so that residents only interact with a limited number of staff people. COVID-19 infected individuals should not be sent to nursing homes, and all new residents should be tested. Sequestering of care home residents who have COVID-19 is also important."
>
> "By way of example, nursing homes should use staff with acquired immunity and perform frequent testing of other staff and all visitors. Staff rotation should be minimized."
>
> Great Barrington Declaration, October 4, 2020[35]

We first note two facts. The first is unsurprising; prior to the vaccination campaign, community spread was found to consistently predict COVID-19 cases and deaths in nursing homes (Abrams et al., 2020; Konetzka et al., 2021), while, as we noted in the last section, nursing home quality ratings generally, do not. In Figure 9-10 we plot total case and death tolls in nursing homes (as a % of residents) against community spread (cases as a % of county population), up until February 28, 2021, and note that few facilities in high transmission counties managed to shield their residents.

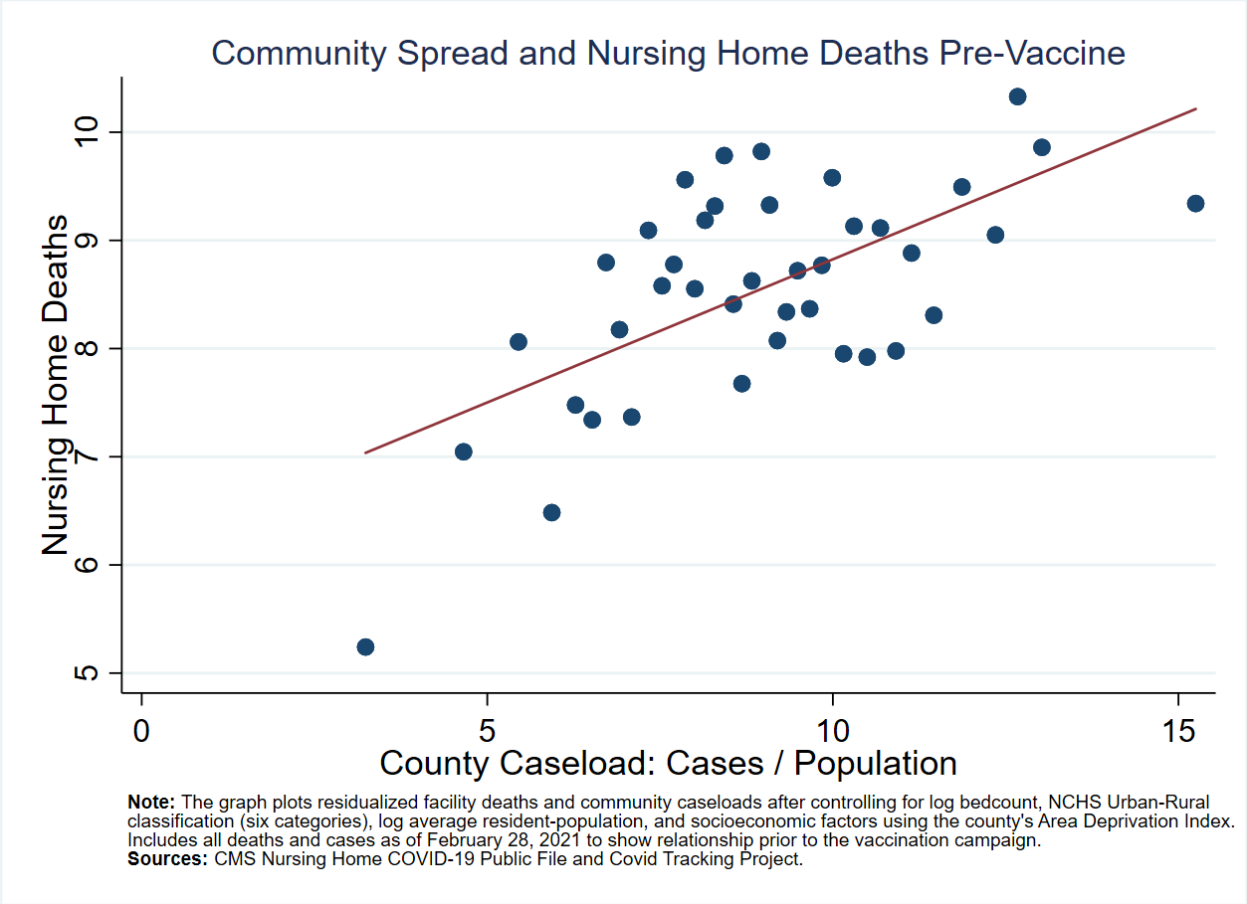
[35] The first quote is from the Frequently Asked Questions section of the Great Barrington Declaration website, while the second is from the declaration itself. For more see www.gbdeclaration.org/ .

Figure 9



Note: The graph plots residualized facility deaths and community caseloads after controlling for log bedcount, NCHS Urban-Rural classification (six categories), log average resident-population, and socioeconomic factors using the county's Area Deprivation Index. Includes all confirmed cases as of February 28, 2021 to show relationship prior to the vaccination campaign.
Sources: CMS Nursing Home COVID-19 Public File and Covid Tracking Project.

Figure 10.



The second point relates to the specific steps needed to protect nursing homes in the focused protection strategy. The points about frequent testing of visitors and isolating COVID-positive residents are essentially moot as CMS required isolating COVID-positive residents since March 2020, and, as we have documented, visitors were essentially banned nationwide for large periods, and there's little evidence to suggest they have come back since.

Sending COVID-19 infected individuals to nursing homes certainly posed a risk, as discussed earlier but many patients admitted from COVID hospitalizations were probably not infectious. Moreover, by June 9 states including California, New York, Florida and Pennsylvania required hospitals to test before discharge, and from August facilities nationwide were required to test anyone with symptoms or known exposure, so, at least from the fall of 2020, this issue would seem to be dealt with.[36]

The remaining proposals were to limit staff rotation, a point that was clear early on (Chen et al., 2021), and finally, that nursing homes ought to use staff that have already acquired natural immunity. It is

[36] The other 5 states were Alabama, Massachusetts, Michigan, New Mexico, and Oklahoma, covering about 35% of residents nationwide. For more on this, see "State Actions Addressing COVID-19 in Long Term Care Facilities" by the National Governors Association, available at www.nga.org/wp-content/uploads/2020/06/State-Actions-Addressing-COVID-19-in-Long-Term-Care-Facilities.pdf .

frankly hard to imagine how this could have been done at scale, especially considering that at the time the declaration was signed, 16% of nursing homes already reported severe shortages for nurses and 19% for nurse aides.

So while we have highlighted areas where we believe more could have been done to protect nursing home residents, a balanced reading of the evidence would have to acknowledge that a significant portion of deaths in nursing homes happened while we *both* maintained a version of the age-wide lockdown and social distancing policies opposed by the GBD *and* focused protection. In other words, the United States implemented focused protection and it didn't work. This is arguably true for the entire third wave that in the nine weeks from the beginning of December 2020 to the end of January 2021, infected almost a quarter million and led to 49,492 residents deaths, a time when nursing homes ran almost 3 million tests per week.

