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Initial Rollout and Real-World Effectiveness of mRNA COVID-19 Vaccines Among Healthcare Workers: Analysis from a Tertiary Healthcare System in the Greater Houston Metropolitan Area

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3 **Initial Rollout and Real-World Effectiveness of mRNA COVID-19 Vaccines Among**
4 **Healthcare Workers: Analysis from a Tertiary Healthcare System in the Greater**
5 **Houston Metropolitan Area**
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ABSTRACT

Background: Despite the demonstrated efficacy of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccines in clinical trials, data on real world vaccine effectiveness (RWE) are fundamental to provide an empirical evidence of the role of vaccination in curtailing the coronavirus disease 2019 (COVID-19) pandemic.

Healthcare Workers (HCWs) have been on the pandemic forefront and continue to provide care for hundreds of hospitalized and critically ill COVID-19 patients. We provide an account of RWE of COVID-19 vaccines among HCWs of a major healthcare system in Texas.

Methods: At the COVID-19 pandemic onset, we instituted a HCW testing and surveillance program wherein SARS-CoV-2 positive HCWs were offered short-term disability leave (STDL). We retrospectively analyzed de-identified summary data of SARS-CoV-2 infections and STDL utilization among HCWs across the healthcare system. Pre- and post-vaccination trends in SARS-CoV-2 positivity and STDL utilization rates were evaluated. The initial 12-week vaccination program period (December 15, 2020 to March 6, 2021) was defined as a rapid rollout phase.

Results: Updated for June 5, 2021, 98.2% (n = 27,291) of all employees had received a full or partial dose of one of the approved mRNA COVID-19 vaccines. The vaccination rate during the rapid rollout phase was approximately 3,700 doses / 7-days. The overall mean weekly SARS-CoV-2 positivity rates among HCWs were significantly lower following vaccine rollout (2.4%), compared to pre-vaccination period (11.8%, $p < 0.001$). An accompanying 69.8% decline in STDL utilization was also observed. During the

1
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3 rapid rollout phase, SARS-CoV-2 positivity rate among HM HCWs declined by 84.3%,
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5 compared to a 54.7% decline in the Houston metropolitan area.
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8 **Conclusion:** In light of the continued emergence of viral variants as well as vaccine
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10 hesitancy, robust HCW vaccination programs are important in sustaining a critical
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12 resource to provide safe and effective care for COVID-19 and non-COVID-19 patients
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14 across healthcare systems.
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Strengths and limitations of this study

- The study describes the initial rollout of a COVID-19 vaccination program instituted across a large healthcare system in a major metropolitan area of the United States.
- Real-world effectiveness was evaluated with respect to reductions in SARS-CoV-2 infections and short-term disability leave utilization among healthcare workers.
- The study presents an account of an employee vaccination program that was successfully implemented while concurrently operating as a state-designated vaccine hub for the public; insights from our experience can help guide similar vaccination programs in other settings.
- Findings may be limited due to non-systematic implementation of the employee SARS-CoV-2 surveillance program.
- Further study of the established immunological protection against infection are needed to understand the population-wide and individual benefits of vaccination.

INTRODUCTION

Safe and rapid rollout of the United States (US) Food and Drug Administration (FDA) approved vaccines is a potentially transformational public health tool in the armamentarium against the coronavirus disease 2019 (COVID-19). Despite impressive efficacy data from Phase 3 clinical trials, there is a need to demonstrate real world effectiveness (RWE) of these vaccines for controlling the pandemic in a variety of settings, across heterogenous population groups. Healthcare workers (HCWs) have been on the forefront of the COVID-19 pandemic and continue to provide critical care to hundreds of COVID-19 patients across all US regions and globally. The pandemic has reestablished the importance of this valuable resource in being a critically important line of defense against human suffering in the face of a healthcare catastrophe. Most tiered vaccination approaches prioritized healthcare workers (HCWs) before expanding administration to those in higher-risk age groups and with underlying health conditions. This is important not only from a public health perspective but is also critical for continued operational viability of large and small healthcare systems, such that they can adequately provide treatment and prevention services to their communities.

We provide an account of COVID-19 vaccine rollout among HCWs of a tertiary healthcare system in Texas and demonstrate a signal of RWE by evaluating reduction in COVID-19 infections and utilization of short-term disability leave (STDL) among HCWs.

METHODS

Study Design and Setting

Houston Methodist (HM) is an 8-hospital healthcare system in the greater Houston metropolitan area, which has been a major hub in the fight against the COVID-19 pandemic since March 2020 [1, 2]. At the onset of the pandemic, HM instituted an employee severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) surveillance initiative coupled with an enhanced STDL program for employees testing positive [3]. The voluntary surveillance program encouraged all HCWs (symptomatic or asymptomatic) to utilize SARS-CoV-2 testing at frequent intervals across all HM testing sites. Additionally, HM established a vaccine prioritization committee in November 2020, which monitored vaccine safety and efficacy data, reviewed Centers for Disease Control and Prevention (CDC) guidelines, developed a prioritization scheme, and provided recommendations for safe and effective vaccine rollout. Following general CDC guidelines, first line HCWs were prioritized to receive COVID-19 vaccines. Based on a tiered approach, HM employees received electronic invitations to schedule vaccination across all HM locations. This study was not regarded as human subjects research by the Houston Methodist (HM) Institutional Review Board (IRB) since this study does not involve direct human participation and was therefore exempt from human subjects approval. This study was approved by the HM Institutional Review Board as a quality improvement project with waiver of informed consent.

Statistical Analysis

We assimilated de-identified summary data of SARS-CoV-2 infections and STDL utilization among HCWs across the period of the pandemic and defined the first 12-

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3 week period (December 15, 2020 to March 6, 2021) as an initial rapid rollout period for
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5 COVID-19 vaccination among HCWs. Summary metrics are provided as frequencies
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7 and proportions. Tests for proportional comparisons and Chi-squared trends were used
8
9 to assess pre- and post-vaccination (including the rapid rollout period) SARS-CoV-2
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11 positivity rates and trends.
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14 *Patient and Public Involvement*

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17 Patients or the public were not involved in the design, or conduct, or reporting, or
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19 dissemination plans of our research.
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24 **RESULTS**

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26 The COVID-19 vaccine rollout was simultaneously initiated at all HM locations on
27
28 December 15, 2020. Updated for June 5, 2021, from among a total of 27,291
29
30 employees, 26,791 (98.2%) have received at least a single dose of either one of the two
31
32 approved mRNA COVID-19 vaccines, whereas 26,723 (97.9%) have completed both
33
34 doses. During the 12-week initial rapid rollout period (December 15, 2020 to March 6,
35
36 2021) the vaccination rate was 3,700 doses / 7-days.
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40 The recent (November 1, 2020 to June 5, 2021) trends in SARS-CoV-2 positivity
41
42 among HCWs are demonstrated in Figure 1. The mean SARS-CoV-2 weekly positivity
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44 rate prior to initiation of the HCW vaccination program (11.8%) was significantly higher
45
46 compared to the positivity rate following vaccination initiation (2.4%, $p < 0.001$). The
47
48 upward trend in SARS-CoV-2 positivity rate observed in the 45-day pre-vaccination
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50 period (November 1, 2020 to December 12, 2020) has significantly trended down during
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52 the post-vaccination phase (December 15, 2020 to June 5, 2021) ($p_{\text{trend}} < 0.001$).
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3 Since the end of January 2021, the weekly SARS-CoV-2 infection rate among
4 HCWs participating in surveillance testing has consistently remained below 3.1%.
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6 During the initial 12-week rapid rollout period, the proportional decline in HM HCW
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8 SARS-CoV-2 positivity rate was 84.3% (8.9% to 1.4%), as compared to a 54.7% decline
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10 (12.8% to 5.8%) observed in the greater Houston metropolitan area. [4].
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14 As a part of the HCW surveillance program, 117 (0.4%) employees were
15
16 reported to have tested positive more than 7 days after receiving the second dose of the
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18 vaccine, which includes both asymptomatic random surveillance of employees as well
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20 as symptomatic referrals from the employee health service. Among these positive
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22 cases, 66 (56.4%) were reported to be symptomatic.
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26 Figure 2 represents the weekly frequency of STDL utilization among HCWs. We
27
28 also report the temporal emergence of known SARS-CoV-2 mutations (D614G) [5] as
29
30 well as detection of viral variants (Alpha B.1.1.7; Beta B.1.351; Gamma P.1 and P.2;
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32 B.1.429 and B.1.427) in the greater Houston area, based on sequencing data of patient
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34 specimens performed at HM [6]. Compared to the peak of STDL utilization during the
35
36 initial weeks of vaccine rollout (January 3 to 9, 2021: 315 leaves), a 69.8% decline has
37
38 been observed during the most recent reporting period (May 30 to June 5, 2021: 95
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40 leaves), with utilization numbers approaching pre-pandemic levels.
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46 **DISCUSSION**

