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MAJOR ARTICLE

Lessons From the Field: Rapid Antigen Testing Is Efficient and Practical for Mitigation of Coronavirus Disease 2019 Outbreaks in Long-Term Care Facilities

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Background. Mitigation of coronavirus disease 2019 (COVID-19) outbreaks in long-term care facilities (LTCFs) is facilitated by rapid identification and isolation of infectious individuals to interrupt viral transmission. Immunochromatographic (IC) tests, or rapid antigen tests, have high sensitivity and specificity during the contagious period for COVID-19. Mathematical modeling predicts frequent IC surveillance will be more efficient than polymerase chain reaction (PCR)-based strategies, especially during community surges when reporting of PCR results can be delayed. However, there are few published field studies evaluating IC testing strategies in this long-term care setting.

Methods. In fall and winter of 2020, the Marin Health and Human Services Department implemented thrice-weekly IC mass testing by nonlaboratory workers in outbreaks that occurred in 2 LTCFs, in addition to then-standard semiweekly PCR testing. The IC test performance was characterized using same-day PCR specimens as reference standard. Cumulative incidence and duration of transmission for the 2 IC intervention facility outbreaks were compared with 6 reference LTCFs that used weekly to semiweekly PCR alone during an outbreak response.

Results. Of 123 same-day test pairs, IC test sensitivity and specificity were 75% (95% confidence interval [CI], 48%–93%) and 100% (95% CI, 97%–100%), respectively. The median duration of outbreak transmission was 19.5 days in the 2 intervention sites and 28 days in the reference facilities ($P = .40$). Cumulative incidence for the outbreaks among LTCF residents was 41% in the intervention facilities versus 52% in the reference facilities ($P = .04$, Fisher 2-sided exact).

Conclusions. Thrice-weekly mass IC testing as used by nonlaboratory personnel can be highly practical and effective for COVID-19 outbreak mitigation in the LTCF setting.

Keywords. COVID-19; nursing home; rapid antigen testing.

In the United States in 2020, long-term care facilities (LTCFs) experienced a disproportionately elevated share of coronavirus disease 2019 (COVID-19)-related morbidity and mortality [1]. These congregate-living settings comprise 2 vulnerable populations: elderly or debilitated residents and essential workers caring for them. Staff often work in multiple facilities, live in dense housing, and share transportation, thus providing multiple avenues of transmission into facilities and back into surrounding communities. Facility staff may have inconsistent clinical guidance, limited access to personal protective equipment, and inadequate workspace ventilation. Moreover, nonmedical staff may be called upon to perform infection-prevention measures, including high-risk intimate care to infectious residents. Despite multipronged viral containment strategies, interrupting the chain of transmission during outbreaks remains a significant challenge [2].

Long-term care facility COVID-19 outbreaks occur despite implementation of nonpharmaceutical interventions, and a key principle to COVID-19 outbreak mitigation in the LTCFs in 2020 was believed to be frequent testing regardless of symptom status to rapidly identify infectious staff for precautionary removal and residents for isolation or clinical triage [3]. Reverse-transcriptase polymerase chain reaction (PCR) platforms provide the highest levels of sensitivity and specificity for COVID-19 diagnosis. However, PCR assays require complex and expensive laboratory resources, contributing to high cost and prolonged turnaround times, especially during community surges when overwhelmed laboratory services can lead to delayed processing and reporting [4]. The LTCFs have no requirement for, and generally do not have, onsite laboratory capabilities, leading to additional transport delays [5].

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Delayed test results increase risk for ongoing severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) transmission from unidentified infectious individuals during their most contagious windows [6].

Compared with PCR, immunochromatographic (IC) tests offer field and performance characteristics better suited for LTCF outbreak mitigation. Immunochromatographic tests, also known as rapid antigen tests, are low cost, have turnaround times as short as 10 minutes, and are easy to perform. The IC tests show reasonable sensitivity and excellent specificity compared with PCR during periods of high viral shedding, which is strongly associated with infectiousness [7]. Despite these characteristics, widespread adoption of IC testing in LCTF outbreaks remained limited at the time of the fieldwork reported here, late in the first year of the COVID-19 pandemic. Mathematical modeling suggests that using IC testing for serial point-prevalence surveys every 2 to 3 days in LTCF outbreaks will improve efficiency and reduce transmission [8]. However, direct clinical validation of this strategy in the LTCF setting is lacking.