So, if the feasible proposals in Focused Protection were largely tried, but failed to protect nursing home residents in combination with lockdowns and social distancing policies, it seems unlikely focused protection would have worked on its own. As Tabarrok (2020) noted, the Great Barrington approach contained an internal contradiction–the goal was to free most of society from COVID restrictions by segregating the elderly but segregating the elderly became much more difficult the fewer the lockdowns, mask mandates, social distancing, and other restrictions imposed on the rest of society. As noted, a lot was done to segregate the nursing home population which was much easier than segregating the elderly but it's always possible to say more could have been done. Does the variance in the data suggest what more might have been done to shield nursing home residents?

To try to get a sense of this we turn to see if any facilities managed to keep their residents acceptably safe while being located in counties with high caseloads, and if so, what do they have in common? We recognize that this analysis exploratory and cannot be considered causal as we are selecting on the dependent variable.

The average U.S. nursing home is located in a county where, as of the end of the pre-vaccine period (up until February 28, 2021), cumulative cases as a share of the county population were 8.95%. We define "oceans of covid" as counties with caseloads in or above the 90th percentile, or 11.94%, with average caseloads of 13.5%. We then define safe islands, as facilities that managed to keep deaths below 2.32% of their residents, the 25th percentile, while located in an ocean of COVID. This level of safety is comparable to what one would expect from a year-long flu season where all facilities are exposed, the virus has an attack rate of 33%, and a case fatality rate of 6.5% (Lansbury et al., 2017). 248 facilities meet these criteria. We exclude 6 children's hospitals which have an average age lower than 50, leaving us with 242 "safe islands."[37]

For islands to provide any information we first have to rule out that their success can be attributed to a substantially different patient population or other factors that can't be replicated elsewhere. In Table 1

[37] Note that occasional missing data for some variables/sources will mean this figure will fluctuate somewhat.

we compare pre-pandemic patient characteristics for “islands” relative to other facilities in “oceans of COVID” and the nationwide average. Islands have patients with comparable age, and gender distributions, slightly lower acuity levels and rates of incontinence, but higher rates of obesity. Overall these differences seem unlikely to explain their performance.

Table 1.

Descriptive Statistics: Outliers vs. Nationwide Average

	Islands		Oceans		Nationwide	
	mean	sd	mean	sd	mean	sd
Admissions from Acute Care Hospital (%)	79.4	16.1	79.9	15.6	84.4	13.4
Average Age	79.1	6.95	79.2	7.36	78.8	7.27
Activities of Daily Living (ADL) Score (0-28)	15.4	3.16	16.0	2.90	16.5	2.69
Case Mix Index	1.12	0.18	1.15	0.19	1.18	0.19
Female (%)	65.8	12.0	64.7	11.6	64.9	12.1
White (%)	84.3	19.7	81.4	22.3	79.0	22.1
Low Cognitive Impairment (%)	42.0	14.1	37.1	11.6	38.4	12.5
Moderate Cognitive Impairment (%)	53.2	13.0	55.8	12.6	54.4	12.5
Bladder Incontinence (%)	76.6	13.1	79.0	12.2	79.7	13.1
Bowel Incontinence (%)	57.6	16.1	61.6	16.0	64.7	15.4
High Blood Pressure (%)	75.8	10.8	77.2	10.7	76.8	10.6
Obese (%)	33.3	10.1	31.5	8.81	30.0	8.37
Hospitalizations per resident-year	2.15	1.04	2.19	0.98	2.37	1.06
Observations	216		994		13961	

This table compare pre-pandemic patient characteristics for outlier facilities relative to the nationwide average. Outliers are located in counties with high community spread, defined as having cases as share of population >11.94% (90th percentile), and successfully shielded their residents from COVID-19, defined as having fewer than 2.32% (25th percentile) of residents die from COVID-19, up until February 28, 2021.
Sources: CMS Nursing Home COVID-19 Public File, Covid Tracking Project, and LTC Focus/Brown University.

We therefore turn to see if their investment decisions and other facility characteristics will give an indication of what it would take to make Focused Protection work.

Table 2.

Descriptive Statistics: Outliers vs. Nationwide Average

	Islands mean	Oceans mean	Nationwide mean
Residents Total COVID-19 Deaths	0.32	10.3	8.66
Residents Total Confirmed COVID-19	14.2	47.6	42.8
Residents Total Admissions COVID-19	6.90	18.5	17.4
Residents Total Non-COVID-19 Deaths	12.0	16.1	19.6
Staff Total Confirmed COVID-19	24.4	43.2	36.8
Weekly Resident Antigen Tests/Residents	0.34	0.30	0.25
Weekly Staff Antigen Tests/Residents	1.46	0.94	0.75
Weekly Resident Lab Tests/Residents	0.31	0.31	0.42
Weekly Staff Lab Tests/Residents	0.78	0.65	1.00
Shortage Nursing Staff (% of Weeks)	18.1	19.9	17.3
Shortage Clinical Staff (% of Weeks)	2.11	2.23	2.21
Shortage Nurse Aides (% of Weeks)	21.5	22.0	19.4
Ventilators available (#)	22.7	18.1	18.0
For profit facility (%)	58.1	65.0	70.5
Non-profit facility (%)	27.4	26.0	23.2
Government operated facility (%)	14.5	8.99	6.27
Number of All Beds	76.1	96.5	106.7
Occupancy rate (avg)	73.8	69.4	70.8
Facility age (years)	26.0	28.5	30.5
Hospital based (%)	10.4	5.30	3.85
Star-rating	3.32	3.12	3.17
County Case toll: Cases/Pop	13.5	13.6	8.88
County Death toll: Deaths/Pop	0.20	0.25	0.17
Area Deprivation Index (Nat'l Rank)	61.2	66.1	54.2
County Vaccination Rate	6.50	6.18	6.34
County Population	421663.5	321351.2	832341.3
Observations	242	1058	15075

This table compare outlier facilities to the nationwide average on key facility- and county-level variables. Outliers are located in counties with high community spread, defined as having cases as share of population >11.94% (90th percentile), and successfully shielded their residents from COVID-19, defined as having fewer than 2.32% (25th percentile) of residents die from COVID-19, up until February 28, 2021.
Sources: CMS Nursing Home COVID-19 Public File and Covid Tracking Project.

A few things stand out. If we account for the difference in size (76.6 vs 106.7 beds), outlier facilities report similar levels of staff cases as the national average (24.6 vs 36.8), so we can say that the shielding occurred not only with the virus surrounding them in the community, but at least as close as the facility's doorstep.