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49 Given the critical need to maintain an effective and safe healthcare workforce
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51 and to minimize inadvertent viral transmission in the healthcare setting, frontline HCWs
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53 were ubiquitously recognized as a priority group for vaccination. In addition to continued
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3 care provided to COVID-19 and non-COVID-19 patients; large healthcare organizations
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5 have been called upon to organize and execute delivery of COVID-19 vaccines among
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7 its HCWs and across the community at large. HM is a state-designated vaccine hub
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9 and, as of June 5, 2021, has administered over 780 thousand vaccines to members of
10
11 the community [7].
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15 Vaccine supply and delivery during the initial nationwide rollout was beset with
16
17 logistical challenges, and administration metrics lagged behind target levels. However,
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19 during the same time period we were able to achieve rapid rates of HCW vaccination
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21 with demonstrated vaccine RWE in terms of curtailing infection rates as well as reducing
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23 utilization of STDL for HCWs. Our vaccination planning started several months prior to
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25 vaccine delivery and required close coordination between a vaccine scientific
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27 committee, operational leadership, physician organization, and the system's infection
28
29 control management. We instituted a seamless vaccination program among our HCWs
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31 while caring for large numbers of COVID-19 and non-COVID-19 patients and
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33 maintaining regular hospital operations. Our initial results with indices of HCW
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35 protection against SARS-CoV-2 infection and related disability indicate that the vaccines
36
37 can be deployed in the real-world settings with high levels of effectiveness. Of note, we
38
39 provide evidence of vaccine effectiveness amid the emergence of multiple variants of
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41 concern (VOC) in the greater Houston area starting in December 2020 [6].
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47 Our results are limited to a narrative and descriptive account of the reduction in
48
49 infection and STDL utilization across one healthcare system. Furthermore, we have not
50
51 analyzed individual HCW characteristics (such as demographics, comorbidities and risk
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53 of occupational exposure) that may be associated with SARS-CoV-2 infection.
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3 Concurrent studies on the established immunological protection against infection are
4 needed to fully understand the population-wide and individual benefits that vaccinations
5 confer. The observed trends in SARS-CoV-2 positivity rate were based on diagnostic
6 tests conducted as part of the employee surveillance program and were requested
7 voluntarily and at the prerogative of the HCW. We did not distinguish results based on
8 either the purpose of testing or whether HCWs experienced viral exposure and / or
9 presented with symptoms. It is possible that the dynamics of program participation
10 differed in the pre- and post-vaccination periods. Nonetheless, we observed testing
11 participation to remain relatively consistent during the initial phase of the vaccination
12 program, with the mean number of weekly tests performed post-vaccination rollout
13 (December 20, 2020 to February 25, 2021: 2,621 tests) continuing at a rate comparable
14 to that during the peak surveillance period prior to vaccination rollout (August 30, 2020
15 to December 12, 2020: 2,599 tests).
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33 Hospitals are a microcosm of the communities they serve as well as a nexus in
34 which there is a high rate of encounters between healthy and ill individuals. Despite
35 determined efforts to vaccinate the broader population, the risk of SARS-CoV-2
36 infections and related COVID-19 hospitalizations has not been fully eliminated,
37 especially due to the continued emergence of VOCs [8, 9] and relaxation of protective
38 public health measures. Furthermore, although robust vaccine effectiveness (VE) has
39 been reported [10, 11], the duration of VE is currently unknown; consequently, booster
40 shots that confer additional protection against VOCs may be recommended and are
41 currently undergoing testing [12].
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3 In spite of varying challenges, vaccination rates in the US have continued at a
4 progressive pace; at the time of this reporting, $\geq 51.5\%$ of individuals are at least
5 partially immunized and $\geq 41.9\%$ are fully immunized [13]. Nonetheless, global
6 vaccination rates are estimated at approximately only $\geq 5\%$ of the population [14]. As
7 efforts to support international partners in their respective vaccination programs
8 proceed, insights from the success of vaccine rollout in the US will provide a valuable
9 model for reference. Furthermore, in the face of continued high rates of vaccine
10 hesitancy [15] as well as the risk of a resurgence in cases globally, assimilating and
11 reporting cumulative evidence of real-world vaccine effectiveness is paramount to build
12 population-wide confidence in vaccination, hence rapidly achieving desirable levels of
13 herd immunity against the current predominant strains of SARS-CoV-2.
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AUTHOR CONTRIBUTIONS:

FV was responsible for the study conception and design. Data acquisition and analysis were performed by AP. Interpretation of results and initial drafting of the manuscript were completed by FV and AP. All authors contributed to critical revision of the manuscript and approval of the final version for submission.

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Figure Legends

Figure 1: SARS-CoV-2 Positivity Rates from the Houston Methodist (HM) Surveillance Employee Program Pre- and Post-COVID-19 Vaccine Initiation. Reference lines for the initial 12-week rapid rollout period for vaccination (December 15, 2020 to March 6, 2021) are shown.

Figure 2: Enhanced Short-Term Disability Leave Utilization by Houston Methodist (HM) Employees Across the COVID-19 Pandemic Timeline. Reference lines for the initial 12-week rapid rollout period for vaccination (December 15, 2020 to March 6, 2021) are shown. Annotations depict relative emergence and detection of SARS-CoV-2 mutations and viral variants in greater Houston.

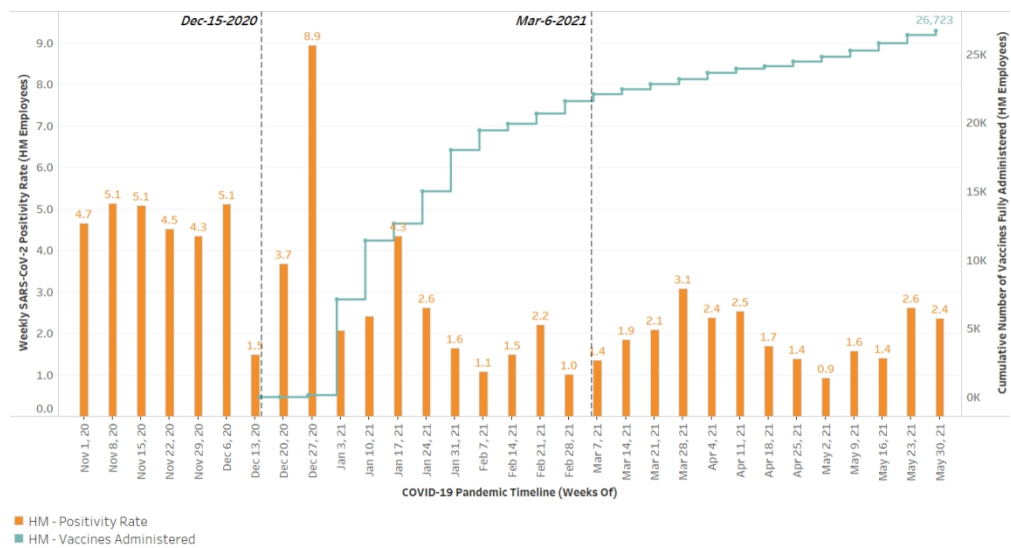


Figure 1. SARS-CoV-2 Positivity Rates from the Houston Methodist (HM) Surveillance Employee Program Pre- and Post-COVID-19 Vaccine Initiation. Reference lines for the initial 12-week rapid rollout period for vaccination (December 15, 2020 to March 6, 2021) are shown.

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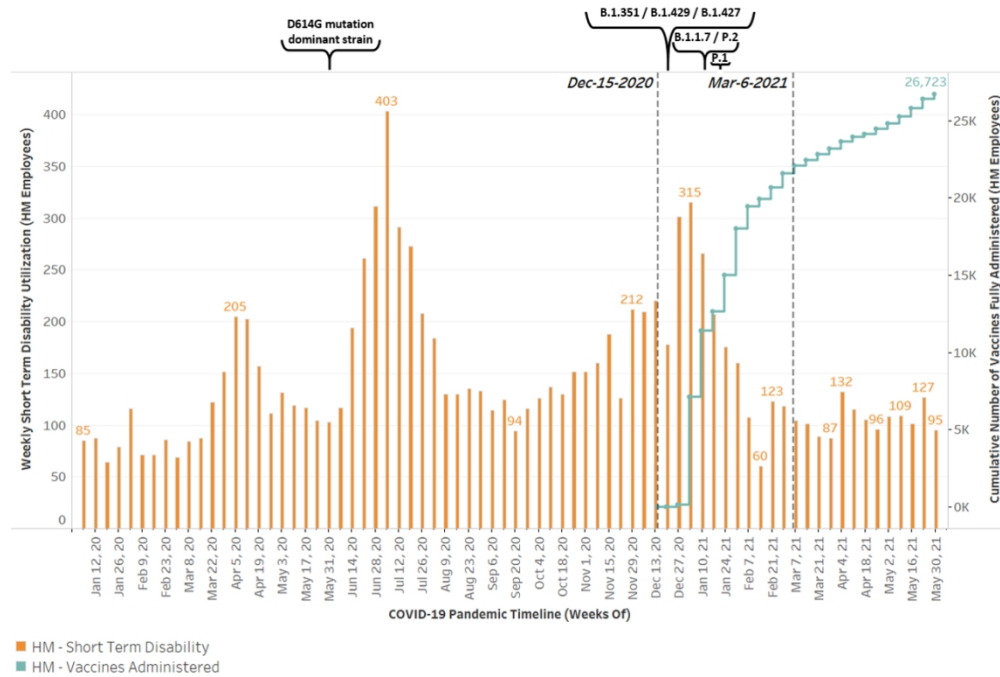