Long-term care facilities provide a closely monitored cohort of individuals in the periconversion phase of infection and, when closed to admissions during outbreaks, are a stable theater to evaluate test performance and track ongoing transmission. In this retrospective evaluation of a field-testing intervention, we implemented thrice-weekly, point-prevalence IC testing in addition to what was then standard of care (ie, weekly or semiweekly PCR testing with companion viral containment strategies) for COVID-19 outbreaks in 2 intervention facilities during the winter surge of 2020. We examined the IC test sensitivity and specificity compared with PCR testing and assessed the impact of implementing IC testing on outbreak cumulative incidence and outbreak median duration compared with 6 reference facility outbreaks during the prior summer surge of 2020, when IC tests were not yet available.

METHODS

Clinical Setting

The Marin County Health and Human Services (HHS) Department assembled a multiagency team in April 2020 in partnership with 2 major hospitals in the county (Kaiser Permanente, San Rafael, and MarinHealth) to address outbreaks in LTCFs and other congregate-living settings in Marin County, California [9]. The California Department of Public Health (CDPH) provided guidance for LTCF COVID-19 outbreaks and adherence monitoring during the study period [10]. The Marin HHS Department of Public Health supported LTCFs to prevent and mitigate outbreaks. Nontesting strategies and infection control policies for mitigation were similar in the intervention and reference facilities during their respective outbreaks. All facilities were required to implement strict masking recommendations, symptom screening, and social distancing in shared spaces. Policies for isolation and quarantine by zone, ensuring adequacy of ventilation, precautionary removal of identified cases into isolation, complete visitation restriction, and closing the facility to new admissions during ongoing case identification were comparable for the period of evaluation.

Testing strategies for outbreak mitigation during the retrospective period included point-prevalence surveys of all staff and residents. The LTCFs utilized weekly or semiweekly PCR point-prevalence surveys for case identification. Testing was carried out regardless of symptoms. During this period, there were significant delays in receiving PCR test results, commonly 1 week or more, limiting their usefulness for outbreak mitigation. In the fall of 2020, IC tests became available, enabling their application in point-prevalence surveys in newly identified LTCF outbreaks. In October 2020, we selected 2 facilities (Intervention Facilities 1 and 2) to overlay thrice-weekly IC testing on the existing weekly or twice-weekly PCR testing regimen to provide immediate actionable results. The overlaid IC testing was instituted on Day 1 of the outbreak in Intervention Facility 1 and on Day 5 of the outbreak in Intervention Facility 2. Six additional LTCFs (Reference Facilities 3, 4, 5, 6, 7, and 8) were selected as a comparator group, comprising all skilled nursing facilities in Marin County hosting previously identified outbreaks with more than 10 cases in a month; these outbreaks had been managed with weekly or semiweekly PCR mass testing. The LTCF COVID-19 vaccination campaign began during the Facility 1 outbreak, with administration of a first dose of BNT162b2 to staff on Day 7 and to residents on Day 26.

Immunochromatographic Testing

We used the Abbott (Scarborough, ME) BinaxNOW for COVID-19 Ag Card IC test based on availability, cost, ease of use, rapid results, and then-emerging favorable performance data [11]. The HHS staff trained LTCF staff (1) in direct specimen collection and (2) to observe self-performed specimen collection. The Pilarowski et al [12] method of visual scoring was applied to ensure optimal specificity while maintaining sensitivity.

Polymerase Chain Reaction Testing

With few exceptions, PCR tests were performed by Avellino Labs (Menlo Park, CA) using private onsite specimen collection for the AvellinoCoV2 test, approved under an Emergency Use Authorization (March 5, 2020) [13]. The AvellinoCoV2 test uses 2 primer and probe sets to detect 2 regions in the SARS-CoV-2 nucleocapsid (N) gene and 1 primer and probe set to detect human RNase P in a clinical sample; the lowest concentration of SARS-CoV-2 ribonucleic acid that yielded a detection rate of ≥95% with a previously approved comparator test was 1000 genomic copies/mL [13].