Interestingly, the successful outlier facilities (islands) ran more point-of-care (rapid) tests per resident-week than those who were not successful (1.46 vs .94 staff tests, and .34 vs .30 resident tests), and significantly more than the national average. However, they actually ran less PCR tests than the national average (.31 vs .42 staff tests, and .78 vs 1.00 resident tests). Workforce shortages were comparable

across all groups, while islands were more likely to be hospital-based (10.4% vs 5.3% vs 3.8%), less likely to be run for-profit (58.1% vs 65% vs 70.5%), and admitted far fewer residents previously hospitalized for COVID (6.9 vs 18.5 vs 17.4). Islands also report having more ventilators available, but this is only reported by a very small % of facilities, so we would interpret this cautiously.

To further explore the differences we find in testing, COVID admissions, and hospital-base, we run separate regressions for each variable on total resident COVID-19 deaths as of February 28, 2021 with a fixed set of control variables. While the decision of how many tests to run, how to run them, and whether to admit patients previously hospitalized with COVID, are to some extent determined by the facilities themselves and could thus be biased, so we interpret with caution. However, before we discuss individual effect estimates, note that if we take each effect estimate at face value and multiply by the average difference we observe between the oceans and islands, these variables would only explain about -0.76 of the difference in deaths between the groups of roughly 10 deaths (though note again the difference in size).

Table 3.

Average Marginal Effect on COVID-19 Deaths.

	(dy/dx)	(dy/dx)	(dy/dx)	(dy/dx)	(dy/dx)	(dy/dx)
Weekly Resident Antigen Tests/Residents	-1.54***					
	(.28)					
Weekly Staff Antigen Tests/Residents		-0.17				
		(.119)				
Weekly Resident Lab Tests/Residents			-1.12***			
			(.216)			
Weekly Staff Lab Tests/Residents				-0.04		
				(.0883)		
Residents Total Admissions COVID-19					0.04***	
					(.0023)	
Hospital based (%)						-0.03***
						(.00533)
Observations	15003	15003	14501	14501	15093	15093

Note: Each estimate (standard errors) is estimated using zero-inflated negative binomial regression of total COVID-19 resident-deaths as of February 28, 2021, on the variable of interest and a fixed set of controls. Estimates adjusted for the log number of beds, facility age (in years), NCHS Urban-Rural classification (six categories), local disease prevalence measured as cumulative COVID-19 cases as a share of the county population, and local socioeconomic factors using the county's Area Deprivation Index. The count portion include an offset term for the log number of resident-weeks. The zero-portion is a logit model with the same control variables. Standard Errors clustered by county.
* $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

Taken at face-value but with the above limitations in mind, the results suggest that if nursing homes ran one additional rapid test on every resident each week (*quadrupling their use*), it would prevent 1.54 deaths over the 1-year period, while one additional weekly lab test for each resident (more than *doubling their use*) would prevent 1.12 deaths. To put this in perspective, nursing homes had on average 8.66 covid deaths, so to bring deaths down to 2-3, what we would expect from a hypothetical year-long influenza season, would require a large increase in testing.

The estimates for both kinds of staff-tests were not statistically significant, perhaps because these were mandated on a surveillance basis by CMS (while resident-testing was only mandated for when symptomatic, in response to outbreaks, or known exposure). The estimate for COVID admissions is statistically significant, but suggests a facility would have to admit 25 former COVID patients (more than double the national average) for it to lead to an additional death.

Finally, the estimate for hospital base is statistically significant, and is consistent with the claim by Gottlieb (2021, p.300-301) that hospital based facilities did a better job at controlling the spread. However, the effect, estimated to -0.03 deaths, means it is probably not very economically relevant, as it implies 33 facilities would have to be brought up to the standard of hospital-based facilities, to prevent 1 death. Nationwide this corresponds to preventing 448 deaths if all of the 14,744 non-hospital based facilities were transformed prior to pandemic.

It is possible that our previous estimates, using the entire country, overestimates the cost of reducing deaths relative to a Great Barrington scenario where community spread is higher. We therefore re-run the same analysis restricted to the counties with high community spread. Together, these estimates multiplied by the average group differences suggest these variables now explain 1.22 of the difference of about 10 deaths between the oceans and the islands.

Our estimate for one additional resident-antigen per week is now quite large, at -3.54 deaths it implies 2 additional antigen tests per resident each week would bring safety levels near that of a year-long flu-season, but keep in mind that this is outside-of-sample. We now find staff-antigen tests to be significant too, with one additional staff test per resident-week predicted to prevent 0.96 deaths.

Table 4.

Average Marginal Effect on COVID-19 Deaths.

	(dy/dx)	(dy/dx)	(dy/dx)	(dy/dx)	(dy/dx)	(dy/dx)
Weekly Resident Antigen Tests/Residents	-3.54***					
	(.852)					
Weekly Staff Antigen Tests/Residents		-0.96**				
		(.352)				
Weekly Resident Lab Tests/Residents			-0.37			
			(.668)			
Weekly Staff Lab Tests/Residents				0.28		
				(.282)		
Residents Total Admissions COVID-19					0.04***	
					(.00767)	
Hospital based (%)						-0.02
						(.00966)
Observations	1281	1281	1252	1252	1285	1285

Note: Each estimate (standard errors) is estimated using zero-inflated negative binomial regression of total COVID-19 resident-deaths as of February 28, 2021, on the variable of interest and a fixed set of controls. Estimates adjusted for the log number of beds, facility age (in years), NCHS Urban-Rural classification (six categories), local disease prevalence measured as cumulative COVID-19 cases as a share of the county population, and local socioeconomic factors using the county's Area Deprivation Index. The count portion include an offset term for the log number of resident-weeks. The zero-portion is a logit model with the same control variables. Standard Errors clustered by county.

* $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

Overall, the indications we get from this exercise is that there is some indication in the data that a very large increase in the use of rapid antigen tests could have averted a significant number of nursing home deaths. The increase in the number of tests required, however, is out-of-sample. Other countries did use rapid antigen tests at much higher levels but at least in the United States our judgment is that the focused protection strategy would certainly have resulted in more deaths outside of nursing homes and even in more deaths in nursing homes making the benefits of the strategy tenuous.

Vaccine Roll Out: Pharmacy Partnership for Long-Term Care

Operation Warp Speed (OWS) produced vaccines in record time but OWS was not in charge of approval or distribution, so warp speed slowed to impulse power on November 20 when Pfizer submitted their application for Emergency Use Authorization (EUA) to the FDA. The Vaccines and Related Biological Products Advisory Committee (VRBPAC) met on December 10, 20 days later, to discuss the vaccine's safety and efficacy in individuals 16 years of age and older.[38] VRBPAC voted in favor and the FDA issued the EUA on December 11. Hope was in the air and HHS secretary Alex Azar told the press every nursing home patient could be vaccinated by Christmas.

The reality proved different. Distribution of vaccines was initially held up in part because CVS and Walgreens insisted facilities collect written consent forms, a logistical hurdle when many nursing home residents need family members to decide on their behalf. Ultimately, the pharmacies allowed verbal consent from residents and emails/phone calls from family members, but by Christmas Eve, less than 25,000 residents had received their first dose.[39] Distribution did not really get going until early January.[40]

The vaccine undoubtedly saved many lives, but the slow start meant that it took until the middle of January before a significant portion of residents had received their first dose, and with another 2 weeks for immunity to develop, it is striking how much of the damage was already done by the time vaccine-acquired immunity developed for many in late January. Cases had fallen from their peak of 33,710 the week of December 20, to 17,002 the week of January 24, and 11,381 the week of January 31st.