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STROBE Statement—Checklist of items that should be included in reports of *cross-sectional studies*

	Item No	Recommendation	Page No
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	5
Objectives	3	State specific objectives, including any prespecified hypotheses	5
Methods			
Study design	4	Present key elements of study design early in the paper	6-7
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants	6
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	6
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	6
Bias	9	Describe any efforts to address potential sources of bias	6-7
Study size	10	Explain how the study size was arrived at	6-7
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	6
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	6
		(b) Describe any methods used to examine subgroups and interactions	N/A
		(c) Explain how missing data were addressed	6
		(d) If applicable, describe analytical methods taking account of sampling strategy	6
		(e) Describe any sensitivity analyses	N/A
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	7-8
		(b) Give reasons for non-participation at each stage	N/A
		(c) Consider use of a flow diagram	N/A
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	7
		(b) Indicate number of participants with missing data for each variable of interest	N/A
Outcome data	15*	Report numbers of outcome events or summary measures	8
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	7-8

		(b) Report category boundaries when continuous variables were categorized	N/A
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	7-8
Discussion			
Key results	18	Summarise key results with reference to study objectives	9
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	9-10
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	9-10
Generalisability	21	Discuss the generalisability (external validity) of the study results	8-11
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	12

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

Impact of mRNA Vaccines in Curtailing SARS-CoV-2 Infection and Disability Leave Utilization Among Healthcare Workers During the COVID-19 Pandemic: Cross Sectional Analysis from a Tertiary Healthcare System in the Greater Houston Metropolitan Area

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1 **Impact of mRNA Vaccines in Curtailing SARS-CoV-2 Infection and Disability**
2 **Leave Utilization Among Healthcare Workers During the COVID-19 Pandemic:**
3 **Cross Sectional Analysis from a Tertiary Healthcare System in the Greater**
4 **Houston Metropolitan Area**

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24 **Running title:** Effectiveness of COVID-19 Vaccines among Healthcare Workers

25 **Word count:** 2,271

27 **ABSTRACT**

28 **Objectives:** We provide an account of Real World Effectiveness (RWE) of COVID-19
29 vaccines among Healthcare workers (HCWs) at a tertiary healthcare system and report
30 trends in SARS-CoV-2 infections and subsequent utilization of COVID-19 specific short-
31 term disability leave (STDL).

32 **Design:** Cross sectional study

33 **Setting and Participants:** Summary data on 27,291 employees at a tertiary healthcare
34 system in the greater Houston metropolitan area between December 15, 2020 and June
35 5, 2021. The initial 12-week vaccination program period (December 15, 2020 to March
36 6, 2021) was defined as a rapid rollout phase.

37 **Main Outcomes and Measures:** At the pandemic onset, HCW testing and surveillance
38 was conducted wherein SARS-CoV-2 positive HCWs were offered STDL. De-identified
39 summary data of SARS-CoV-2 infections and STDL utilization among HCWs were
40 analyzed. Pre- and post-vaccination trends in SARS-CoV-2 positivity and STDL
41 utilization rates were evaluated.

42 **Results:** Updated for June 5, 2021, 98.2% (n = 26,791) of employees received a full or
43 partial dose of one of the approved mRNA COVID-19 vaccines. The vaccination rate
44 during the rapid rollout phase was approximately 3,700 doses / 7-days. The overall
45 mean weekly SARS-CoV-2 positivity rates among HCWs were significantly lower
46 following vaccine rollout (2.4%), compared to pre-vaccination period (11.8%, p < 0.001).
47 An accompanying 69.8% decline in STDL utilization was also observed (315 to 95
48 weekly leaves). During the rapid rollout phase, SARS-CoV-2 positivity rate among HM

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3 49 HCWs declined by 84.3% (8.9% to 1.4% positivity rate), compared to a 54.7% (12.8% to
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5 50 5.8% positivity rate) decline in the Houston metropolitan area.
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7
8 51 **Conclusion:** Despite limited generalizability of regional hospital-based studies –
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10 52 wherein factors such as the emergence of viral variants and population-level vaccine
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12 53 penetrance may differ – accounts of robust HCW vaccination programs provide
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14 54 important guidance for sustaining a critical resource to provide safe and effective care
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16 55 for COVID-19 and non-COVID-19 patients across healthcare systems.
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57 **Strengths and limitations of this study**

- 58 • We report data on utilization of COVID-19 specific short-term disability leave
59 (STDL) which was implemented as part of an employee testing and surveillance
60 program.
- 61 • A vaccine advisory committee (VAC) was established which reviewed available
62 data and guidance in order to develop a risk-based tiered approach for rapid
63 vaccine rollout.
- 64 • The generalizability of our findings are limited to the setting of our healthcare
65 system; nonetheless, such accounts are important to guide planning and
66 assessment of future vaccine administration programs.

67

68 INTRODUCTION

69 Safe and rapid rollout of the United States (US) Food and Drug Administration
70 (FDA) approved vaccines is a potentially transformational public health tool in the
71 armamentarium against the coronavirus disease 2019 (COVID-19). Despite impressive
72 efficacy data from Phase 3 clinical trials, there is a need to demonstrate real world
73 effectiveness (RWE) of these vaccines for controlling the pandemic in a variety of
74 settings, across heterogenous population groups. Healthcare workers (HCWs) have
75 been on the forefront of the COVID-19 pandemic and continue to provide critical care to
76 hundreds of COVID-19 patients across all US regions and globally. The pandemic has
77 reestablished the importance of this valuable resource in being a critically important line
78 of defense against human suffering in the face of a healthcare catastrophe. Most tiered
79 vaccination approaches prioritized HCWs before expanding administration to those in
80 higher-risk age groups and with underlying health conditions. This is important not only
81 from a public health perspective but is also critical for continued operational viability of
82 large and small healthcare systems, such that they can adequately provide treatment
83 and prevention services to their communities.

84 In the state of Texas, vaccine eligibility initially included frontline workers (Phase
85 1A) and individuals aged 65 years or older as well as those with underlying health
86 conditions (Phase 1B) [1]. We provide an account of COVID-19 vaccine rollout among
87 HCWs of a tertiary healthcare system in Texas. At the time of vaccination program
88 initiation, the healthcare system was in the midst of a surge in COVID-19 cases and
89 maintaining a viable HCW workforce was critical [1, 2]. Across the system, a program of
90 COVID-19 specific short-term disability leave (STDL) among HCWs had been initiated

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3 91 and tracking its utilization not only served as an important indicator of severe acute
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5 92 respiratory syndrome coronavirus 2 (SARS-CoV-2) infection among HCWs, but also
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8 93 provided a valuable metric to assess impact of vaccination towards maintaining a
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10 94 healthy HCW workforce. In this report, we demonstrate a signal of RWE of COVID-19
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12 95 vaccines by evaluating reduction in SARS-CoV-2 infections and subsequent utilization
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14 96 of STDL among HCWs.
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24 100 **METHODS**

26 101 *Study Design and Setting*

28 102 Houston Methodist (HM) is an 8-hospital healthcare system in the greater
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31 103 Houston metropolitan area, which has been a major hub in the fight against the COVID-
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33 104 19 pandemic since March 2020 [3, 4]. At the onset of the pandemic, HM instituted an
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35 105 employee SARS-CoV-2 surveillance initiative coupled with an enhanced COVID-19
36
37 106 specific STDL program for employees testing positive [5]. Surveillance testing occurred
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40 107 pre- and post-vaccine rollout and was based on polymerase chain reaction (PCR) tests
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42 108 for presence of SARS-CoV-2 RNA in nasopharyngeal specimens. The voluntary
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44 109 surveillance program encouraged all HCWs (symptomatic or asymptomatic) to utilize
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47 110 SARS-CoV-2 testing at frequent intervals across all HM testing sites. Testing results
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49 111 were typically available in employee health portals within 24 to 48 hours. Upon the
50
51 112 detection of a positive test, employees were required to take STDL and were contacted
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54 113 by supervisors for additional follow-up. Additionally, HM established a system-wide
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3 114 vaccine advisory committee (VAC) in October 2020 to review safety and efficacy data
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5 115 submitted by vaccine producers to the FDA for consideration of Emergency Use
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7 116 Authorization (EUA). The overarching agenda for the VAC was to independently review
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9 117 any available data or guidance before offering vaccines to employees. The VAC
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11 118 subsequently evaluated preliminary data and guidance being provided by the Advisory
12
13 119 Committee on Immunization Practices (ACIP) of the Centers for Disease Control and
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15 120 Prevention (CDC) and developed a risk-based tiered approach for vaccine
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17 121 administration among the employees. Patient-facing HCWs directly involved in the care
18
19 122 of COVID-19 patients were prioritized within the initial weeks after vaccination began on
20
21 123 December 15, 2020; all other employees were encouraged to wait until vaccine supply
22
23 124 for non-frontline HCWs was available to make an appointment. HM employees received
24
25 125 electronic invitations to schedule vaccination across all HM locations and were offered a
26
27 126 mRNA vaccine (BNT162b2 or mRNA-1273) being administered on the day of the
28
29 127 appointment. During the early stages of vaccine rollout, various incentives for
30
31 128 vaccination were provided and subsequently vaccination was mandated on June 7,
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33 129 2021. Our analyses represent the pre-mandate time period. This study was not
34
35 130 regarded as human subjects research by the Houston Methodist Institutional Review
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37 131 Board (IRB) since this study does not involve direct human participation and was
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39 132 therefore exempt from human subject research approval. This study was approved by
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41 133 the HM Institutional Review Board as a quality improvement project with waiver of
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43 134 informed consent.
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51 135 *Statistical Analysis*
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3 136 We assimilated de-identified summary data of SARS-CoV-2 infections and STDL
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5 137 utilization among HCWs across the period of the pandemic and defined the first 12-
6
7 138 week period (December 15, 2020 to March 6, 2021) as an initial rapid rollout period for
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9 139 COVID-19 vaccination among HCWs. Summary metrics are provided as frequencies
10
11 140 and proportions. Tests for proportional comparisons and Chi-squared trends were used
12
13 141 to assess pre- and post-vaccination (including the rapid rollout period) SARS-CoV-2
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15 142 positivity rates and trends. Reporting of vaccine efficacy was limited to descriptive
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17 143 accounts of the number and proportion of breakthrough infections as assessed through
18
19 144 the employee surveillance program.