Test Performance

Sensitivity and specificity for the IC test (with exact binomial 95% confidence intervals [CIs]) were calculated using the PCR test as the reference standard (Stata 15.1; StataCorp College Station, TX). The study population included any staff or resident with at least 1 occurrence of IC and PCR testing collected on the same day, and events were limited to the initial same-day PCR-IC pairing for each subject. We reviewed staffing and residency records at the participating facilities to estimate the denominator populations at risk. We compared cycle threshold (CT) values for positive PCR tests associated with true-positive IC test results to those with false-negative IC test results. In addition, we calculated median turnaround time (TAT) for each respective outbreak as the median number of days from specimen collection to the date the results were reported in the lab for all positive PCR results; negative PCR test result TATs were not utilized due to limitations in the automated state laboratory reporting system in 2020.

Impact on Outbreaks

Outbreaks were defined as 1 or more residents and/or 3 or more staff cases in a facility with epidemiologic linkage in that facility, in accordance with CDPH health advisories [14]. The outbreak transmission period began with the day the facility met outbreak definition and ended with the specimen collection date of the final test-positive case that was followed by 14 days without new infections. We assessed pandemic activity in the community at the start of each outbreak by calculating the 7-day incidence, reported as cases per week per 10^3 population, beginning on Day 1 of each outbreak [15]. We used a 2-sided Fisher exact test to compare the cumulative incidence of infection among residents versus staff in Intervention Facilities 1 and 2 combined and in Reference Facilities 3–8 combined (Stata 15.1). We also compared the cumulative incidence of infection among residents and staff separately in Intervention Facilities 1 and 2 combined versus that in Reference Facilities 3–8 combined. Finally, we compared the median duration of outbreak transmission in Intervention Facilities 1 and 2 combined versus that in Reference Facilities 3–8 combined.

RESULTS

Demographic Characteristics of Participants

Median age was 44.4 years for staff and 83 years for residents of Intervention Facilities 1 and 2 (Table 1). Sixty-five percent of residents and 70% of staff were female. Eighty-six percent of residents with race and/or ethnicity information were non-Hispanic White. In contrast, Hispanics were the largest ethnic group among staff, comprising 40% of staff with available race/ethnicity information. Demographic data of the reference facilities was incomplete for the purposes of this retrospective review.

Participating Long-Term Care Facilities

Intervention Facilities 1 and 2 served fewer residents and had smaller staffs, on average, than did Reference Facilities 3–8 (Table 2). The onset of outbreaks in Intervention Facilities 1 and 2 occurred in December and November 2020, respectively, whereas outbreaks in Reference Facilities 3–8 occurred between late June and early September 2020. Community infection rates in the first week of each outbreak ranged from 50.7 to 225.1 cases/week/10^3. Cumulative incidence of infection among residents at the termination of outbreaks was greater than twice that of staff personnel in all participating facilities ($P > .001$) (Table 2). The cumulative incidence of infection among residents in Intervention Facilities 1 and 2 combined was less than that in Reference Facilities 3–8 combined (41% vs 52%, $P = .04$). The cumulative incidence of infection among staff was comparable in Intervention Facilities 1 and 2 combined and Reference Facilities 3–8 combined (16% vs 20%, $P = .25$). Outbreak transmission periods ranged from 14 to 74 days (Table 2 and Figure 1). Median duration of outbreak transmission was 30% shorter in Intervention Facilities 1 and 2 combined compared with Reference Facilities 3–8 combined, but this difference was not statistically significant (19.5 vs 28 days; Wilcoxon rank-sum test, $P = .40$). The median TAT in participating facilities ranged from 1.2 to 8 days. Median TAT in participating facilities was not correlated with cumulative incidence in the community during the first week of the outbreak ($r_{Spearman}$ 0.36, $P = .39$).

