



BRIEF REPORT

Epidemiological Population Study of SARS-CoV-2 in Lake County, Illinois (CONTACT): Methodology and Baseline Characteristics of a Community-Based Surveillance Study

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ABSTRACT

Introduction: Epidemiological Population Study of SARS-CoV-2 in Lake County, Illinois (CONTACT) is an observational, epidemiological study with a 9-month longitudinal follow-up of nonhospitalized persons aged 18 years or older currently living or employed in Lake County, IL. We describe the study design and report baseline

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characteristics of the study participants, including the proportion of participants with acute or previous SARS-CoV-2 infection at enrollment.

Methods: At enrollment and subsequent time-points, participants recruited through digital and paper-based advertising campaigns reported their occupational and school-based exposure, risk factors, and behaviors, and provided nasal and serum specimens. Stratified enrichment was used to enhance enrollment into medium- and higher-risk groups within four occupational risk groups for SARS-CoV-2 infection. RT-PCR and serologic (IgG) testing were conducted to detect acute or previous SARS-CoV-2 infection in participants, respectively.

Results: Between November 2020 and January 2021, 1008 participants (female 70.7%, mean age \pm SD 51 ± 13.8 years) completed the questionnaire and diagnostic testing. Among participants, 41.8% ($n = 421$) were considered low risk, 24.6% ($n = 248$) were medium-to-low risk, 22.3% ($n = 225$) were medium-to-high risk, and 11.3% ($n = 114$) were high risk. Of 56 (5.6%) participants with evidence of acute or previous SARS-CoV-2 infection at baseline, 11 (19.6%) were RT-PCR-positive, 36 (64.3%) were IgG-seropositive, and 9 (16.1%) were positive by both assays. Participants who were adherent vs nonadherent to social distancing measures (odds ratio [95% CI] 0.8 [0.4–1.8]) were less likely, while those in higher vs lower occupational risk groups (2.0 [1.0–4.4]) were more

likely to have evidence for acute or previous SARS-CoV-2 infection.

Conclusion: In fall/winter 2020/21, 5.6% of adults in a Lake County convenience sample had evidence for acute or previous SARS-CoV-2 infection at baseline. Nonadherence to social distancing measures and high-risk professions were associated with SARS-CoV-2 infection. The study is ongoing and future analyses will assess infection status over time.

Clinical Trial Registration: NCT04611230.

Keywords: SARS-CoV-2; COVID-19; Epidemiology; Community-based research

Key Summary Points

Why carry out this study?

Current understanding of COVID-19 epidemiology, transmission dynamics, and clinical and demographic characteristics of individuals with SARS-CoV-2 is continually evolving.

Real-world community-based studies are important for understanding population-level drivers of risk and transmission dynamics of the pandemic, and informing future public health policy decision-making.

Epidemiologic POPulation Study of SARS-CoV-2 in Lake County, Illinois (CONTACT) study is a prospective, longitudinal, community-based study design assessing the proportion of study participants in Lake County, IL with acute or previous SARS-CoV-2 infection overall and in relation to demographic, occupational, clinical, and behavioral characteristics at baseline.

What was learned from this study?

We report on the unique study design of this community-based study and baseline assessment of participants working or residing in Lake County, IL.

In this cohort, serologic and RT-PCR assessments showed that 5.6% of study participants had evidence for acute or previous SARS-CoV-2 infection and nonadherence to social distancing measures and traveling domestically since December 1, 2019 were identified as factors associated with SARS-CoV-2 infection.

INTRODUCTION

Since first appearing in late 2019, coronavirus disease 2019 (COVID-19), which is caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), has spread globally [1, 2]. The current understanding of COVID-19 epidemiology, transmission dynamics, and clinical and demographic characteristics of individuals with SARS-CoV-2 is continually evolving [3]. In the USA as well as other countries, SARS-CoV-2 susceptibility, symptoms, and severity vary by patient demographics, particularly age, race, and sex, comorbidities, occupations, behaviors, and clinical characteristics [3–13]. Activities that may influence exposure and increase risk of SARS-CoV-2 infection include unprotected exposure in social settings, travel history (between US states and internationally), higher-risk occupational environments, and close contact with a person known to be positive [14–18]. Identifying patients who are at higher risk for SARS-CoV-2 infection is necessary to prioritize screening and transmission prevention measures, as these factors vary by geographical regions [19]. Real-world community-based studies are important for evaluating the effectiveness of interventions, understanding population-level drivers of risk and transmission dynamics of the pandemic, and informing future public health policy decision-making.