23 145 *Patient and Public Involvement*

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26 146 Patients or the public were not involved in the design, or conduct, or reporting, or
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28 147 dissemination plans of our research.

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32 33 149 **RESULTS**

34
35 150 The COVID-19 vaccine rollout was simultaneously initiated at all HM locations on
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37 151 December 15, 2020. Updated for June 5, 2021, from among a total of 27,291
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39 152 employees, 26,791 (98.2%) had received at least a single dose of either one of the two
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41 153 approved mRNA COVID-19 vaccines, whereas 26,723 (97.9%) had completed both
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43 154 doses. During the 12-week initial rapid rollout period (December 15, 2020 to March 6,
44
45 155 2021) the vaccination rate was 3,700 doses / 7-days.

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49 156 The recent (November 1, 2020 to June 5, 2021) trends in SARS-CoV-2 positivity
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51 157 among HCWs are demonstrated in Figure 1. The mean SARS-CoV-2 weekly positivity
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53 158 rate prior to initiation of the HCW vaccination program (11.8%) was significantly higher

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3 159 compared to the positivity rate following vaccination initiation (2.4%, $p < 0.001$). The
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5 160 upward trend in SARS-CoV-2 positivity rate observed in the 45-day pre-vaccination
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7 161 period (November 1, 2020 to December 12, 2020) has significantly trended down during
8
9 162 the post-vaccination phase (December 15, 2020 to June 5, 2021) ($p_{\text{trend}} < 0.001$).

12 163 Since the end of January 2021, the weekly SARS-CoV-2 infection rate among
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14 164 HCWs participating in surveillance testing has consistently remained below 3.1%.
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16 165 During the initial 12-week rapid rollout period, the proportional decline in HM HCW
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18 166 SARS-CoV-2 positivity rate was 84.3% (8.9% to 1.4%), as compared to a 54.7% decline
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20 167 (12.8% to 5.8%) observed in the greater Houston metropolitan area [1].
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22

23 168 As a part of the HCW surveillance program, 117 (0.4%) employees were
24
25 169 reported to have tested positive more than 7 days after receiving the second dose of the
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27 170 vaccine, which includes both asymptomatic random surveillance of employees as well
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29 171 as symptomatic referrals from the employee health service. Among these positive
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31 172 cases, 66 (56.4%) were reported to be symptomatic.
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34 173 Figure 2 represents the weekly frequency of STDL utilization among HCWs. We
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36 174 also report the approximate temporal emergence of known SARS-CoV-2 mutations
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38 175 (D614G) [6] as well as detection of viral variants (Alpha B.1.1.7; Beta B.1.351; Gamma
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40 176 P.1 and P.2; B.1.429 and B.1.427) in the greater Houston area, based on sequencing
41
42 177 data of patient specimens performed at HM [7]. Compared to the peak of STDL
43
44 178 utilization during the initial weeks of vaccine rollout (January 3 to 9, 2021: 315 leaves), a
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46 179 69.8% decline has been observed during the most recent reporting period (May 30 to
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48 180 June 5, 2021: 95 leaves), with utilization numbers approaching pre-pandemic levels.
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182 **DISCUSSION**

183 Given the critical need to maintain an effective and safe healthcare workforce
184 and to minimize inadvertent viral transmission in the healthcare setting, frontline HCWs
185 were ubiquitously recognized as a priority group for vaccination. In addition to continued
186 care provided to COVID-19 and non-COVID-19 patients; large healthcare organizations
187 have been called upon to organize and execute delivery of COVID-19 vaccines among
188 its HCWs and across the community at large. HM is a state-designated vaccine hub
189 and, as of June 5, 2021, has administered over 780 thousand vaccines to members of
190 the community [8].

191 Vaccine supply and delivery during the initial nationwide rollout was beset with
192 logistical challenges, and administration metrics lagged behind target levels. However,
193 during the same time period we were able to achieve rapid rates of HCW vaccination
194 with demonstrated vaccine RWE in terms of curtailing infection rates as well as reducing
195 utilization of STDL for HCWs. Our vaccination planning started several months prior to
196 vaccine delivery and required close coordination between a vaccine scientific
197 committee, operational leadership, physician organization, and the system's infection
198 control management. We instituted a seamless vaccination program among our HCWs
199 while caring for large numbers of COVID-19 and non-COVID-19 patients and
200 maintaining regular hospital operations. Furthermore, hospital leadership maintained a
201 consistent and transparent line of communication with the workforce. This included
202 weekly communication of the latest scientific and policy updates, reminders on public
203 health guidance, and encouragement of individual vaccination. Our initial results with
204 indices of HCW protection against SARS-CoV-2 infection and related disability indicate

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3 205 that the vaccines can be deployed in the real-world settings with high levels of
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5 206 effectiveness. Of note, we provide evidence of vaccine effectiveness amid the
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7 207 emergence of multiple variants of concern (VOC) in the greater Houston area starting in
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9 208 December 2020 [7].

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12 209 Interpretation of our findings should take into account the contextual differences
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14 210 between our healthcare system setting and the general Houston public. During the 12-
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16 211 week rapid rollout period (December 15, 2020 to March 6, 2021), vaccines were made
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18 212 available to all HM employees. At the same time, vaccine administration throughout the
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20 213 greater Houston metropolitan area followed recommendations set by the state of Texas
21
22 214 and was only available to frontline workers (Phase 1A) and individuals aged 65 years
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24 215 and older or with co-existing conditions (Phase 1B) [1]. Vaccine administration for
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26 216 individuals aged 50 years and older in the general public was not initiated until Phase
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28 217 1C (March 15, 2021). Given this, it is possible that the phased differences in vaccine
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30 218 eligibility and administration contributed to the observed differences in SARS-CoV-2
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32 219 positivity rate between the HM workforce and the general Houston population.

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35 220 Furthermore, it is important to note circumstances influencing the implementation
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37 221 of protective public health measures. Throughout the duration of the pandemic, our
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39 222 hospital system has consistently followed public health recommendations. Personal
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41 223 protective equipment (PPE) for frontline workers was always made available; masks
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43 224 and social distancing guidelines were followed, even in non-clinical settings. Patients
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45 225 were required to wear masks and the allowance of visitors was restricted, depending on
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47 226 the severity of case surges at the time. Conversely, although a statewide mask mandate
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3 227 was in effect for a duration of the pandemic (July 2020 – March 2021), adherence to
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5 228 these public health measures may have not been consistently enforced.
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8 229 Our results are limited to a narrative and descriptive account of the reduction in
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10 230 infection and STDL utilization across one healthcare system. Furthermore, we have not
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12 231 analyzed individual HCW characteristics (such as demographics, comorbidities and risk
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14 232 of occupational exposure) that may be associated with SARS-CoV-2 infection.
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17 233 Concurrent studies on the established immunological protection against infection are
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19 234 needed to fully understand the population-wide and individual benefits that vaccinations
20
21 235 confer. The observed trends in SARS-CoV-2 positivity rate were based on diagnostic
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23 236 tests conducted as part of the employee surveillance program and were requested
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25 237 voluntarily and at the prerogative of the HCW. We did not distinguish results based on
26
27 238 either the purpose of testing or whether HCWs experienced viral exposure and / or
28
29 239 presented with symptoms. It is possible that the dynamics of program participation
30
31 240 differed in the pre- and post-vaccination periods. Nonetheless, we observed testing
32
33 241 participation to remain relatively consistent during the initial phase of the vaccination
34
35 242 program, with the mean number of weekly tests performed post-vaccination rollout
36
37 243 (December 20, 2020 to February 25, 2021: 2,621 tests) continuing at a rate comparable
38
39 244 to that during the peak surveillance period prior to vaccination rollout (August 30, 2020
40
41 245 to December 12, 2020: 2,599 tests). Finally, although our data demonstrate a high
42
43 246 degree of correlation between vaccination and reduction in infection and STDL
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45 247 utilization, the potential influence of protective effect offered by lower community spread
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47 248 of the virus or differences in behavioral patterns between health system employees and
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49 249 the general community cannot be ruled out.
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3 250 Hospitals are a microcosm of the communities they serve as well as a nexus in
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6 251 which there is a high rate of encounters between healthy and ill individuals. Despite
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8 252 determined efforts to vaccinate the broader population, the risk of SARS-CoV-2
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10 253 infections and related COVID-19 hospitalizations has not been fully eliminated,
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12 254 especially due to the continued emergence of VOCs [9, 10] and relaxation of protective
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14 255 public health measures. Furthermore, although robust vaccine effectiveness (VE) has
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16 256 been reported [11], the duration of VE is currently unknown; consequently, booster
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18 257 shots that confer additional protection against VOCs may be recommended and are
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20 258 currently undergoing testing [12].