Test Results

There were 2479 test results (1421 PCR and 1058 IC) from 301 residents or staff at Intervention Facilities 1 and 2 during site-specific COVID-19 outbreaks. There were 123 participants with a PCR test paired with an IC test collected on the same calendar day.

Test Performance

There were 16 (13.0%) positive PCR results among the 123 same-day test pairs. Of these pairs, 119 (96.7%) yielded concordant results between PCR and IC testing (Table 3). The observed sensitivity and specificity for IC tests were 75% (12 of 16; 95% CI, 48%–93%) and 100% (107 of 107; 95% CI, 97%–100%), respectively. All 4 discordant pairs were false-negative IC test results. Of these, 2 participants had subsequent positive IC test results 2 days after collection of the initial discordant test pair, and 1 participant had a positive IC test 5 days after collection of the initial discordant test pair. (No intervening tests were collected in these cases.) The remaining participant had a positive IC test 2 days before the collection of the discordant test pair. The CT values were available for 9 of the 12 concordant positive IC-PCR results, and all 4 discordant IC-negative paired results. Median CT values for these 2 groups were 25.9 (range, 19.5–33.7) and 37. 3 (range, 30.7–38.6),

Table 1. Selected Demographic Characteristics for Residents and Staff With Same-Day Paired[a] Tests for COVID-19 in 2 Long-Term-Care Facilities in Marin County, CA, 2020–2021

	Intervention Facility 1		(Intervention Facility 2)		Total	
Characteristic	Residents	Staff	Residents	Staff	Residents	Staff
Total subjects tested (n)	21	30	19	53	40	83
Age (years)						
Median	78.4	49.8	83.2	41.4	80.7	44.4
Interquartile range	72–87	37–61	76–88	34–50	74–88	34–52
Sex (n [column %])						
Male	7 (33)	10 (33)	7 (37)	15 (28)	14 (35)	25 (30)
Female	14 (67)	20 (67)	12 (63)	38 (72)	26 (65)	58 (70)
Race/Ethnicity (n, %)						
Asian	1 (5)	3 (10)	1 (5)	3 (6)	2 (5)	6 (7)
Black	0 (0)	0 (0)	1 (5)	1 (2)	1 (3)	1 (1)
Hispanic	2 (10)	5 (17)	0 (0)	8 (15)	2 (5)	13 (16)
Non-Hispanic White	15 (71)	6 (20)	15 (79)	6 (11)	30 (75)	12 (14)
Other, unknown, no match	3 (14)	16 (53)	2 (11)	35 (66)	5 (13)	51 (61)
Job Description (n, %)						
Caregiver	…	19 (63)	…	30 (57)	…	49 (59)
Food Service	N/A	3 (10)	N/A	7 (13)	N/A	10 (12)
Custodial	…	5 (17)	…	6 (11)	…	11 (13)
Administrative	…	3 (10)	…	1 (2)	…	4 (5)
Other or unknown	…	0 (0)	…	9 (17)	…	9 (11)

Abbreviations: COVID-19, coronavirus disease 2019; N/A, not applicable.

[a]Test pairs consist of the polymerase chain reaction test as reference standard and an Immunochromatographic test drawn on the same calendar day.

respectively. Statistical testing was not conducted owing to small sample size.

DISCUSSION

This fieldwork provides practical evidence that frequent serial IC testing, when paired with companion mitigation measures, is an effective mitigation strategy for SARS-CoV2 outbreaks in LTCFs. Addition of thrice-weekly IC testing to conventional infection control practices (including weekly or semiweekly PCR testing) was associated with reduced cumulative incidence among residents at the end of transmission (41% vs 52%, $P = .04$). The duration of outbreak transmission (median 19.5 vs 28 days, nonsignificant) was associated with a reduction compared with conventional practices alone. Higher cumulative incidence early in the outbreak transmission period, such as in intervention Facilities 1 and 2 (Figure 1), suggests conditions conducive to transmission that may portend a greater duration of transmission and/or cumulative incidence before viral containment is achieved. However, more efficacious outbreak mitigation in the intervention facilities was, in part, facilitated by the rapid availability of IC test results, which enabled timely, targeted quarantine and isolation measures during the patients' most transmissible infectious periods. In addition, compared with PCR testing, IC testing was available at a fraction of the cost, often with a more flexible specimen collection time (ie, immediately before working a shift or at the onset of symptoms).

