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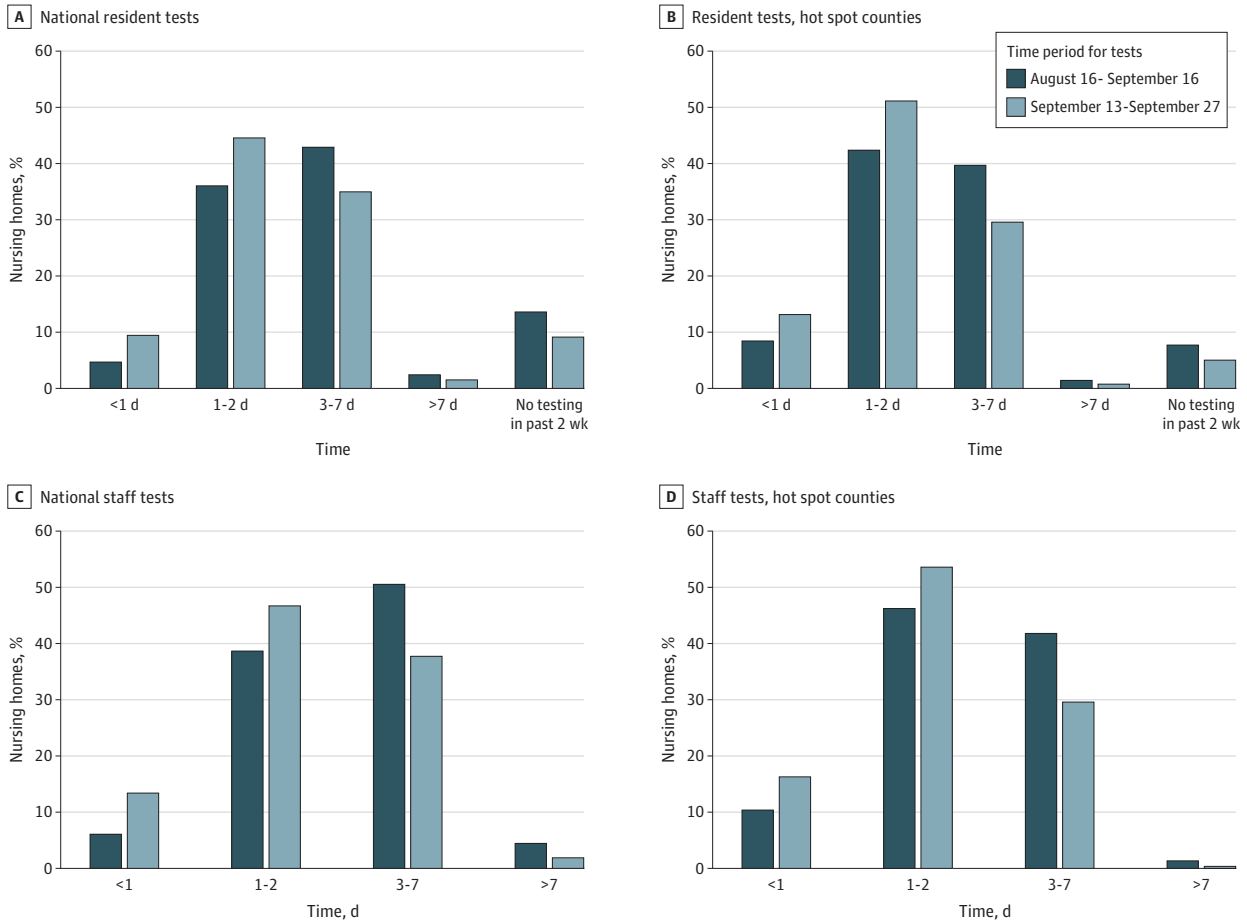
COVID-19 Test Result Turnaround Time for Residents and Staff in US Nursing Homes

Skilled nursing facility (SNF) residents comprise over 40% of coronavirus disease 2019 (COVID-19) deaths nationally.[1] Surveillance testing is critical for controlling asymptomatic and presymptomatic viral transmission in these high-risk settings.[2] For surveillance testing in SNFs to effectively guide infection control, results need to be obtained in less than 1 day.[3] To facilitate such rapid testing,[4] Medicare began distributing point-of-care severe acute respiratory syndrome coronavirus 2 antigen test instruments in July 2020, focused on SNFs in COVID-19 hot spot counties.[5] Little is known about the adequacy of test result turnaround in SNFs.