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24 259 In spite of varying challenges, vaccination rates in the US have continued at a
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26 260 progressive pace; at the time of this reporting, $\geq 62.9\%$ of individuals are at least
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28 261 partially immunized and $\geq 53.6\%$ are fully immunized [13]. Nonetheless, global
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30 262 vaccination rates are estimated at approximately only $\geq 41.5\%$ of the population [14]. As
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32 263 efforts to support international partners in their respective vaccination programs
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34 264 proceed, insights from the success of vaccine rollout in the US will provide a valuable
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36 265 model for reference. Furthermore, in the face of continued high rates of vaccine
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38 266 hesitancy [15] as well as the risk of a resurgence in cases globally, assimilating and
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40 267 reporting cumulative evidence of real-world vaccine effectiveness is paramount to build
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42 268 population-wide confidence in vaccination, hence rapidly achieving desirable levels of
43
44 269 herd immunity against the current predominant strains of SARS-CoV-2.

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4

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6
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8
9
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11
12 276 Employee Health and Occupational Medicine), Mr. Stephen Spielman (SVP & COO of
13
14 277 Specialty Physician Group), Mr. Jeff Carr (VP Finance) and Dr. Dan Metzen (System
15
16 278 Director of Pharmacy). All individuals are full time employees of Houston Methodist and
17
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19
20 280 Houston Methodist employees and physicians for their services during the COVID-19
21
22 281 pandemic.
23
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27
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29
30 284 public, commercial or not-for-profit sectors.
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33 285
34
35 286 **COMPETING INTEREST:** None declared.
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40 288 **DATA AVAILABILITY STATEMENT:** Data cannot be shared publicly because of
41
42 289 hospital employee confidentiality concerns. Reasonable requests by researchers who
43
44 290 meet the criteria for access to confidential data can be made to the corresponding
45
46 291 author (fvahidy@houstonmethodist.org).
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49 292
50
51 293 **RESEARCH ETHICS APPROVAL STATEMENT:** This study was not regarded as
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53 294 human subjects research by the Houston Methodist (HM) Institutional Review Board
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3 295 (IRB) since this study does not involve direct human participation and was therefore
4
5 296 exempt from human subjects approval. This study was approved by the HM Institutional
6
7 297 Review Board as a quality improvement project with waiver of informed consent.
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12 299 **AUTHOR CONTRIBUTIONS:**

13
14 300 FV was responsible for the study conception and design. Data acquisition and analysis
15
16 301 were performed by AP. Interpretation of results and initial drafting of the manuscript
17
18 302 were completed by FV and AP. FV, AP, KH, AB, DS, RS, RP, and MB contributed to
19
20 303 critical revision of the manuscript and approved the final version for submission.
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3 375 **Figure Legends**
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8 377 **Figure 1:** SARS-CoV-2 Positivity Rates from the Houston Methodist (HM) Surveillance
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10 378 Employee Program Pre- and Post-COVID-19 Vaccine Initiation. Reference lines for the
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12 379 initial 12-week rapid rollout period for vaccination (December 15, 2020 to March 6,
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14 380 2021) are shown.
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21 383 **Figure 2:** Enhanced Short-Term Disability Leave Utilization by Houston Methodist (HM)
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23 384 Employees Across the COVID-19 Pandemic Timeline. Reference lines for the initial 12-
24
25 385 week rapid rollout period for vaccination (December 15, 2020 to March 6, 2021) are
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27 386 shown. Annotations depict relative emergence and detection of SARS-CoV-2 mutations
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29 387 and viral variants in greater Houston.
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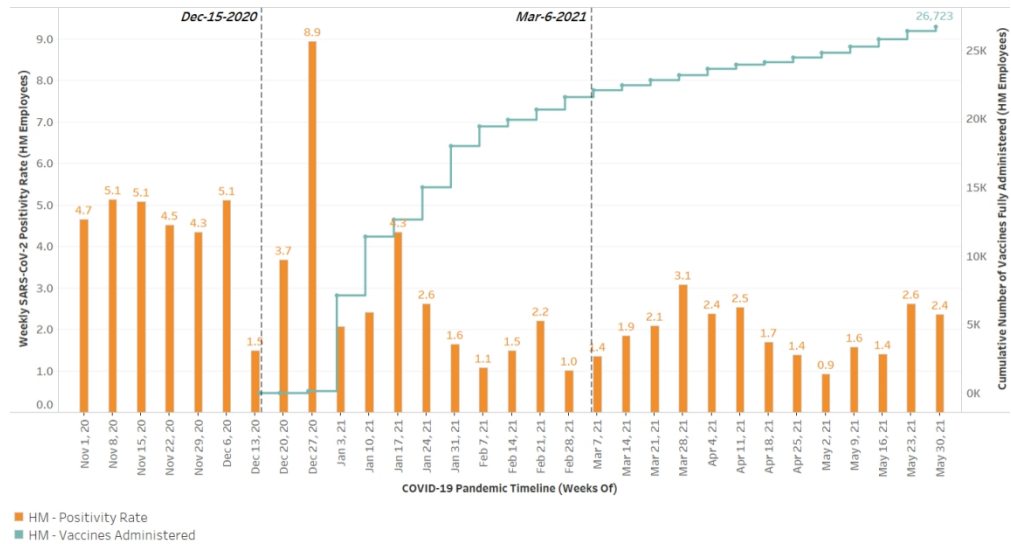


Figure 1. SARS-CoV-2 Positivity Rates from the Houston Methodist (HM) Surveillance Employee Program Pre- and Post-COVID-19 Vaccine Initiation. Reference lines for the initial 12-week rapid rollout period for vaccination (December 15, 2020 to March 6, 2021) are shown.

119x64mm (300 x 300 DPI)

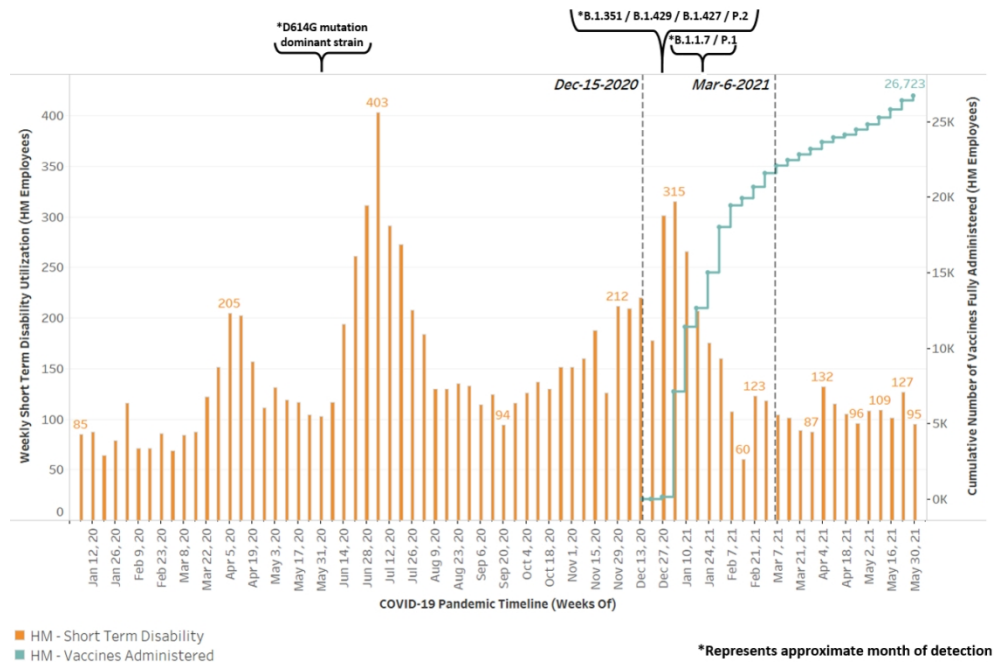


Figure 2: Enhanced Short-Term Disability Leave Utilization by Houston Methodist (HM) Employees Across the COVID-19 Pandemic Timeline. Reference lines for the initial 12-week rapid rollout period for vaccination (December 15, 2020 to March 6, 2021) are shown. Annotations depict relative emergence and detection of SARS-CoV-2 mutations and viral variants in greater Houston.