The major strengths of this study include its real-world context, demonstrating its applicability to community LTCFs, and that the study used parallel IC and PCR testing, with the latter as reference standard. The crucial disadvantage of IC testing is reduced sensitivity compared with PCR, particularly early or late in the course of infection when viral antigen levels may be too low to trigger a positive IC test result. Our data suggest that patients testing negative early in their illness will be identified on subsequent testing, often before an initial PCR value would have returned, and that false-negative IC test results correlate with CT values over 30, when virus may not be culturable or transmissible [3].

The study also demonstrated the practicality of utilizing trained nonclinical personnel for sample collection, facilitating high volume testing in the outbreak setting when clinical and laboratory personnel may be overwhelmed with other duties. Although specimen collection by nonclinical personnel may have contributed to reduced sensitivity, the observed sensitivity of 75% and specificity of 100% are adequate for outbreak mitigation as demonstrated here and according to mathematical modeling [8]. See et al [8] predicted that even with a PCR turnaround-time of 24 hours, an IC test with 75% sensitivity performed every 3 days will be more effective than weekly PCR testing and similarly effective as thrice-weekly PCR testing.

Table 2. Cumulative Incidence and Outbreak Transmission Periods in Residents and Staff by Facility, Marin County, CA

Facility	Testing Regimen	Date of Onset of Outbreak	Community Incidence Week 1[a] (Cases/week * 0.001)	Total Infected Residents (n/n, %)	Total Infected Staff (n/n, %)	Outbreak Transmission Period[b] (days)	Median Turnaround Time (Positive Tests Only) (days)
Intervention Facility 1	2x-weekly PCR[c] + 3x-weekly IC[d]	12/13/2020	225.1	28/79 (35%)	13/109 (12%)	19	8.0
Intervention Facility 2	2x-weekly PCR[c] + 3x-weekly IC[d]	11/6/2020	50.7	16/29 (55%)	18/84 (21%)	20	3.0
Intervention Facilities 1 and 2 Combined				44/108 (41%)[e,g]	31/193 (16%)[e]	19.5 (median)	5.5
Reference Facility 3	1x-weekly PCR[c]	6/22/2020	143.4	73/112 (65%)	35/130 (27%)	33	2.8
Reference Facility 4	1x-weekly PCR[c]	7/21/2020	123.0	28/45 (62%)	12/60 (20%)	63	1.2
Reference Facility 5	1x-weekly PCR[c]	7/04/2020	148.1	87/177 (49%)	50/220 (23%)	74	1.7
Reference Facility 6	1x-weekly PCR[c]	9/10/2020	53.4	12/90 (13%)	6/95 (6%)	14	1.6
Reference Facility 7	2x-weekly PCR[c]	7/13/2020	179.5	83/92 (90%)	24/100 (24%)	23	2.7
Reference Facility 8	2x-weekly PCR[c]	7/2/2020	124.9	9/45 (20%)	8/67 (12%)	19	1.5
Reference Facilities 3–8 Combined				292/561 (52%)[f,g]	135/672 (20%)[f]	28 (median)	1.7

Abbreviations: IC, immunochromatographic; PCR, polymerase chain reaction.

[a]Sum of incident cases on day 1 through day 7 divided by community population in thousands.

[b]Days from outbreak definition to the collection date of the final test-positive case followed by 14 days without new infections.

[c]Real-time PCR testing.

[d]Immunochromatographic testing.

[e]Cumulative incidence of infection, residents versus staff (Facilities 1 and 2): $P < .001$, Fisher exact test.

[f]Cumulative incidence of infection, residents versus staff (Facilities 3–8): $P < .001$, Fisher exact test.

[g]Cumulative incidence of infection among residents, Facilities 1 and 2 versus Facilities 3–8: $P = .04$, Fisher exact test.