The COVID-19 pandemic highlighted the need to develop rapid decentralized clinical and epidemiological evaluations within the USA. Any such epidemiological studies would optimally include longitudinal patient assessments.

Here we report on the unique prospective cohort, longitudinal, community-based study design of the EpidemiologiCal POpulation STudy of SARS-CoV-2 in Lake CounTy, Illinois (CONTACT) study as well as participants' baseline characteristics, behaviors, and level of potential occupational or school-based exposure, for the study population enrolled between November 2020 and January 2021. Objectives of this study are to determine the proportion of study participants in Lake County, IL with acute or previous SARS-CoV-2 infection overall and in relation to demographic, occupational, clinical, and behavioral characteristics at baseline.

METHODS

Study Design

This is a 12-month (November 2020 to October 2021; including a 3-month enrollment and 9-month follow-up) observational, community-based prospective epidemiological study of persons aged 18 years or older who are currently living or employed in Lake County, IL. Study data, self-reported by participants within the web-based study portal, were collected at baseline, and are being collected at future time-points (3, 6, and 9 months \pm 3 days). Participants are also queried via the online questionnaire every other week for self-reported signs and symptoms. Nasal and serum specimens, taken by trained healthcare personnel at one of three sites located in Lake County, IL, for molecular (reverse transcriptase polymerase chain reaction [RT-PCR]) and serologic testing (immunoglobulin G [IgG] seropositivity) were collected at baseline and are being collected at 3, 6, and 9 months (\pm 1 week) (Fig. 1). Participants are being followed longitudinally for a 9-month period.

Study Cohort/Sample Selection

Recruitment for the CONTACT study was activated through targeted advertisements in Lake County, IL using social media, postcards, and posters in specific locations, featuring

highlights of the study and both the individual and social benefits of participating. To be eligible for the study, participants had to (a) provide informed consent, (b) be proficient in English or Spanish, (c) have access to the web-based study portal, and (d) not be hospitalized at the time of enrollment. Attempts were made to enhance enrollment into the higher of four occupational risk groups (i.e., minimize the low risk group) dependent on exposure risks associated with their places of work at enrollment, adapted from Occupational Safety and Health Administration guidance [20]. Low risk was defined as jobs that do not require close contact with the general public or coworkers, low-medium risk was defined as infrequent contact with the general public or coworkers, medium-high risk was defined as jobs requiring frequent contact with the general public or coworkers, and high risk was defined as jobs requiring frequent and/or close contact with individuals with high potential risk for exposure to known or suspected cases of COVID-19. Each occupational risk group was capped at approximately 420 participants with no minimum number of participants required. The full analysis set contains all enrolled participants who completed the baseline questionnaires and the SARS-CoV-2 molecular and serologic testing.

Data Collection

An Electronic Data Capture System was used to capture participants' self-reported questionnaire data. This system administered the study questionnaires to participants and permitted participants to schedule visits for specimen sample collection and receive test results. Participants were allowed 3 days for completion of questionnaires and 1 week for completion of specimen collection from the day the patient agrees to participate.

Serologic and molecular SARS-CoV-2 testing was performed at baseline (\pm 1 week) and scheduled quarterly at 3, 6, and 9 months (\pm 1 week). Test results were integrated into the database and available to participants through the web-based study portal. Virtual consultation was provided to participants with positive RT-

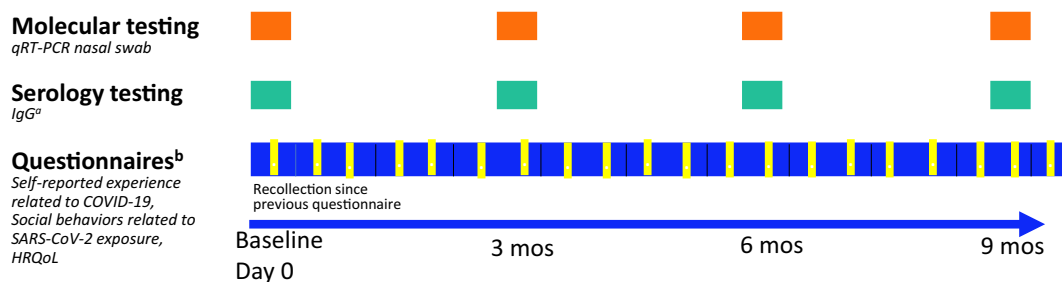


Fig. 1 Study design and illustration of questionnaire administration and specimen collection. ^aSerology testing for quantitative IgG will be done from banked samples after adequate test is available. ^bQuestionnaires about health experience related to COVID-19 and social behaviors would be completed at the time of testing or every 2 weeks depending on the item to accommodate recall and HRQoL survey will be available online for completion soon after PCR and serology testing has been