353x239mm (96 x 96 DPI)

STROBE Statement—Checklist of items that should be included in reports of *cross-sectional studies*

	Item No	Recommendation	Page No
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2-3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	5-6
Objectives	3	State specific objectives, including any prespecified hypotheses	5-6
Methods			
Study design	4	Present key elements of study design early in the paper	6-8
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6-7
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants	6-7
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	6-8
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	6-8
Bias	9	Describe any efforts to address potential sources of bias	6-7
Study size	10	Explain how the study size was arrived at	6-8
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	7-8
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	7-8
		(b) Describe any methods used to examine subgroups and interactions	N/A
		(c) Explain how missing data were addressed	7-8
		(d) If applicable, describe analytical methods taking account of sampling strategy	7-8
		(e) Describe any sensitivity analyses	N/A
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	8-9
		(b) Give reasons for non-participation at each stage	N/A
		(c) Consider use of a flow diagram	N/A
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	8-9
		(b) Indicate number of participants with missing data for each variable of interest	N/A
Outcome data	15*	Report numbers of outcome events or summary measures	8-9
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	8-9

		(b) Report category boundaries when continuous variables were categorized	N/A
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	8-9
Discussion			
Key results	18	Summarise key results with reference to study objectives	10-12
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	12
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	10-12
Generalisability	21	Discuss the generalisability (external validity) of the study results	10-13
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	14

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

Impact of mRNA Vaccines in Curtailing SARS-CoV-2 Infection and Disability Leave Utilization Among Healthcare Workers During the COVID-19 Pandemic: Cross Sectional Analysis from a Tertiary Healthcare System in the Greater Houston Metropolitan Area

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1 **Impact of mRNA Vaccines in Curtailing SARS-CoV-2 Infection and Disability**
2 **Leave Utilization Among Healthcare Workers During the COVID-19 Pandemic:**
3 **Cross Sectional Analysis from a Tertiary Healthcare System in the Greater**
4 **Houston Metropolitan Area**

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24 **Running title:** Effectiveness of COVID-19 Vaccines among Healthcare Workers

25 **Word count:** 2,271

27 **ABSTRACT**

28 **Objectives:** We provide an account of Real World Effectiveness (RWE) of COVID-19
29 vaccines among Healthcare workers (HCWs) at a tertiary healthcare system and report
30 trends in SARS-CoV-2 infections and subsequent utilization of COVID-19 specific short-
31 term disability leave (STDL).

32 **Design:** Cross sectional study

33 **Setting and Participants:** Summary data on 27,291 employees at a tertiary healthcare
34 system in the greater Houston metropolitan area between December 15, 2020 and June
35 5, 2021. The initial 12-week vaccination program period (December 15, 2020 to March
36 6, 2021) was defined as a rapid rollout phase.

37 **Main Outcomes and Measures:** At the pandemic onset, HCW testing and surveillance
38 was conducted wherein SARS-CoV-2 positive HCWs were offered STDL. De-identified
39 summary data of SARS-CoV-2 infections and STDL utilization among HCWs were
40 analyzed. Pre- and post-vaccination trends in SARS-CoV-2 positivity and STDL
41 utilization rates were evaluated.

42 **Results:** Updated for June 5, 2021, 98.2% (n = 26,791) of employees received a full or
43 partial dose of one of the approved mRNA COVID-19 vaccines. The vaccination rate
44 during the rapid rollout phase was approximately 3,700 doses / 7-days. The overall
45 mean weekly SARS-CoV-2 positivity rates among HCWs were significantly lower
46 following vaccine rollout (2.4%), compared to pre-vaccination period (11.8%, p < 0.001).
47 An accompanying 69.8% decline in STDL utilization was also observed (315 to 95
48 weekly leaves). During the rapid rollout phase, SARS-CoV-2 positivity rate among HM

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3 49 HCWs declined by 84.3% (8.9% to 1.4% positivity rate), compared to a 54.7% (12.8% to
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5 50 5.8% positivity rate) decline in the Houston metropolitan area.
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7
8 51 **Conclusion:** Despite limited generalizability of regional hospital-based studies –
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10 52 wherein factors such as the emergence of viral variants and population-level vaccine
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12 53 penetrance may differ – accounts of robust HCW vaccination programs provide
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14 54 important guidance for sustaining a critical resource to provide safe and effective care
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16 55 for COVID-19 and non-COVID-19 patients across healthcare systems.
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57 **Strengths and limitations of this study**

- 58 • We tracked COVID-19 specific short-term disability leave utilization over time
59 among employees of a large tertiary healthcare system in Houston, Texas which
60 instituted early mandates for COVID-19 vaccination.
- 61 • We additionally evaluated data from an employee SARS-CoV-2 surveillance
62 program with information on COVID-19 vaccination, and symptomatic and
63 breakthrough infections.
- 64 • The generalizability of our findings are limited to the setting of our healthcare
65 system.
- 66 • Surveillance for SARS-CoV-2 positivity among employees was highly
67 encouraged and testing was readily available across several locations, however
68 surveillance program was voluntary.

69

70 INTRODUCTION

71 Safe and rapid rollout of the United States (US) Food and Drug Administration
72 (FDA) approved vaccines is a potentially transformational public health tool in the
73 armamentarium against the coronavirus disease 2019 (COVID-19). Despite impressive
74 efficacy data from Phase 3 clinical trials, there is a need to demonstrate real world
75 effectiveness (RWE) of these vaccines for controlling the pandemic in a variety of
76 settings, across heterogenous population groups. Healthcare workers (HCWs) have
77 been on the forefront of the COVID-19 pandemic and continue to provide critical care to
78 hundreds of COVID-19 patients across all US regions and globally. The pandemic has
79 reestablished the importance of this valuable resource in being a critically important line
80 of defense against human suffering in the face of a healthcare catastrophe. Most tiered
81 vaccination approaches prioritized HCWs before expanding administration to those in
82 higher-risk age groups and with underlying health conditions. This is important not only
83 from a public health perspective but is also critical for continued operational viability of
84 large and small healthcare systems, such that they can adequately provide treatment
85 and prevention services to their communities.

86 In the state of Texas, vaccine eligibility initially included frontline workers (Phase
87 1A) and individuals aged 65 years or older as well as those with underlying health
88 conditions (Phase 1B) [1]. We provide an account of COVID-19 vaccine rollout among
89 HCWs of a tertiary healthcare system in Texas. At the time of vaccination program
90 initiation, the healthcare system was in the midst of a surge in COVID-19 cases and
91 maintaining a viable HCW workforce was critical [1, 2]. Across the system, a program of
92 COVID-19 specific short-term disability leave (STDL) among HCWs had been initiated

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3 93 and tracking its utilization not only served as an important indicator of severe acute
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5 94 respiratory syndrome coronavirus 2 (SARS-CoV-2) infection among HCWs, but also
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8 95 provided a valuable metric to assess impact of vaccination towards maintaining a
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10 96 healthy HCW workforce. In this report, we demonstrate a signal of RWE of COVID-19
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12 97 vaccines by evaluating reduction in SARS-CoV-2 infections and subsequent utilization
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15 98 of STDL among HCWs.
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102 **METHODS**

103 *Study Design and Setting*

104 Houston Methodist (HM) is an 8-hospital healthcare system in the greater
105 Houston metropolitan area, which has been a major hub in the fight against the COVID-
106 19 pandemic since March 2020 [3, 4]. At the onset of the pandemic, HM instituted an
107 employee SARS-CoV-2 surveillance initiative coupled with an enhanced COVID-19
108 specific STDL program for employees testing positive [5]. Surveillance testing occurred
109 pre- and post-vaccine rollout and was based on polymerase chain reaction (PCR) tests
110 for presence of SARS-CoV-2 RNA in nasopharyngeal specimens. The voluntary
111 surveillance program encouraged all HCWs (symptomatic or asymptomatic) to utilize
112 SARS-CoV-2 testing at frequent intervals across all HM testing sites. Testing results
113 were typically available in employee health portals within 24 to 48 hours. Upon the
114 detection of a positive test, employees were required to take STDL and were contacted
115 by supervisors for additional follow-up. Additionally, HM established a system-wide

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3 116 vaccine advisory committee (VAC) in October 2020 to review safety and efficacy data
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5 117 submitted by vaccine producers to the FDA for consideration of Emergency Use
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7 118 Authorization (EUA). The overarching agenda for the VAC was to independently review
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9 119 any available data or guidance before offering vaccines to employees. The VAC
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11 120 subsequently evaluated preliminary data and guidance being provided by the Advisory
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13 121 Committee on Immunization Practices (ACIP) of the Centers for Disease Control and
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15 122 Prevention (CDC) and developed a risk-based tiered approach for vaccine
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17 123 administration among the employees. Patient-facing HCWs directly involved in the care
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19 124 of COVID-19 patients were prioritized within the initial weeks after vaccination began on
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21 125 December 15, 2020; all other employees were encouraged to wait until vaccine supply
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23 126 for non-frontline HCWs was available to make an appointment. HM employees received
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25 127 electronic invitations to schedule vaccination across all HM locations and were offered a
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27 128 mRNA vaccine (BNT162b2 or mRNA-1273) being administered on the day of the
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29 129 appointment. During the early stages of vaccine rollout, various incentives for
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31 130 vaccination were provided and subsequently vaccination was mandated on June 7,
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33 131 2021. Our analyses represent the pre-mandate time period. This study was not
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35 132 regarded as human subjects research by the Houston Methodist Institutional Review
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37 133 Board (IRB) since this study does not involve direct human participation and was
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39 134 therefore exempt from human subject research approval. This study was approved by
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41 135 the HM Institutional Review Board as a quality improvement project with waiver of
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43 136 informed consent.