The LTCF laboratory testing is typically performed offsite, often resulting in >24 hour TAT, and much longer during times of surge [16]. We documented median TAT for positive PCR test results ranging from 1.2 to 8.0 days. Due to local factors in each facility, there may have been additional delays in reporting the laboratory results to Marin HHS, and therefore median TAT may underestimate the true time to acquire actionable positive PCR test results. The difference in PCR TATs for the different facilities likely reflects the challenges of the analytic laboratories to abruptly scale up to meet the demands of a community surge, further highlighting the time-based performance advantage of IC testing to interrupt transmission chains. Although IC testing without confirmatory PCR results appears sufficient for outbreak mitigation, we recommend including PCR testing with the initial outbreak point-prevalence survey to provide individualized care to COVID-19 patients who may be in the later stages of illness when reduced sensitivity of the IC tests may fail to identify disease.

There are several limitations that warrant caution when interpreting the statistical comparisons between the intervention and reference facilities. These include that there were unmeasured factors affecting outbreak duration and cumulative incidence, and that the number of outbreaks evaluated is small. The small study size prevented examination of organizational characteristics that may affect viral containment, eg, staffing levels, sick leave policy, and building design features related to ventilation or cohorting capacity. Other important factors such as masking adherence remain difficult to measure objectively. It is notable that the intervention facility outbreaks occurred later in the initial pandemic year, conceivably leading to improved performance of mitigation strategies due to greater staff experience. We also documented the community incidence at the onset of outbreaks (Table 2) to acknowledge potential ongoing community-acquired contribution to cumulative incidence during this dynamic period of the pandemic.

However, we believe the study provides an example of how more timely disease identification facilitated outbreak mitigation compared with outbreaks managed with longer testing TATs. All facility outbreaks were managed in a single California county where there was continuity of outbreak team leadership and consistency of nontest-based infection control policies for the reference and intervention facilities. Although there was opportunity for improved viral preparedness over time, all facilities were noted to be ill-prepared for their first outbreak, struggling to mask consistently and to implement strict quarantine and isolation practices. California