communicated to the participant (regardless of the test result—positive or negative) allowing for data collection approximately within 2 weeks after time of testing (i.e., at 0.5, 3.5, 6.5, and 9.5 months). Questionnaire dynamic will be based on current symptoms related to COVID-19. COVID-19 coronavirus disease 2019, HRQoL health-related quality of life, IgG immunoglobulin G, mos months, qRT-PCR quantitative reverse transcription polymerase chain reaction

PCR to aid in interpreting test results. The EuroQol-5 Dimension-5 Level (EQ-5D-5L) questionnaire was used as a measure of health-related quality of life (HRQoL) and made available for completion by participants within 2 weeks of testing after each round of sampling. The baseline questionnaire included demographics, occupational exposure, current lifestyle behaviors including travel history, relevant medical history (i.e., comorbidities, respiratory illnesses, and influenza-like illness or symptoms), household exposure, healthcare resource utilization (HRU), and HRQoL (Fig. 1). Participants are being followed longitudinally, with online symptom questionnaires performed every other week, including concurrently with serologic and molecular SARS-CoV-2 sampling. Symptoms included in the online symptom questionnaires were based on Federal Drug Administration defined symptoms at the time of the study design [21]. If a participant tests positive for acute infection or self-reports a COVID-19 diagnosis, COVID-19-related HRU data are collected every other week until symptom resolution. Additionally, changes in household exposures (i.e., household family member changed work setting or received COVID-19 diagnosis) are captured every other week. At 3, 6, and 9 months, participants are

asked to complete follow-up questionnaires that capture changes in occupational exposure and current lifestyle behaviors including travel history. Data collection was adjusted to collect vaccine status once the vaccines were available.

Baseline Molecular and Serologic Testing

Molecular testing was used to determine current infection status and was conducted by qualitative RT-PCR according to manufacturer's instructions, which includes positive and negative controls (Roche Cobas[®] [Roche Diagnostics, Basel, Switzerland]; assay with a reported sensitivity of 100% and specificity of 95.5%) [14]. Samples for the RT-PCR test were collected by nasal swab. Qualitative results of "detected" and "presumptive positive" were an indication of positive for SARS-CoV-2 acute infection at baseline. A result of "not detected" was indicative of no acute infection at baseline and "invalid" was considered as missing and excluded from the analysis. Serologic testing to determine IgG seropositivity status was conducted using the qualitative Abbott ARCHITECT SARS-CoV-2 IgG (Abbott, IL, USA) assay with a sensitivity of 100% and specificity of 99.6% [22–24]. IgG seropositivity (≥ 1.4 index [S/C] cutoff) was indicative of SARS-CoV-2 previous infection. A negative serology test (< 1.4 index

[S/C]) could be indicative of either no recent SARS-CoV-2 infection or no antibodies developed yet from a recent SARS-CoV-2 infection [23, 24]. Vaccination is not expected to confer IgG seropositivity with this assay.

Molecular and serologic follow-up testing are scheduled quarterly at 3, 6, and 9 months (\pm 1 week) and utilize the same methodology as baseline testing.

Study Objectives

Primary Objectives

The primary objectives of the baseline analysis presented herein were to determine (1) the proportion of participants with evidence for previous SARS-CoV-2 infection at enrollment by either IgG serologic testing or self-reported previous diagnosis at baseline and (2) proportion of participants with evidence of acute SARS-CoV-2 infection at enrollment via RT-PCR testing. Self-reported diagnosis was defined as the participant reporting a positive test result for SARS-CoV-2 infection since December 1, 2019 or having been diagnosed by a healthcare provider with SARS-CoV-2 infection since December 1, 2019.

Future analyses of the study aim to describe incident infection (3, 6, and 9 months) of SARS-CoV-2 over time and the association between incident infections over time and variables of interest (i.e., baseline characteristics, occupational exposure, and behaviors) will be examined using multivariable logistic regression modeling.