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51 137 *Statistical Analysis*
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3 138 We assimilated de-identified summary data of SARS-CoV-2 infections and STDL
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5 139 utilization among HCWs across the period of the pandemic and defined the first 12-
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7 140 week period (December 15, 2020 to March 6, 2021) as an initial rapid rollout period for
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9 141 COVID-19 vaccination among HCWs. Summary metrics are provided as frequencies
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11 142 and proportions. Tests for proportional comparisons and Chi-squared trends were used
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13 143 to assess pre- and post-vaccination (including the rapid rollout period) SARS-CoV-2
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15 144 positivity rates and trends. Reporting of vaccine efficacy was limited to descriptive
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17 145 accounts of the number and proportion of breakthrough infections as assessed through
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19 146 the employee surveillance program.

23 147 *Patient and Public Involvement*

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26 148 Patients or the public were not involved in the design, or conduct, or reporting, or
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28 149 dissemination plans of our research.

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32 151 **RESULTS**

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34
35 152 The COVID-19 vaccine rollout was simultaneously initiated at all HM locations on
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37 153 December 15, 2020. Updated for June 5, 2021, from among a total of 27,291
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39 154 employees, 26,791 (98.2%) had received at least a single dose of either one of the two
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41 155 approved mRNA COVID-19 vaccines, whereas 26,723 (97.9%) had completed both
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43 156 doses. During the 12-week initial rapid rollout period (December 15, 2020 to March 6,
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45 157 2021) the vaccination rate was 3,700 doses / 7-days.

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49 158 The recent (November 1, 2020 to June 5, 2021) trends in SARS-CoV-2 positivity
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51 159 among HCWs are demonstrated in Figure 1. The mean SARS-CoV-2 weekly positivity
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53 160 rate prior to initiation of the HCW vaccination program (11.8%) was significantly higher

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3 161 compared to the positivity rate following vaccination initiation (2.4%, $p < 0.001$). The
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5 162 upward trend in SARS-CoV-2 positivity rate observed in the 45-day pre-vaccination
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7 163 period (November 1, 2020 to December 12, 2020) has significantly trended down during
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9 164 the post-vaccination phase (December 15, 2020 to June 5, 2021) ($p_{\text{trend}} < 0.001$).

12 165 Since the end of January 2021, the weekly SARS-CoV-2 infection rate among
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14 166 HCWs participating in surveillance testing has consistently remained below 3.1%.
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16 167 During the initial 12-week rapid rollout period, the proportional decline in HM HCW
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18 168 SARS-CoV-2 positivity rate was 84.3% (8.9% to 1.4%), as compared to a 54.7% decline
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20 169 (12.8% to 5.8%) observed in the greater Houston metropolitan area [1].

23 170 As a part of the HCW surveillance program, 117 (0.4%) employees were
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25 171 reported to have tested positive more than 7 days after receiving the second dose of the
26
27 172 vaccine, which includes both asymptomatic random surveillance of employees as well
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29 173 as symptomatic referrals from the employee health service. Among these positive
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31 174 cases, 66 (56.4%) were reported to be symptomatic.

33 175 Figure 2 represents the weekly frequency of STDL utilization among HCWs. We
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35 176 also report the approximate temporal emergence of known SARS-CoV-2 mutations
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37 177 (D614G) [6] as well as detection of viral variants (Alpha B.1.1.7; Beta B.1.351; Gamma
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39 178 P.1 and P.2; B.1.429 and B.1.427) in the greater Houston area, based on sequencing
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41 179 data of patient specimens performed at HM [7]. Compared to the peak of STDL
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43 180 utilization during the initial weeks of vaccine rollout (January 3 to 9, 2021: 315 leaves), a
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45 181 69.8% decline has been observed during the most recent reporting period (May 30 to
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47 182 June 5, 2021: 95 leaves), with utilization numbers approaching pre-pandemic levels.
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184 **DISCUSSION**

185 Given the critical need to maintain an effective and safe healthcare workforce
186 and to minimize inadvertent viral transmission in the healthcare setting, frontline HCWs
187 were ubiquitously recognized as a priority group for vaccination. In addition to continued
188 care provided to COVID-19 and non-COVID-19 patients; large healthcare organizations
189 have been called upon to organize and execute delivery of COVID-19 vaccines among
190 its HCWs and across the community at large. HM is a state-designated vaccine hub
191 and, as of June 5, 2021, has administered over 780 thousand vaccines to members of
192 the community [8].

193 Vaccine supply and delivery during the initial nationwide rollout was beset with
194 logistical challenges, and administration metrics lagged behind target levels. However,
195 during the same time period we were able to achieve rapid rates of HCW vaccination
196 with demonstrated vaccine RWE in terms of curtailing infection rates as well as reducing
197 utilization of STDL for HCWs. Our vaccination planning started several months prior to
198 vaccine delivery and required close coordination between a vaccine scientific
199 committee, operational leadership, physician organization, and the system's infection
200 control management. We instituted a seamless vaccination program among our HCWs
201 while caring for large numbers of COVID-19 and non-COVID-19 patients and
202 maintaining regular hospital operations. Furthermore, hospital leadership maintained a
203 consistent and transparent line of communication with the workforce. This included
204 weekly communication of the latest scientific and policy updates, reminders on public
205 health guidance, and encouragement of individual vaccination. Our initial results with
206 indices of HCW protection against SARS-CoV-2 infection and related disability indicate

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3 207 that the vaccines can be deployed in the real-world settings with high levels of
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5 208 effectiveness. Of note, we provide evidence of vaccine effectiveness amid the
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7 209 emergence of multiple variants of concern (VOC) in the greater Houston area starting in
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9 210 December 2020 [7].

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12 211 Interpretation of our findings should take into account the contextual differences
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14 212 between our healthcare system setting and the general Houston public. During the 12-
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16 213 week rapid rollout period (December 15, 2020 to March 6, 2021), vaccines were made
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18 214 available to all HM employees. At the same time, vaccine administration throughout the
19
20 215 greater Houston metropolitan area followed recommendations set by the state of Texas
21
22 216 and was only available to frontline workers (Phase 1A) and individuals aged 65 years
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24 217 and older or with co-existing conditions (Phase 1B) [1]. Vaccine administration for
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26 218 individuals aged 50 years and older in the general public was not initiated until Phase
27
28 219 1C (March 15, 2021). Given this, it is possible that the phased differences in vaccine
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30 220 eligibility and administration contributed to the observed differences in SARS-CoV-2
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32 221 positivity rate between the HM workforce and the general Houston population.

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35 222 Furthermore, it is important to note circumstances influencing the implementation
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37 223 of protective public health measures. Throughout the duration of the pandemic, our
38
39 224 hospital system has consistently followed public health recommendations. Personal
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41 225 protective equipment (PPE) for frontline workers was always made available; masks
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43 226 and social distancing guidelines were followed, even in non-clinical settings. Patients
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45 227 were required to wear masks and the allowance of visitors was restricted, depending on
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47 228 the severity of case surges at the time. Conversely, although a statewide mask mandate
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3 229 was in effect for a duration of the pandemic (July 2020 – March 2021), adherence to
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5 230 these public health measures may have not been consistently enforced.
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8 231 Our results are limited to a narrative and descriptive account of the reduction in
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10 232 infection and STDL utilization across one healthcare system. Furthermore, we have not
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12 233 analyzed individual HCW characteristics (such as demographics, comorbidities and risk
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14 234 of occupational exposure) that may be associated with SARS-CoV-2 infection.
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16
17 235 Concurrent studies on the established immunological protection against infection are
18
19 236 needed to fully understand the population-wide and individual benefits that vaccinations
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21 237 confer. The observed trends in SARS-CoV-2 positivity rate were based on diagnostic
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23 238 tests conducted as part of the employee surveillance program and were requested
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25 239 voluntarily and at the prerogative of the HCW. We did not distinguish results based on
26
27 240 either the purpose of testing or whether HCWs experienced viral exposure and / or
28
29 241 presented with symptoms. It is possible that the dynamics of program participation
30
31 242 differed in the pre- and post-vaccination periods. Nonetheless, we observed testing
32
33 243 participation to remain relatively consistent during the initial phase of the vaccination
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35 244 program, with the mean number of weekly tests performed post-vaccination rollout
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37 245 (December 20, 2020 to February 25, 2021: 2,621 tests) continuing at a rate comparable
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39 246 to that during the peak surveillance period prior to vaccination rollout (August 30, 2020
40
41 247 to December 12, 2020: 2,599 tests). Finally, although our data demonstrate a high
42
43 248 degree of correlation between vaccination and reduction in infection and STDL
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45 249 utilization, the potential influence of protective effect offered by lower community spread
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47 250 of the virus or differences in behavioral patterns between health system employees and
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49 251 the general community cannot be ruled out.
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3 252 Hospitals are a microcosm of the communities they serve as well as a nexus in
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5 253 which there is a high rate of encounters between healthy and ill individuals. Despite
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7 254 determined efforts to vaccinate the broader population, the risk of SARS-CoV-2
8
9 255 infections and related COVID-19 hospitalizations has not been fully eliminated,
10
11 256 especially due to the continued emergence of VOCs [9, 10] and relaxation of protective
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13 257 public health measures. Furthermore, although robust vaccine effectiveness (VE) has
14
15 258 been reported [11], the duration of VE is currently unknown; consequently, booster
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17 259 shots that confer additional protection against VOCs may be recommended and are
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19 260 currently undergoing testing [12].
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24 261 In spite of varying challenges, vaccination rates in the US have continued at a
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26 262 progressive pace; at the time of this reporting, $\geq 62.9\%$ of individuals are at least
27
28 263 partially immunized and $\geq 53.6\%$ are fully immunized [13]. Nonetheless, global
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30 264 vaccination rates are estimated at approximately only $\geq 41.5\%$ of the population [14]. As
31
32 265 efforts to support international partners in their respective vaccination programs
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34 266 proceed, insights from the success of vaccine rollout in the US will provide a valuable
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36 267 model for reference. Furthermore, in the face of continued high rates of vaccine
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38 268 hesitancy [15] as well as the risk of a resurgence in cases globally, assimilating and
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40 269 reporting cumulative evidence of real-world vaccine effectiveness is paramount to build
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42 270 population-wide confidence in vaccination, hence rapidly achieving desirable levels of
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44 271 herd immunity against the current predominant strains of SARS-CoV-2.
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4