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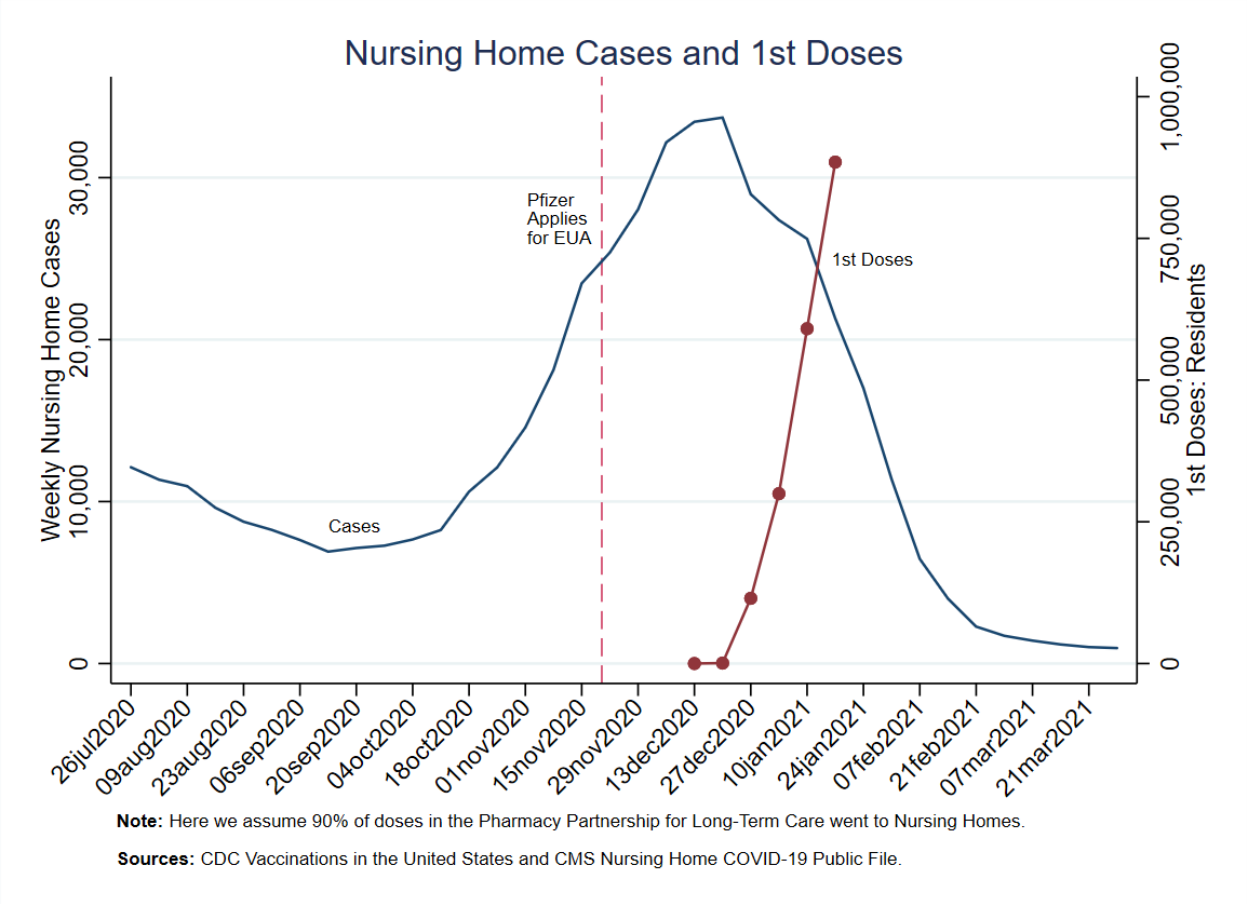
[38] Specifically, whether it was "reasonable to believe that the Pfizer-BioNTech COVID-19 Vaccine may be effective in preventing COVID-19 in individuals 16 years of age and older," and if "the known and potential benefits of the Pfizer-BioNTech COVID-19 Vaccine outweigh its known and potential risks for use in individuals 16 years of age and older."

[39] For more on this see www.washingtonpost.com/health/nursing-homes-covid-vaccine-consent-delays/2020/12/19/730ecd4a-3fd5-11eb-8bc0-ae155bee4aff_story.html .

[40] Note that the Pharmacy Partnership for Long-Term Care was also responsible for administering the vaccine to assisted living facilities and while nursing homes were generally prioritized, this was not always feasible (or desirable), for instance in cases where facilities offer both skilled nursing and assisted living. In our graphs we assume 90% of doses went to nursing homes in the first 6 weeks.

Figure 11.



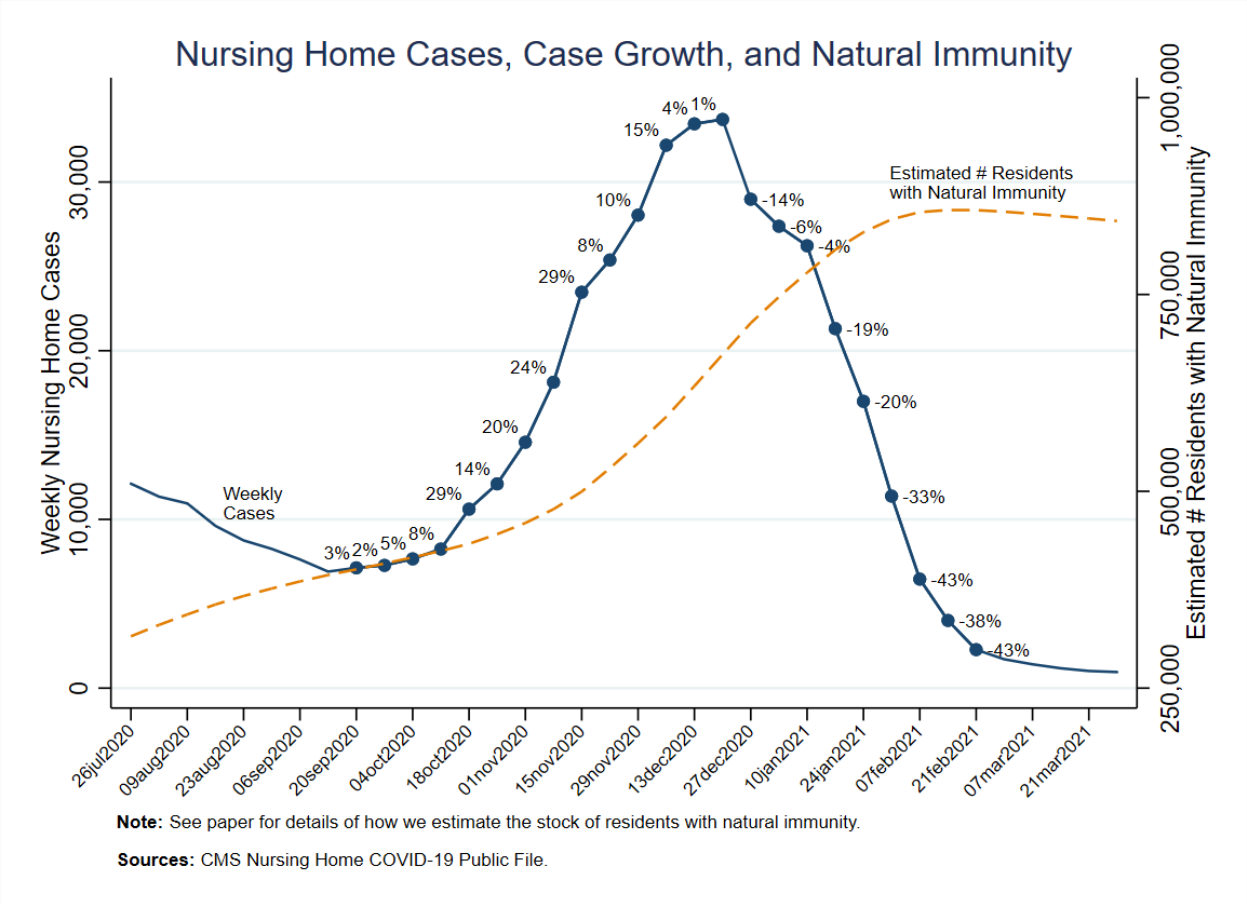
The question we ask is how much of this illness and death could have been avoided with reasonable changes in the vaccine approval and administration process? We first consider an approach similar to the one discussed by Gottlieb(2021 p. 301) where VRBPAC convenes a day or two after EUA submission to consider a limited EUA for residents of nursing homes and other congregate settings–patients for whom it was already abundantly clear the known and potential benefits outweighed the known and potential risks. If this was pursued together with better coordination of the initial launch of the Pharmacy Partnership for Long-Term Care Program, it is entirely plausible to move administration up a total of 5 weeks.