Secondary Objectives

Secondary outcomes included the proportions of participants reporting COVID-19 symptoms prior to enrollment and over time during follow-up as well as the proportion of participants reporting hospitalization due to COVID-19 prior to enrollment and over time for future analysis. Among those reporting prior hospitalization, hospital length of stay was reported. The proportion of RT-PCR-positive participants reporting symptoms at baseline was reported.

Quality Assurance

Self-reported data, except for HRQoL data, are collected prior to each specimen sampling to minimize bias. To ensure quality of the testing samples collected, each testing collection site was remotely monitored after the conclusion of each sampling (baseline, 3-, 6-, and 9-month visit). Additionally, testing sites are monitored on a weekly basis to ensure rapid turnaround and delivery of results back to participants.

Statistical Analysis

This 12-month study is descriptive and exploratory in nature. Analysis of the primary outcomes for the baseline data presented here was conducted for all participants completing enrollment. Quantitative variables were reported as number of participants with nonmissing value and mean and standard deviation (SD). Categorical variables are summarized as number and percentage of participants with nonmissing values in each category. The proportions of participants with evidence for acute or previous SARS-CoV-2 infections were reported overall and by occupational exposure risk groups and other covariates of interest, such as demographics, comorbidities, overall symptomatic or asymptomatic COVID-19 symptoms, household exposure, travel history, and behaviors. Odds ratios (ORs) were utilized to explore the associations between covariates and acute or previous infection status.

All baseline analyses were conducted using SAS[®] version 9.4 (SAS Institute, Cary, NC, USA).

Ethics

The protocol, informed consent form, and all communications to study participants including advertising pieces were reviewed and approved by an Institutional Review Board (Advarra, Inc). All participants provided informed consent prior to completion of questionnaires and specimen collection.

Table 1 Participant disposition

Characteristic	All participants (<i>N</i> = 1008)
State of residence ^a , <i>n</i> (%)	
Illinois	992 (98.4)
Indiana	16 (1.6)
Age at baseline (years) ^b	
Mean ± SD	51.4 ± 13.8
Age group (years), <i>n</i> (%)	
18–29 years	78 (7.7)
30–39 years	147 (14.6)
40–49 years	173 (17.2)
50–64 years	451 (44.7)
65–74 years	140 (13.9)
75–84 years	15 (1.5)
85+ years	4 (0.4)
Gender, <i>n</i> (%)	
Female	713 (70.7)
Male	293 (29.1)
Other	2 (0.2)
Race, <i>n</i> (%)	
White	924 (91.7)
Asian	40 (4.0)
Other	28 (2.8)
Black or African American	10 (1.0)
American Indian or Alaska Native	4 (0.4)
Native Hawaiian or Other Pacific Islander	2 (0.2)
Ethnic origin, <i>n</i> (%)	
Not Hispanic or Latino	954 (94.6)
Hispanic or Latino	53 (5.3)
Prefer not to say	1 (< 0.1)
BMI (kg/m ²) at baseline ^c	
Mean ± SD	28.4 ± 6.2

Table 1 continued

Characteristic	All participants (<i>N</i> = 1008)
Vaccination against COVID-19, <i>n</i> (%)	
Yes	7 (0.7)
No	968 (96.0)
I don't know	33 (3.3)
Participating in another COVID-19 study, <i>n</i> (%)	11 (1.1)
Smoking status, <i>n</i> (%)	
Never smoked	703 (69.7)
Past smoker	267 (26.5)
Current smoker	38 (3.8)
Level of exposure risk to SARS-CoV-2 in their occupation, <i>n</i> (%)	
Low risk	421 (41.8)
Medium–low risk	248 (24.6)
Medium–high risk	225 (22.3)
High risk	114 (11.3)
Currently employed or in school	743 (73.7)
Participants with acute or previous SARS-CoV-2 infection at baseline	
Overall	
Tested positive as part of the study	56 (5.6)
Positive qualitative RT-PCR test	20 (2.0)
Positive IgG test	45 (4.5)
Symptomatic	
Tested positive as part of the study	24 (26.1)
Positive qualitative RT-PCR test	14 (15.2)
Positive IgG test	17 (18.5)
Asymptomatic	
Tested positive as part of the study	32 (3.5)
Positive qualitative RT-PCR test	6 (0.7)