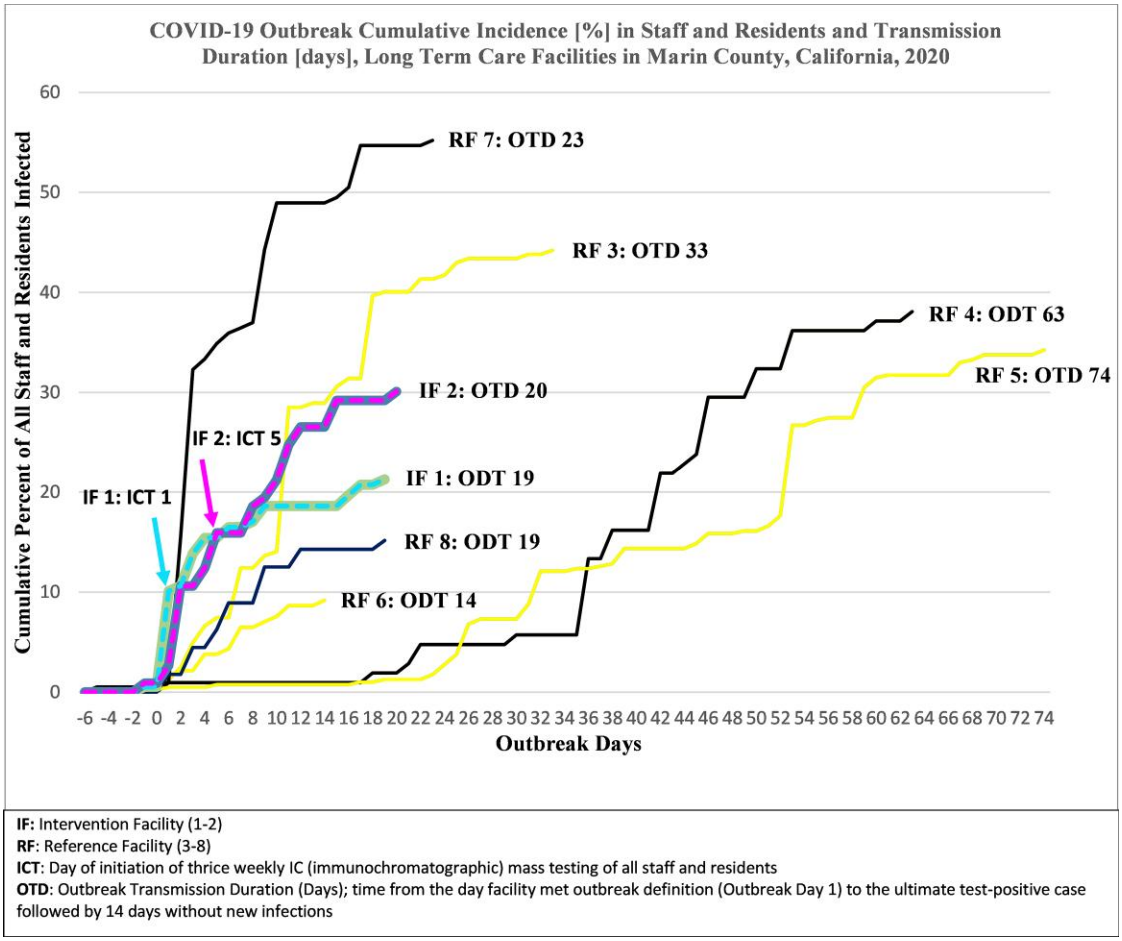

Figure 1. Coronavirus disease 2019 outbreak cumulative incidence (%) in staff and residents and transmission duration (days), long-term care facilities in Marin County, California 2020.

Table 3. Test Concordance for paired[a] Same-Day PCR[b] and IC[c] Test Results

	PCR Test Result ("Gold Standard")		
Initial IC Test Result	Positive	Negative	Total
Positive	12	0	12
Negative	4	107	111
Total	16	107	123

Abbreviations: IC, immunochromatographic; PCR, polymerase chain reaction.

[a]Test pairs consist of the PCR test and an IC test drawn on the same day.

[b]Real-time reverse-transcriptase PCR test measuring viral RNA.

[c]Immunochromatographic ("rapid antigen") test measuring viral antigen.

county LTCFs are similar to many across the world, and the results reported here may be helpful to a broad segment of LTCFs.

Another limitation of the study was that Facility 1 staff were vaccinated on Outbreak Day 7, with expectations for vaccine protection to commence 12 days later [17]. Although this may have contributed to outbreak resolution, the sharp decline in cases predates the expectations for vaccine-induced protection.

We did not focus on symptoms as an indicator of transmission. Symptoms are often absent in persons infected with COVID-19 and were not consistently addressed in clinical notes. The utility of symptom detection during outbreaks may be limited by the inability of some residents to communicate. In addition, escalated demands on staff likely contribute to symptom reporting bias and reduced priority for symptom documentation [3]. Accordingly, diagnosis and clinical decisions for outbreak mitigation are primarily guided by exposure-based testing strategies. Clinical care decisions after diagnosis are informed by ongoing clinical monitoring and medical evaluation.

Since the study period, mass vaccination has decreased the threat to LTCFs posed by COVID-19, and the general comfort with IC testing has vastly improved. The capacity to perform point-of-care (POC) testing in LTCFs will remain important because the COVID-19 pandemic is marked by waning population immunity as well as the emergence of variants with

increased transmissibility and immune evasiveness. In addition, future pandemics and supply chain disruptions are expected [18]. Point-prevalence surveys will remain an important tool to consider when confronting transmissible diseases in congregate settings, particularly when signs and symptoms of infection may be subclinical and therefore inadequate to prompt timely procedures for transmission interruption or treatment.

CONCLUSIONS

This fieldwork demonstrates the importance of evaluating POC test characteristics, not only for the health of an individual but explicitly as a practical tool for transmission interruption—when test cost, availability, operability, actionability (eg, targeted isolation), and TAT may be assessed alongside sensitivity and specificity. Public health research focused on tools and strategies for outbreak mitigation deserves more attention.

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Potential conflicts of interest. The authors declare that they have no conflict of interest.

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