The question becomes how nursing home cases would evolve with earlier vaccine administration. To get a sense of this, we create an estimate of natural immunity among nursing home residents, note how this relates to the growth rate in cases, and use it to inform us how cases might have evolved with earlier vaccinations.[41] We don't mean to imply that the 3rd wave *necessarily* came down only as a result of

[41] For any given week, the flow of residents acquiring immunity are those who contract the disease but do not die. Some difficulties include asymptomatic cases, lack of testing especially in the beginning, as well as residents that are tested while no longer infectious, to account for this we assume that on average there are 50% more cases than we observe. The stock of immune residents then equals that week's flow, plus some fraction of last week's stock, as natural deaths imply the stock decays. We use 0.5% per week, which we take from data on weekly non-covid deaths / population.

natural immunity, however, we do think it gives us a reasonable indication, note for instance that cases peaked in nursing homes the week ending December 20, about 3 weeks earlier than the rest of the country, and, as can be seen in Figure 12., it is striking how many residents our estimates suggest were exposed to the virus in the nursing homes.

Figure 12.



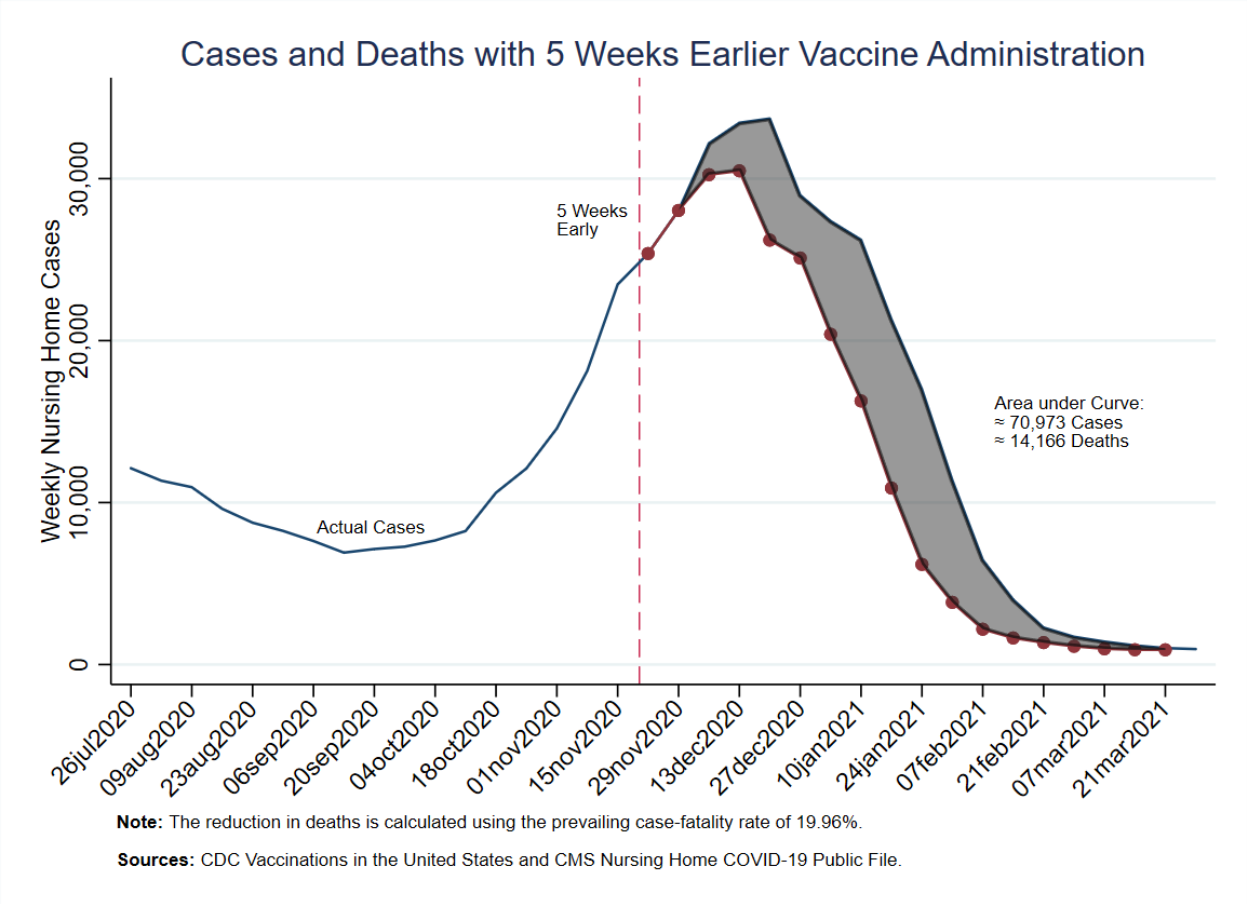
From Figure 12 we note that cases grew exponentially through large parts of October, and then peaked the week of December 20, when an estimated 675,000 current residents had been exposed to the virus. Cases then started falling, at a rate that increased as vaccine-acquired immunity started to kick in towards the end of January, and continued to fall until it stabilized around 1,000 weekly cases mid-March. In comparison, prior to the vaccine, we never went below 6,900 weekly cases.