Table 1 continued

Characteristic	All participants (N = 1008)
Positive IgG test	28 (3.1)

BMI body mass index, *IgG* immunoglobulin G, *RT-PCR* reverse transcriptase polymerase chain reaction, *SARS-CoV-2* severe acute respiratory syndrome coronavirus 2, *SD* standard deviation

^aNo participants enrolled from Wisconsin

^bAge at baseline = (2020 – year of birth)

^cBMI = (weight (kg)/height (m)²)

RESULTS

Study Cohort

A total of 1008 participants were enrolled between November 2020 and January 2021 and completed both the questionnaire and the serologic and RT-PCR testing at baseline (Fig. S1 in the supplementary material). The study cohort was predominantly White (91.7%) and female (70.7%), with an average age \pm SD of 51.4 ± 13.8 years (Table 1). The low workplace exposure risk group ($n = 421$, 41.8%) was the largest group, followed by medium-to-low risk ($n = 248$, 24.6%) and medium-to-high risk ($n = 225$, 22.3%), while the high-risk group ($n = 114$) contained 11.3% of all participants (Table 1). For comorbid conditions at baseline, 10.7% ($n = 108$) of participants had autoimmune diseases, 6.6% ($n = 67$) had cardiovascular diseases (including 4.7% [$n = 47$] with hypertension), 5.7% ($n = 57$) had lung disease, and 1.2% ($n = 12$) had active cancer (Table S1). Seven (0.7%) participants reported having received at least one dose of SARS-CoV-2 vaccine at enrollment.

Serologic and RT-PCR Testing of Study Population

Overall, 56 (5.6%) participants had evidence for acute or previous SARS-CoV-2 infection (Table 1), of whom 11 (19.6%) were RT-PCR-

positive, 36 (64.3%) were IgG-seropositive, and 9 (16.1%) were RT-PCR-positive and IgG-seropositive. Symptomatic infections presented differently between currently and previously infected participants. Of the 20 participants who had an acute infection, 70.0% ($n = 14/20$) reported one or more COVID-19 symptom, while only 37.8% ($n = 17/45$) of those with evidence of previous infection reported having had symptoms (Table 1).

Most demographic factors were not significantly associated with an increased likelihood of having evidence for acute or previous SARS-CoV-2 infections except race (other races vs White race; OR 3.8 [1.9–7.3]). Participants of Asian race had evidence of previous infection in higher proportions compared to other, although the number of Asian participants was small (4.0%, $n = 40$) (Table 2; Fig. S2). Participants in the higher-risk groups for occupational exposure were slightly more likely to have tested positive for either acute or previous infection in comparison to the low-occupational-risk group (OR 1.3 [0.6–2.5], and 2.0 [1.0–4.4] for medium-high, and high-risk groups, respectively) (Table 2; Fig. S2).

Social Behavioral Characteristics

Household Exposure

Most participants (88.2%, $n = 889$) lived with others and the mean number of household members was 1.9 ± 1.4 . Exposure to COVID-19 at baseline through family members/household exposure is shown in Table S2. A larger proportion of participants with at least one individual in their household with suspected or test-confirmed COVID-19 had evidence for acute or previous SARS-CoV-2 infection compared to those with no household exposure (suspected OR range 5.2–17.7; test confirmed OR range 0.9–3.7) (Table S3; Fig. S3).

Travel and Behavioral Habits

Approximately 14.9% ($n = 150$) of participants had traveled internationally and 63.3% ($n = 638$) had traveled domestically since December 1, 2019. Private or personal vehicle (75.1%, $n = 479$) was the most frequent method

Table 2 Number and proportion of participants with acute SARS-CoV-2 infection and evidence of previous infection at baseline