Supplemental content

Methods | We performed a cross-sectional study using the Medicare COVID-19 Nursing Home Database, a federally mandated weekly survey of all Medicare-certified SNFs, to examine facility-reported test result turnaround time. Beginning on August 16, 2020, the survey included 2 questions on test result turnaround: "During the past 2 weeks, on average how long did it take your long-term care facility to receive COVID-19

Figure. National Distribution of Staff and Resident Testing Turnaround Times, August 16 to September 27, 2020



Distribution of test result turnaround times by survey response category for all skilled nursing facilities (SNFs) nationally for (A) residents (14 972 SNFs for time period 1 and 15 036 for time period 2) and (B) staff (14 967 SNFs for time period 1 and 14 988 for time period 2). There were 15 065 SNFs that submitted a nonmissing response to either the resident or staff testing question in time period 2. C and D, The same data for SNFs in 62 hot spot counties (1524 SNFs for resident testing in time period 1 and 1532 for time period 2; 1523 SNFs for staff testing in time period 1 and 1522 for time period 2). The difference in sample size between staff and resident categories within a time period is because, by design, the SNFs that reported that they did not perform resident tests in the preceding 2 weeks did not provide testing result turnaround answers; also, in some time periods, up to 2.5% of 15 355 total SNFs had missing data. There was no option for SNFs to indicate that they did not perform staff testing in the preceding 2 weeks. All estimates are weighted by facility bed size.

Table. Association of Skilled Nursing Facility Characteristics and COVID-19 Testing Turnaround Times of More Than 2 Days for the Week Ending September 27, 2020