We take 675,000 as a rough estimate of the number of immune residents required for cases to peak. With some assumptions of efficacy and administration, we find that immunity would now reach this level on December 9.[42] We then assume cases would start to fall at the same rate as we observed,

[42] Specifically, we assume 1st doses have zero effect until 14 days have passed, at which point they are 90% as effective as our measure of prior natural infection, which recall likely include some false positives as well as waning

before the rate of decline further increases once the stock of immunized residents reaches 800-850,000. We approximate this by moving the growth rates forward one period the week of December 20. While this is clearly somewhat arbitrary, we again believe it is conservative given that the stock of immune residents would be growing much faster in this scenario, than what actually happened.

Figure 13.



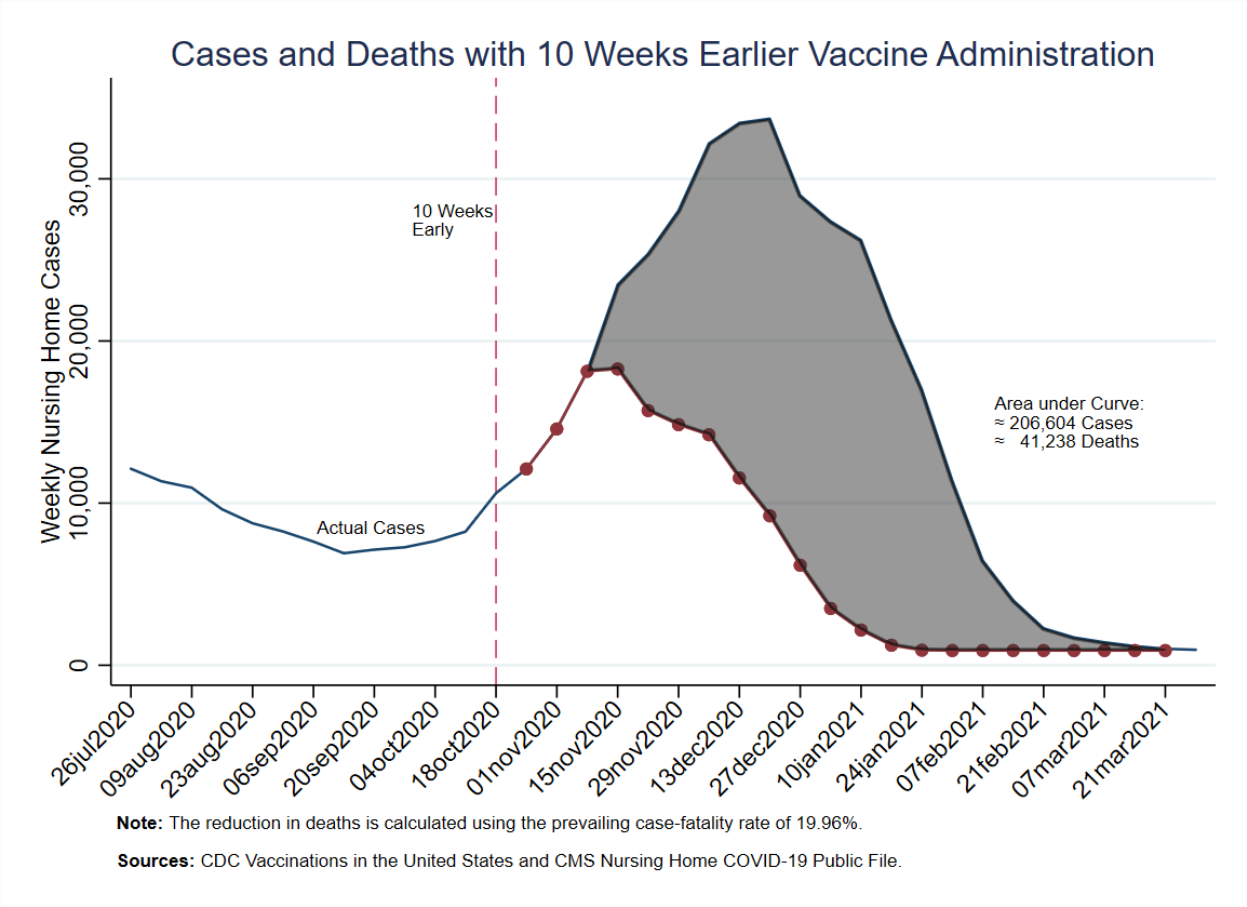
This exercise suggests moving the vaccine program up 5 weeks could have prevented 70,973 nursing home cases, which, at the prevailing case-fatality rate of 19.96%, would translate to about 14,166 fewer deaths. While we have noted several limitations of this approach, we think it's a conservative estimate and that it is quite possible cases would have fallen even faster had this been carried out.

We now repeat the exercise with administration moved up 10 weeks. This has a much larger potential impact as it could prevent more of the exponential growth we saw in November, but also because a given number of doses would do more to increase immunity when there is less natural immunity. As a first approximation we find immunity levels would approach 680,000 the week of November 15, which, if enough to see cases peak and fall would have prevented on the order of 200,000 cases and 40,000

protection. We further assume doses are given equally to residents with and without prior exposure, and that vaccinating a resident with prior exposure effectively raises the stock of immune residents by 1/10th of a resident.

deaths. To put that in perspective, this alone would reduce COVID deaths by almost 30% for the entire pandemic.

Figure 14.



A final caution about these scenarios is that an EUA limited to nursing home residents would probably not have not included staff members, which might overstate the benefits of moving administration up as staff members were being vaccinated as part of the Pharmacy Partnership for Long-Term Care and thus would have contributed to the dramatic declines seen in cases during January and February. The caveat to that is that staff vaccination rates, especially early on, were much lower than that for residents. As late as July 18, 2021, vaccination rates among Certified Nurse Aides working in nursing homes were still below 50% nationwide (McGarry et al., 2021b), so for many types of direct care staff vaccine coverage was likely less than half that during January and February.

While coarse, this exercise still shows the enormous potential benefits of speedier vaccine approval and administration in a situation when a virus is spreading exponentially, and it is abundantly clear where the pain will be felt. Structuring our regulatory system towards speed, even just as a minor exception for a limited, high-risk population, would far outweigh the other sacrifices we made for vulnerable nursing home residents, of which there were many.

Conclusions

It became clear early on that COVID was especially deadly to the aged and the infirm. In response, the United States implemented a policy of nursing home isolation and testing, in addition to extensive lockdowns and non-pharmaceutical interventions in society at-large. Judged by inputs, the policy was reasonably successful. Nursing homes were isolated and nursing home residents and staff were extensively tested. Nevertheless, judged by outputs, focused protection mostly failed. A large percentage of the total deaths from COVID in the United States came from nursing homes, especially in 2020.