	Acute (RT-PCR) or previous (IgG-positive) infection, <i>n</i> (%), [95% CI]	Acute infection, <i>n</i> (%), [95% CI]	Previous infection, <i>n</i> (%), [95% CI]
Level of risk in occupation			
Low risk (<i>n</i> = 421)	21 (5.0, [3.11–7.52])	7 (1.7, [0.67–3.40])	15 (3.6, [2.01–5.81])
Medium–low risk (<i>n</i> = 248)	10 (4.0, [1.95–7.29]) 0.80 (0.37–1.73)	3 (1.2, [0.25–3.49]) 0.72 (0.19–2.83)	9 (3.63, [1.67–6.78]) 1.02 (0.44–2.37)
OR (vs low risk)			
Medium–high risk (<i>n</i> = 225)	14 (6.2, [3.44–10.22]) 1.26 (0.63–2.54)	6 (2.7, [0.99–5.71]) 1.62 (0.54–4.88)	12 (5.3, [2.79–9.13]) 1.53 (0.70–3.32)
OR (vs low risk)			
High risk (<i>n</i> = 114)	11 (9.7, [4.92–16.61])	4 (3.5, [0.96–8.74])	9 (7.9, [3.67–14.46])
OR (vs low risk)	2.03 (0.95–4.35)	2.15 (0.62–7.48)	2.32 (0.99–5.45)
Age group			
18–29 years (<i>n</i> = 78)	7 (9.0, [3.69–17.62])	3 (3.9, [0.80–10.83])	6 (7.7, [2.88–16.00])
30–39 years (<i>n</i> = 147)	9 (6.1, [2.84–11.30])	1 (0.7, [0.02–3.73])	8 (5.4, [2.38–10.44])
OR (vs 18–29 years)	0.66 (0.24–1.85)	0.17 (0.02–1.67)	0.69 (0.23–2.07)
40–49 years (<i>n</i> = 173)	10 (5.8, [2.81–10.37])	5 (2.9, [0.95–6.62])	7 (4.1, [1.64–8.16])
OR (vs 18–29 years)	0.62 (0.23–1.70)	0.74 (0.17–3.19)	0.51 (0.16–1.56)
50–64 years (<i>n</i> = 451)	21 (4.7, [2.91–7.03])	9 (2.0, [0.92–3.75])	16 (3.6, [2.04–5.70])
OR (vs 18–29 years)	0.50 (0.20–1.21)	0.51 (0.14–1.92)	0.44 (0.17–1.17)
65+ years (<i>n</i> = 1159)	9 (5.7, [2.62–10.47])	2 (1.3, [0.15–4.47])	8 (5.0, [2.20–9.67])
OR (vs 18–29 years)	0.61 (0.22–1.70)	0.32 (0.05–1.95)	0.64 (0.21–1.90)
Gender			
Female (<i>n</i> = 713)	37 (5.2, [3.68–7.08])	14 (2.0, [1.08–3.27])	29 (4.1, [2.74–5.79])
Male (<i>n</i> = 293)	19 (6.5, [3.95–9.94])	6 (2.1, [0.76–4.40])	16 (5.5, [3.15–8.72])
OR (vs female)	1.27 (0.72–2.24)	1.04 (0.40–2.74)	1.36 (0.73–2.55)
Other (<i>n</i> = 1)	0	0	0
Prefer not to answer (<i>n</i> = 1)	0	0	0
Race			
White (<i>n</i> = 924)	43 (4.5, [3.39–6.22])	15 (1.6, [0.91–2.66])	34 (3.7, [2.56–5.10])
OR (all other races vs White race)	3.75 (1.93–7.30)	3.84 (1.36–10.83)	3.95 (1.92–8.11)