Characteristic	Overall sample characteristics (%)[a]	Residents		Staff	
		Turnaround time >2 d (%)	Adjusted difference, percentage points (95% CI)[b]	Turnaround time >2 d (%)	Adjusted difference, percentage points (95% CI)[b]
Ownership type					
Nonprofit	23.6	35.2	1 [Reference]	37.6	1 [Reference]
Government owned	6.4	32.5	−2.2 (−6.0 to 1.7)	32.7	−2.9 (−6.4 to 0.7)
For profit	69.8	40.5	4.2 (1.8 to 6.6)	39.2	0.5 (−1.7 to 2.8)
Bed size, No					
1-50	14.0	34.4	1 [Reference]	36.0	1 [Reference]
51-100	38.6	37.8	1.2 (−1.7 to 4.2)	37.9	0.1 (−2.5 to 2.7)
101-150	31.8	39.3	2.5 (−0.7 to 5.8)	37.9	1.0 (−1.9 to 3.9)
151-200	10.2	42.3	2.8 (−1.1 to 6.6)	41.9	0.7 (−2.9 to 4.3)
≥201	5.2	44.8	2.3 (−2.2 to 6.9)	45.1	−0.5 (−4.8 to 3.8)
Chain affiliation					
No	39.2	37.3	1 [Reference]	38.0	1 [Reference]
Yes	54.6	40.2	2.5 (0.6 to 4.5)	39.1	2.2 (0.4 to 3.9)
Missing	6.2	34.2	6.0 (0.3 to 11.7)	34.7	6.2 (0.7 to 11.6)
Quartile of Medicaid revenue share					
1 (lowest)	23.5	36.3	1 [Reference]	36.7	1 [Reference]
2	23.4	39.0	0.9 (−1.5 to 3.4)	38.7	0.7 (−1.5 to 3.0)
3	23.5	39.7	1.9 (−0.6 to 4.4)	39.8	2.4 (0.0 to 4.7)
4 (highest)	23.4	41.2	3.7 (1.2 to 6.1)	39.4	2.7 (0.4 to 5.1)
Quartile of non-White resident share					
1 (lowest)	23.0	36.9	1 [Reference]	38.2	1 [Reference]
2	22.5	37.4	−0.7 (−3.3 to 1.8)	37.3	−1.1 (−3.5 to 1.3)
3	22.6	39.1	−0.4 (−3.1 to 2.4)	38.2	−0.5 (−3.2 to 2.1)
4 (highest)	22.6	43.5	1.2 (−1.9 to 4.3)	41.9	0.4 (−2.6 to 3.4)
Missing	9.3	33.1	−6.3 (−11.1 to −1.4)	33.9	−5.3 (−9.9 to −0.7)
Overall quality score					
1	16.5	42.3	1 [Reference]	40.9	1 [Reference]
2	19.4	40.4	−1.0 (−3.8 to 1.7)	39.4	−1.7 (−4.3 to 0.9)
3	17.5	37.9	−3.6 (−6.4 to −0.9)	38.2	−3.2 (−5.9 to −0.6)
4	21.1	37.7	−2.5 (−5.2 to 0.1)	36.5	−4.3 (−6.8 to −1.7)
5	24.2	36.2	−3.4 (−6.2 to −0.5)	37.5	−3.8 (−6.5 to −1.0)
Quartile of county new COVID-19 case rate[c]					
1 (lowest)	25.1	42.6	1 [Reference]	44.4	1 [Reference]
2	25.2	39.4	0.3 (−2.9 to 3.5)	39.5	−2.1 (−5.1 to 0.8)
3	24.8	37.2	1.7 (−1.7 to 5.1)	35.9	−0.6 (−4.3 to 3.1)
4 (highest)	24.9	35.8	3.2 (−0.5 to 6.9)	33.8	−1.9 (−5.5 to 1.6)
Any resident COVID-19 cases[d]					
No	20.4	38.6	1 [Reference]	38.1	1 [Reference]
Yes	79.6	38.7	−0.6 (−2.9 to 1.7)	38.5	0.8 (−1.3 to 2.8)
Any staff COVID-19 cases[d]					
No	6.3	38.1	1 [Reference]	37.9	1 [Reference]
Yes	93.7	38.8	1.8 (−2.0 to 5.7)	38.5	2.4 (−0.9 to 5.6)
Hot spot county[e]					
No	89.8	39.5	1 [Reference]	39.4	1 [Reference]
Yes	10.2	32.5	−4.0 (−7.6 to −0.4)	30.2	−3.7 (−7.6 to 0.1)

Abbreviation: COVID-19, coronavirus disease 2019.

[a] A total of 15 065 skilled nursing facilities.

[b] Adjusted differences in the probability of reporting a test result turnaround time longer than 2 days were estimated using linear probability regressions that contained all the facility and county characteristics included in the table, state fixed effects, the weekly rate of new resident and staff cases in the facility, and indicators for the type of lab used for test processing (private, state health department, other). Standard errors were clustered at the county level.

[c] New county case rate refers to the 7-day average of new daily COVID-19 cases for the same week in which test result turnaround times were reported. County case rates obtained from the publicly available New York Times Coronavirus (COVID-19) Data in the United States repository.

[d] COVID-19 cases defined as either suspected or confirmed cases since January 1, 2020, as reported by the skilled nursing facility.

[e] Hot spot counties are those designated by the US Centers for Medicare Services to receive point-of-care testing kits during the first wave of distribution based on community rates of COVID-19.

viral (nucleic acid or antigen) test results of residents?" or "staff and/or facility personnel?" with possible answers of less than 1 day, 1 to 2 days, 3 to 7 days, more than 7 days, or, for residents only, "no testing in the past 2 weeks" (eAppendix in the Supplement). We combined these data with SNF characteristics from the National Institute on Aging–funded LTCFocus.org database and the 2020 Medicare Nursing Home Compare database.