Focused protection without extensive non-pharmaceutical interventions elsewhere would almost certainly have resulted in more deaths, both in nursing homes and elsewhere. Moreover, nursing homes were the ideal case for a strategy of focused protection. In a future pandemic it could be the young or the middle-aged who are most at risk, making focused protection more difficult and less likely to succeed.

Government policies could have been better but even the highest quality nursing homes, as measured by pre-COVID ratings, failed to offer much additional protection. If it existed, a successful strategy of focused protection was out-of-sample. The only exception was vaccines. Vaccines were by far the most successful intervention and only modest increases in the speed of vaccine distribution would have saved 14 to 40 thousand lives.

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Appendix

Table 1 presents the plotted estimates from Figure 6.

Predicted Resident COVID-19 Cases and Deaths by Star Rating.

	Cases March-May	Cases May-Aug	Cases Sept-Dec	Cases Post Vaccine	Deaths March-May	Deaths May-Aug	Deaths Sept-Dec	Deaths Post Vaccine
*	7.50	10.30	18.23	16.04	1.85	2.17	2.77	3.02
	(.401)	(.446)	(.526)	(.437)	(.108)	(.112)	(.105)	(.116)
**	7.62	9.56	18.67	16.14	2.04	2.19	2.89	3.11
	(.42)	(.384)	(.497)	(.373)	(.112)	(.112)	(.0962)	(.114)
***	6.91	8.85	19.11	16.94	1.80	1.90	2.86	3.17
	(.443)	(.403)	(.477)	(.419)	(.103)	(.105)	(.0975)	(.113)
****	6.97	8.73	18.88	16.63	2.07	1.85	3.13	3.17
	(.369)	(.371)	(.452)	(.366)	(.118)	(.092)	(.108)	(.107)
*****	6.22	7.67	17.60	15.88	1.97	1.56	3.03	2.98
	(.341)	(.352)	(.464)	(.336)	(.102)	(.0792)	(.0989)	(.104)
Observations	14008	14808	14860	14792	14008	14808	14860	14792

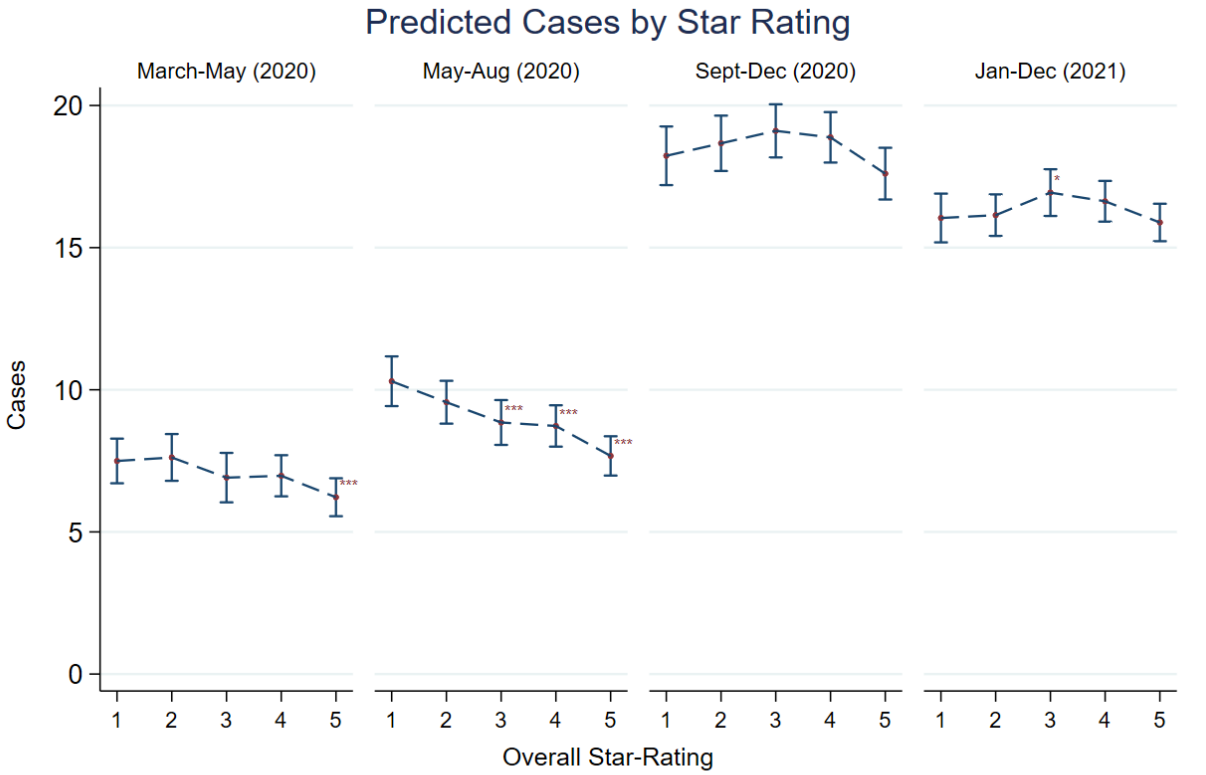
Note: Adjusted predictions and (95%) confidence intervals estimated using zero-inflated negative binomial regression of total cases and deaths during each period on pre-pandemic star ratings. Standard Errors clustered by county. Estimates adjusted for the log number of beds, NCHS Urban-Rural classification (six categories), local immunity prior to the period (measured as cumulative COVID-19 cases as a share of the county population), local disease prevalence (measured as cases as a share of the county population during the period), and local socioeconomic factors using the county's Area Deprivation Index. The estimates from 2021 also control for the county's average vaccination rate during the period. The count portion include an offset term for the log number of resident-weeks. The zero-portion is a logit model with the same control variables. The first (5th) column shows cases before May 24, 2020, the second (6th) between May 25 and August 30, 2020, the third (7th) between Sept. 1 and December 27, 2020, and the fourth (8th) from December 28, 2020, to December 5th, 2021.

Table 2 tests whether outcomes were different in facilities rated 2, 3, 4, and 5 stars compared to those rated 1-stars.

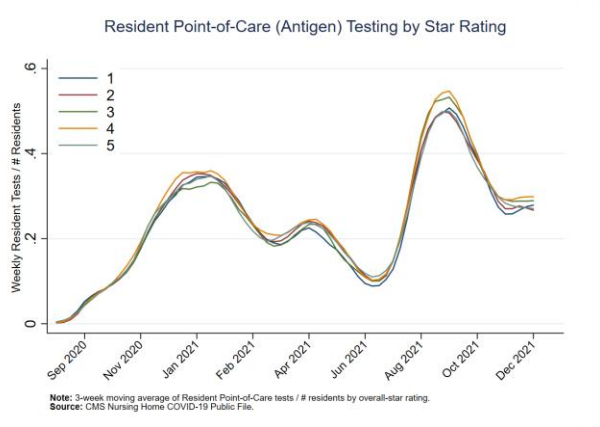
Resident COVID-19 Cases and Deaths Contrasted by Star Rating.