Table 2 continued

	Acute (RT-PCR) or previous (IgG-positive) infection, <i>n</i> (%), [95% CI]	Acute infection, <i>n</i> (%), [95% CI]	Previous infection, <i>n</i> (%), [95% CI]
American Indian or Alaska Native (<i>n</i> = 4)	0 ([0.00–60.24])	0 ([0.00–60.24])	0 [0.00–60.24])
Asian (<i>n</i> = 40)	6 (15.0, [5.71–29.84])	0 ([0.00–8.81])	6 (15.0, [5.71–29.84])
Black or African American (<i>n</i> = 10)	0 ([0.00–30.85])	0 ([0.00–30.85])	0 ([0.00–30.85])
Other (<i>n</i> = 24)	7 (29.17, [12.62–51.20])	5 (20.83, [7.13–42.15])	5 (20.83, [7.13–42.15])
Prefer not to say (<i>n</i> = 4)	0 ([0.00–60.24])	0 ([0.00–60.24])	0 ([0.00–60.24])
BMI category			
Normal (<i>n</i> = 329)	22 (6.7, [4.24–9.95])	4 (1.2, [0.33–3.08])	20 (6.1, [3.75–9.23])
Overweight (<i>n</i> = 337)	13 (3.9, [2.07–6.51])	5 (1.5, [0.48–3.43])	12 (3.6, [1.85–6.14])
OR (vs normal)	0.56 (0.28–1.13)	1.22 (0.33–4.60)	0.57 (0.27–1.19)
Obese (<i>n</i> = 342)	21 (6.1, [3.84–9.23])	11 (3.22, [1.62–5.68])	13 (3.8, [2.04–6.41])
OR (vs normal)	0.91 (0.49–1.69)	2.70 (0.85–8.57)	0.61 (0.30–1.25)
Any comorbidity			
No (<i>n</i> = 719)	41 (5.7, [4.12–7.66])	15 (2.1, [1.17–3.42])	32 (4.5, [3.06–6.23])
Yes (<i>n</i> = 289)	15 (5.2, [2.93–8.42])	5 (1.7, [0.56–3.99])	13 (4.5, [2.42–7.57])
OR (yes vs no)	0.91 (0.49–1.66)	0.83 (0.30–2.30)	1.01 (0.52–1.96)
Symptomatic			
No (<i>n</i> = 916)	32 (3.5, [2.40–4.90])	6 (0.7, [0.24–1.42])	28 (3.1, [2.04–4.39])
Yes (<i>n</i> = 92)	24 (26.1, [17.48–36.29])	14 (15.2, [8.58–24.21])	17 (18.5, [11.15–27.93])
OR (yes vs no)	9.75 (5.44–17.48)	27.22 (10.18–72.82)	7.19 (3.76–13.73)

BMI body mass index, *CI* confidence interval, *IgG* immunoglobulin G, *RT-PCR* reverse transcriptase polymerase chain reaction, *SARS-CoV-2* severe acute respiratory syndrome coronavirus 2

Data are *n* (%) [95% CI]

of transportation among those who traveled domestically. All baseline behavioral habits are shown in Table S4. Regular mask use was reported by almost the entire study population (1007/1008).

A slightly larger proportion of participants who traveled internationally or domestically had evidence of acute or previous SARS-CoV-2

infection compared to those who did not report traveling (7.3% vs 5.3%; OR 1.4 [0.7–2.8] and 6.3% vs 4.3%; OR 1.5 [0.8–2.7], respectively) (Table S5; Fig. S4). Fewer participants who reported avoiding domestic travel and staying home to minimize exposure to COVID-19 had evidence for acute or previous SARS-CoV-2 infection compared to those who did not

intentionally avoid domestic traveling (4.1% vs 7.8%, OR 0.5 [0.3–0.9]) and those who did not stay home (5.1% vs 10.1%; OR 0.5 [0.2–0.9]), respectively (Table S5; Fig. S4).

Quality of Life Assessment

The mean HRQoL state, as measured on a visual analog scale from 1 to 100 with higher scores indicating better health status, ranged from 81.3 to 84.8, with the lowest scores reported among those who were RT-PCR-positive. Individuals who were RT-PCR-positive had increased anxiety/depression compared with individuals who tested RT-PCR-negative, IgG-seronegative, or IgG-seropositive (Table S6).

DISCUSSION

While the use of RT-PCR or serologic testing has formed an important part of many COVID-19 studies, few analyses have included both as measures of SARS-CoV-2 positivity on a longitudinal basis, with symptomatic questionnaires collected at scheduled testing timepoints and every other week during the study observational period. The use of a prospective cohort study design is also relatively uncommon among SARS-CoV-2 studies. We estimated the proportion of both acute and previous SARS-CoV-2 infections in a community-based convenience sample of those who live or work in Lake County, IL. The proportion of participants with evidence for acute infection by RT-PCR testing at baseline (from November 2020 to January 2021) observed in this study (2.0%, $n = 20/1008$) was slightly higher than that observed in Lake County, IL during the same time period (per 100,000 population between November and January [0.5–0.9%]) [25], which may be reflective of the attempts to enhance enrollment in the higher occupational risk groups. The percentage of RT-PCR-positive participants among all symptomatic participants (15.2%; $n = 14/92$) was comparable to the overall Lake County SARS-CoV-2 RT-PCR-positivity rate between November 2020 and January 2021 (10.1–16.5%) [25]. These results underscore the reliability of the study methods for community-

based recruitment, sample collection, and questionnaire administration. There are potential challenges to recruitment, retention, and data completeness when conducting such a study within a population of mostly asymptomatic, voluntary individuals. Strategies such as the use of mobile applications, posters, social media, and mailers within hyper-local cohorts with easy access to on-the-ground recruitment and nearby dedicated study sites were seen as potential success factors and highlight how studies such as this one (which currently shows a high retention rate of 97.1% at 3 months) can effectively evaluate community-level transmission dynamics and inform on the epidemiology of the pandemic. To reduce the number of participants lost to follow-up, this study asked participants to provide contact information for another individual who could be contacted if the participant becomes unreachable, permitting proxy data collection.