Per institutional policy, institutional review board approval and written informed consent were not required for research using publicly available data. Using surveys from the weeks ending August 16 to September 6, 2020, compared with September 13 to September 27, 2020, we examined test result turnaround for SNF staff and residents nationally and in Medicare-designated hot spot counties (eAppendix in the Supplement).[5] We used multivariable linear probability models to estimate the association between SNF characteristics and result turnaround time longer than 2 days, controlling for SNF characteristics and state fixed effects, with county-level clustered standard errors (eAppendix in the Supplement). Analyses were performed using Stata statistical software (version 16, Stata Corp).

Results | Among the 15 065 respondents (98% of 15 355 Medicare-certified SNFs included in the data set), test result turnaround time was less than 1 day for 960 (6.2%) and 713 (4.8%) SNFs testing staff and residents respectively by September 7, 2020 (**Figure**, A and C). Rates rose to 2188 (13.5%) and 1516 (9.5%) by the week ending September 27. In hot spot counties, 167 (10.4%) and 125 (8.5%) SNFs testing staff and residents had less than 1 day turnaround by September 7, increasing to 248 (16.4%) and 196 (13.2%) by the week ending September 27.

Nationally, test result turnaround time was 3 days or longer for 8117 (55.1%) and 6394 (45.5%) SNFs testing staff and residents and 642 (43.3%) and 621 (41.3%) in hot spot counties by September 7, 2020 (Figure). By September 27, this decreased to 5768 (39.8%) and 5145 (36.6%) of SNFs testing staff and residents nationally and 459 (29.9%) and 469 (30.4%) in hot spot counties.

There were statistically significant differences in the proportion of SNFs with test result turnaround times longer than 2 days for staff or residents across different characteristics, but they were mostly small in magnitude (**Table**). Turnaround time of more than 2 days was weakly correlated with new county-level COVID-19 cases that week ending September 27, after adjustment.

Discussion | In a comprehensive federal survey, only a small fraction of SNFs had less than 1 day turnaround for staff or resident testing by late September 2020. Although testing delays improved over time, the state of testing is far behind the less than 24-hour turnaround that epidemiological modeling suggests is essential to prevent COVID-19 outbreaks in SNFs.[2,3]

Unfortunately, even in hot spot counties where all facilities should have received point-of-care instruments by mid-August, less than 17% of SNFs had a turnaround of less than 1 day. Conflicting regulations and testing supply shortages may be hampering efforts to take advantage of these devices.[6]

Limitations of this study include reliance on facility-reported test result turnaround times, an inability to differentiate between turnaround times of 1 and 2 days owing to survey design, and lack of data on the type of testing used by SNFs.

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Speed, Evidence, and Safety Characteristics of Vaccine Approvals by the US Food and Drug Administration

There is an urgent need to develop a safe and effective vaccine to prevent coronavirus disease 2019 (COVID-19). However, recent surveys suggest that more than half of Americans are hesitant about receiving a potential COVID-19 vaccine, owing to concerns about adverse effects or lack of effectiveness.[1] There is also concern that the US Food and Drug Administration (FDA) might authorize a vaccine prematurely.[2] To understand the usual approval process followed by the FDA, we systematically evaluated all novel vaccines approved by the FDA over the last decade, characterizing the premarket development and regulatory review times, the clinical evidence on which approval was based, and the size and follow-up duration of the prelicensure safety database.

Methods | We identified all original biologics licensing applications (BLAs) for vaccines approved by the FDA between January 2010 and June 2020, excluding supplemental approvals of existing vaccines. Using publicly available FDA documents,[3] we identified 3 regulatory dates for each vaccine: investigational new drug submission (when human testing can begin), BLA submission, and FDA approval. We first identified all trials that provided safety and efficacy evidence for approval, characterizing them by study purpose and number of patients. Next, we identified all pivotal efficacy trials and determined the use of randomization, masking, comparator group, and primary end point using methods described previously.[4] For pivotal efficacy trials using a clinical primary end point, we collected vaccine efficacy. Finally, we estimated the total number of patients in the prelicensure safety database and determined the longest duration of follow-up for serious adverse events among all trials included in the safety database. The study did not require Yale University institutional review board approval or patient informed consent because it was based on publicly available information and involved no patient records.