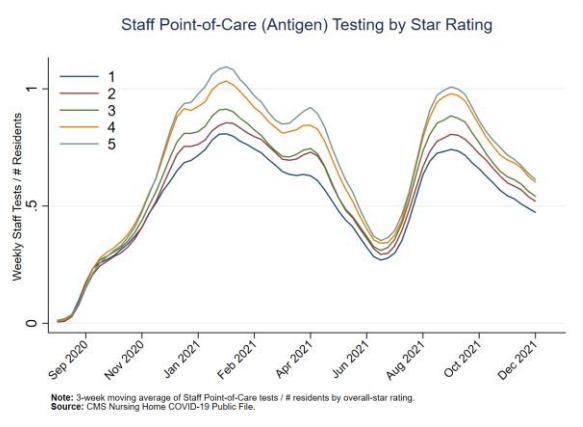
	Cases March-May	Cases May-Aug	Cases Sept-Dec	Cases Post Vaccine	Deaths March-May	Deaths May-Aug	Deaths Sept-Dec	Deaths Post Vaccine
Rated 2 vs. 1	0.12	-0.74	0.44	0.10	0.19	0.03	0.12	0.10
	(.516)	(.503)	(.593)	(.518)	(.14)	(.14)	(.134)	(.149)
Rated 3 vs. 1	-0.59	-1.45	0.88	0.89	-0.05	-0.26	0.09	0.15
	(.492)	(.509)	(.618)	(.506)	(.133)	(.129)	(.14)	(.145)
Rated 4 vs. 1	-0.52	-1.57	0.65	0.59	0.22	-0.31	0.35	0.15
	(.48)	(.537)	(.645)	(.538)	(.154)	(.138)	(.154)	(.147)
Rated 5 vs. 1	-1.28	-2.63	-0.63	-0.16	0.12	-0.61	0.25	-0.03
	(.475)	(.507)	(.683)	(.503)	(.132)	(.134)	(.146)	(.153)

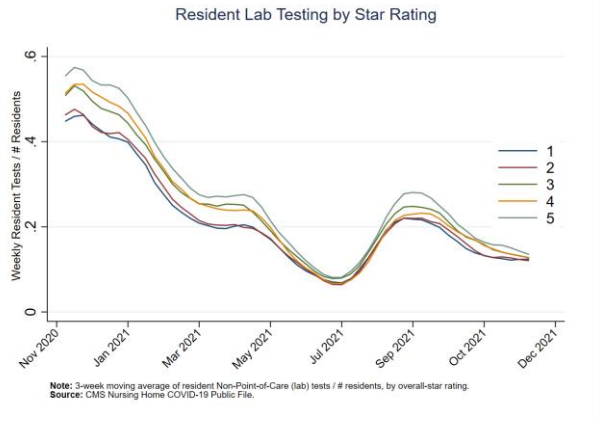
Note: Model estimated using zero-inflated negative binomial regression of total cases and deaths during each period on pre-pandemic star ratings. Standard Errors clustered by county. Estimates adjusted for the log number of beds, NCHS Urban-Rural classification (six categories), local immunity prior to the period (measured as cumulative COVID-19 cases as a share of the county population), local disease prevalence (measured as cases as a share of the county population during the period), and local socioeconomic factors using the county's Area Deprivation Index. The estimates from 2021 also control for the county's average vaccination rate during the period. The count portion include an offset term for the log number of resident-weeks. The zero-portion is a logit model with the same control variables. The first (5th) column shows cases before May 24, 2020, the second (6th) between May 25 and August 30, 2020, the third (7th) between Sept. 1 and December 27, 2020, and the fourth (8th) from December 28, 2020, to December 5th, 2021.

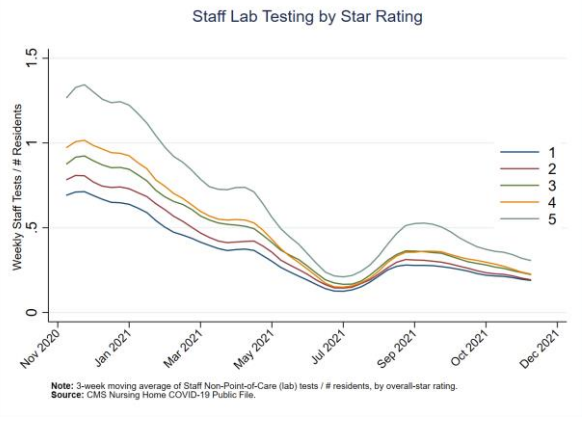


Note: Adjusted predictions and 95% confidence intervals estimated using zero-inflated negative binomial regression of total cases during each period on pre-pandemic star ratings. Significance stars show estimate is statistically different to homes rated 1-Stars, at 1% (***), 5% (**), and 10% (*) levels. Standard Errors clustered by county. Estimates adjusted for the log bedcount, NCHS Urban-Rural classification (six categories), local immunity prior to the period (measured as cumulative COVID-19 cases as a share of the county population), local disease prevalence (measured as cases as a share of the county population during the period), and local socioeconomic factors using the county's Area Deprivation Index. The estimates from 2021 also control for the county's average vaccination rate during the period. The count portion include an offset term for the log number of resident-weeks. The zero-portion is a logit model with the same control variables.


Resident Point-of-Care (Antigen) Testing by Star Rating
Weekly Resident Tests / # Residents
0
.2
.4
.6
1
2
3
4
5
Sep 2020
Nov 2020
Jan 2021
Feb 2021
Apr 2021
Jun 2021
Aug 2021
Oct 2021
Dec 2021
Note: 3-week moving average of Resident Point-of-Care tests / # residents by overall-star rating.
Source: CMS Nursing Home COVID-19 Public File.


Staff Point-of-Care (Antigen) Testing by Star Rating
Weekly Staff Tests / # Residents
0
.5
1
1
2
3
4
5
Sep 2020
Nov 2020
Jan 2021
Feb 2021
Apr 2021
Jun 2021
Aug 2021
Oct 2021
Dec 2021
Note: 3-week moving average of Staff Point-of-Care tests / # residents by overall-star rating.
Source: CMS Nursing Home COVID-19 Public File.


Resident Lab Testing by Star Rating
Weekly Resident Tests / # Residents
0
.2
.4
.6
1
2
3
4
5
Nov 2020
Jan 2021
Mar 2021
May 2021
Jul 2021
Sep 2021
Oct 2021
Dec 2021
Note: 3-week moving average of resident Non-Point-of-Care (lab) tests / # residents, by overall-star rating.
Source: CMS Nursing Home COVID-19 Public File.


Staff Lab Testing by Star Rating
Weekly Staff Tests / # Residents
0
.5
1
1.5
1
2
3
4
5
Nov 2020
Jan 2021
Mar 2021
May 2021
Jul 2021
Sep 2021
Oct 2021
Dec 2021
Note: 3-week moving average of Staff Non-Point-of-Care (lab) tests / # residents, by overall-star rating.
Source: CMS Nursing Home COVID-19 Public File.