Identifying demographic, clinical, and behavioral characteristics associated with SARS-CoV-2 infection status may help to influence screening prioritization, risk mitigation strategies, and control measures, especially with changes arising from introduction of the vaccine [3, 5]. In the current study, most participants were female and between ages 50 and 64 years. A higher proportion of participants of Asian race were IgG antibody-positive (i.e., had previous infection) compared to other races, though the overall number of participants of Asian race was small ($n = 40$) and no participants of Asian race had evidence of acute infection at baseline. A recent report by the Centers for Disease Control and Prevention also found a higher proportion of breakthrough infections among Asian participants (8.3% vaccinated vs 3.1% among unvaccinated) [26]. Further characterization of risk behaviors and occupational risk groups by race are needed to explain why IgG positivity was more common in participants of Asian race. In our study, similar to findings from other studies, individuals who did not practice social distancing behaviors, who continued to travel, and who were in higher occupational risk groups were more likely to have acute or previous SARS-CoV-2 infection compared with those who followed

public health measures and were in lower occupational risk groups [5, 9, 11, 14, 15, 17, 18]. Mitigation measures in place during the majority of the baseline period included virtual schools and masks were required. Planned follow-up analyses will provide an opportunity to better understand social distancing behaviors and how they influence transmission dynamics over time, including the impact of loosening restrictions after the rate of COVID-19-positive cases began to slow and vaccine distribution increased.

Strengths and Limitations

Strengths of the study included the unique longitudinal, prospective, community-based study design, which included serologic and molecular testing as measures of SARS-CoV-2 positivity on a longitudinal basis with symptomatic questionnaires at testing timepoints. The quality assurance measures, specifically remote monitoring of sites, utilized for the molecular and serologic testing were another strength of this study compared to other community-based studies. All questionnaire data are self-reported by participants and may be subject to differential recall and other reporting biases. Self-reported data, except for HRQoL data, were collected prior to each specimen sampling to reduce differential recall based on infection status. This study is not intended to be representative, so participants may not be reflective of the overall population of Lake County, IL. The gender and racial distribution of our study (70.7% female and 91.7% White) differs from publicly available information of the distribution of those demographics in Lake County, IL (50.0% female, 80.9% White, 7.5% Black) which may be a limitation of the recruitment and convenience sample strategy utilized. Unmeasured confounding variables, including those related to potential COVID-19 exposures and participant characteristics, are possible and may influence the results obtained. The highest-risk group based on age is people older than age 80 years; however, few participants in this age group enrolled in this study. There were mask requirements, as well as several restrictions on

travel, social interaction, attendance of in-person schools, and access to public locations, including places of employment, in Lake County during the baseline observation period; these restrictions may have reduced the potential for occupational exposures to COVID-19.

CONCLUSION

This was a baseline assessment of an ongoing prospective longitudinal cohort study of participants working or residing in Lake County, IL. In this cohort, serologic and RT-PCR assessments showed that 5.6% of study participants had evidence for acute or previous SARS-CoV-2 infection. The current study provides the latest evidence further supporting the public health and risk mitigation measures put in place for COVID-19 prevention and control. Similar to previous studies, we identified nonadherence to social distancing measures and travelling domestically since December 1, 2019 as factors associated with SARS-CoV-2 infection. The study is ongoing and follow-up analyses through a 9-month (final) data collection timepoint are planned. As the pandemic continues, future analyses are scheduled to further assess SARS-CoV-2 infection status over time and provide additional data on factors associated with SARS-CoV-2 infection. The impact of vaccination on changes in SARS-CoV-2 epidemiology over time is also an important factor to consider in future analyses.

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Compliance with Ethics Guidelines. The protocol, informed consent form, and all communications to study participants including advertising pieces were reviewed and approved by an Institutional Review Board (Advarra, Inc). All participants provided informed consent prior to completion of questionnaires and specimen collection.

Data Availability. All data generated or analyzed during this study are included in this published article and associated supplementary material files.

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