Results | Between January 2010 and June 2020, the FDA approved 21 vaccines, most commonly for influenza (5 [23.8%]) and meningococcus (5 [23.8%]). Of these, 4 (19.0%) received Accelerated Approval. The median premarket clinical development period (investigational new drug submission to FDA approval) was 8.1 (interquartile range [IQR], 6.1-10.5) years, including a median FDA review period (BLA submission to FDA approval) of 12.0 (10.8-21.0) months (**Table 1**).

Each vaccine approval was supported by a median total of 7 (IQR, 5-13) clinical trials, including 2 (IQR, 1-3) pivotal efficacy trials and 1 (IQR, 1-1) trial considered essential to establishing lot-to-lot consistency. The median number of patients in the prelicensure safety database was 6710 (IQR, 4576-15 997), and the median follow-up for serious adverse events was 6 months (IQR, 6-12). The median aggregated number of patients enrolled among all pivotal efficacy trials supporting a given vaccine approval was 4961 (IQR, 3537-7775). All 21 vaccines were approved based on at least 1 randomized pivotal efficacy trial and 14 (66.7%) based on at least 2 pivotal efficacy

Table 1. Characteristics of 21 Vaccines Approved by the FDA From 2010 to 2020

Characteristic	Median (IQR)
Indication, No. (%)	
Influenza	5 (23.8)
Meningococcus	5 (23.8)
DTaP[a]	2 (9.5)
Other[b]	9 (42.9)
Vaccines granted accelerated approval, No. (%)	4 (19.0)
Clinical development period, y[c]	8.1 (6.1-10.5)
FDA review period, mo[d]	12.0 (10.8-21.0)
No. of clinical trials supporting vaccine approval[e]	7 (5-13)
No. of pivotal efficacy trials	2 (1-3)
No. of trials considered essential to establish lot-to-lot consistency[f]	1 (1-1)
No. of patients in the safety database	6710 (4576-15 997)
Duration of follow-up for serious adverse events, mo	6 (6-12)

Abbreviations: BLA, biologics licensing applications; DTaP, diphtheria, tetanus, and acellular pertussis; FDA, US Food and Drug Administration; IND, investigational new drug; IQR, interquartile range.

[a] Category includes all combination vaccines in which DTaP was a component.

[b] Includes 1 vaccine each for pneumococcus, adenovirus, human papillomavirus, cholera, shingles, hepatitis B, dengue virus, smallpox and monkeypox, and ebolavirus.

[c] Defined as IND (when clinical testing can begin) to FDA approval.

[d] Defined as BLA submission (when vaccine sponsors submit data for FDA approval) to FDA approval.

[e] Total clinical trials include pivotal and supportive studies supporting vaccine approval.

[f] If a pivotal efficacy study was also considered essential to establish lot-to-lot consistency, it was included in both categories.

Table 2. Features of the Aggregated Pivotal Efficacy Trials Supporting 21 Vaccines Approved by the FDA From 2010 to 2020

Feature	Median (IQR)
Total enrolled patients[a]	4961 (3537-7775)
Total patients in intervention group[a]	3552 (2398-4561)
≥1 Pivotal trial, No. (%)	
With randomization	21 (100.0)
With masking	17 (81.0)
With active/placebo comparator	20 (95.2)
With clinical primary end point[b]	8 (38.1)
Vaccine efficacy, %[c]	91.9 (79.6-98.0)

Abbreviations: FDA, US Food and Drug Administration; IQR, interquartile range.

[a] Values represent the total number of patients across all pivotal efficacy trials supporting FDA approval of given vaccine.

[b] Clinical primary end points represent the rate of laboratory-confirmed infection. The remaining 13 vaccine approvals were based on antibody immune response.

[c] Calculated among the 8 vaccines approved on the basis of a clinical primary end point. For vaccines with multiple pivotal efficacy trials using a clinical primary end point, the pooled vaccine efficacy was used. For Gardasil 9 (Merck), vaccine efficacy was only reported for human papillomavirus types 31, 33, 45, 52, and 58 because types 6, 11, 16, and 18 had an existing vaccine (Gardasil) that was used as a comparator in the pivotal efficacy trial.