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6
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8
9
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11
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15
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21
22 283 pandemic.
23
24
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26 284

27
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29
30 286 public, commercial or not-for-profit sectors.
31
32

33 287
34
35 288 **COMPETING INTEREST:** None declared.
36
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40 290 **DATA AVAILABILITY STATEMENT:** Data cannot be shared publicly because of
41
42 291 hospital employee confidentiality concerns. Reasonable requests by researchers who
43
44 292 meet the criteria for access to confidential data can be made to the corresponding
45
46 293 author (fvahidy@houstonmethodist.org).
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51 295 **RESEARCH ETHICS APPROVAL STATEMENT:** This study was not regarded as
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53 296 human subjects research by the Houston Methodist (HM) Institutional Review Board
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2
3 297 (IRB) since this study does not involve direct human participation and was therefore
4
5 298 exempt from human subjects approval. This study was approved by the HM Institutional
6
7 299 Review Board as a quality improvement project with waiver of informed consent.
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12 301 **AUTHOR CONTRIBUTIONS:**

13
14 302 FV was responsible for the study conception and design. Data acquisition and analysis
15
16 303 were performed by AP. Interpretation of results and initial drafting of the manuscript
17
18 304 were completed by FV and AP. FV, AP, KH, AB, DS, RS, RP, and MB contributed to
19
20 305 critical revision of the manuscript and approved the final version for submission.
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For peer review only

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3 377 **Figure Legends**
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8 379 **Figure 1:** SARS-CoV-2 Positivity Rates from the Houston Methodist (HM) Surveillance
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10 380 Employee Program Pre- and Post-COVID-19 Vaccine Initiation. Reference lines for the
11
12 381 initial 12-week rapid rollout period for vaccination (December 15, 2020 to March 6,
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14 382 2021) are shown.
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21 385 **Figure 2:** Enhanced Short-Term Disability Leave Utilization by Houston Methodist (HM)
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23 386 Employees Across the COVID-19 Pandemic Timeline. Reference lines for the initial 12-
24
25 387 week rapid rollout period for vaccination (December 15, 2020 to March 6, 2021) are
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27 388 shown. Annotations depict relative emergence and detection of SARS-CoV-2 mutations
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29 389 and viral variants in greater Houston.
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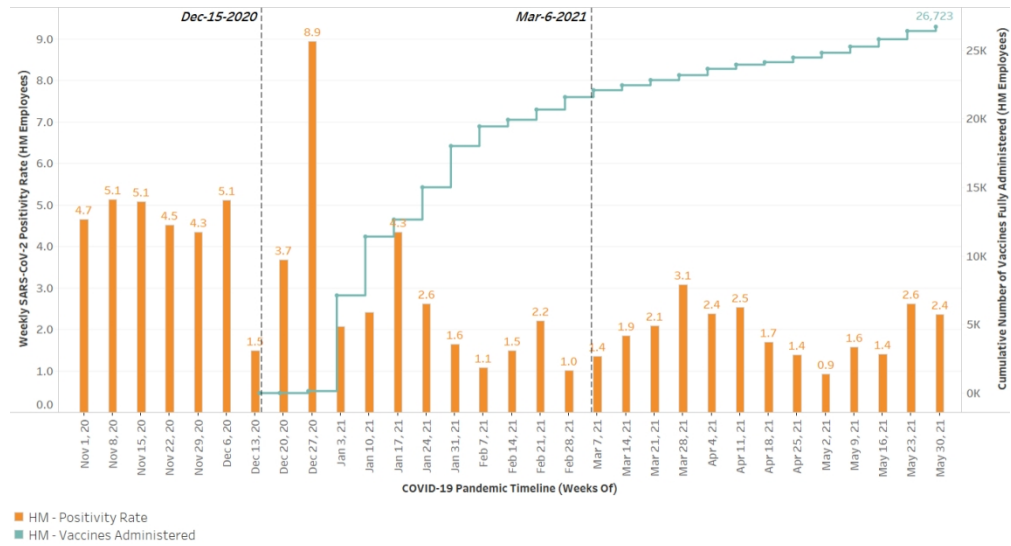


Figure 1. SARS-CoV-2 Positivity Rates from the Houston Methodist (HM) Surveillance Employee Program Pre- and Post-COVID-19 Vaccine Initiation. Reference lines for the initial 12-week rapid rollout period for vaccination (December 15, 2020 to March 6, 2021) are shown.

119x64mm (300 x 300 DPI)

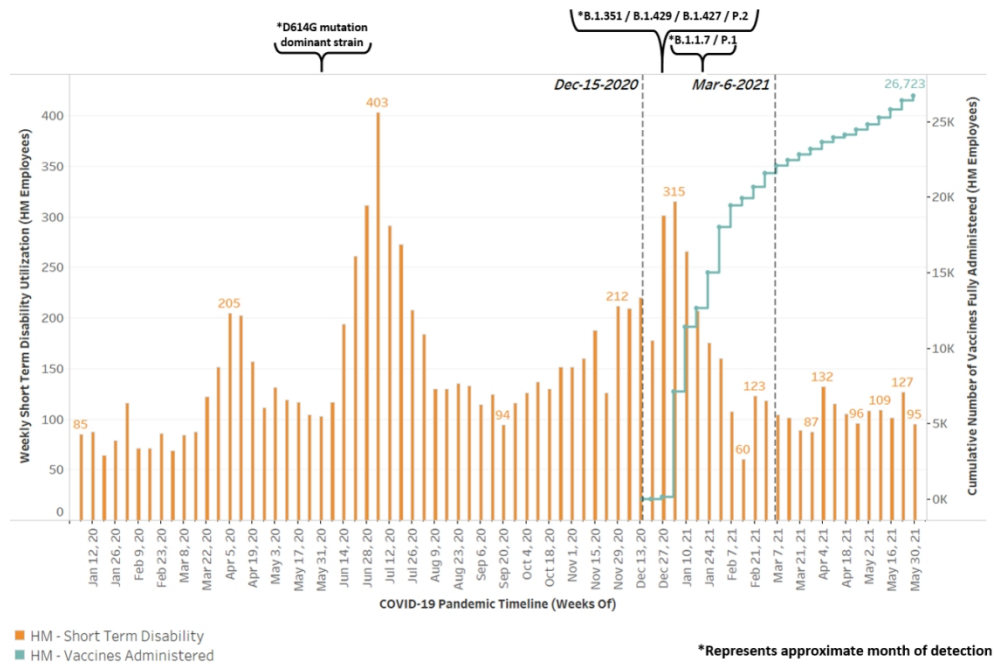


Figure 2: Enhanced Short-Term Disability Leave Utilization by Houston Methodist (HM) Employees Across the COVID-19 Pandemic Timeline. Reference lines for the initial 12-week rapid rollout period for vaccination (December 15, 2020 to March 6, 2021) are shown. Annotations depict relative emergence and detection of SARS-CoV-2 mutations and viral variants in greater Houston.

353x239mm (96 x 96 DPI)

STROBE Statement—Checklist of items that should be included in reports of *cross-sectional studies*

	Item No	Recommendation	Page No
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2-3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	5-6
Objectives	3	State specific objectives, including any prespecified hypotheses	5-6
Methods			
Study design	4	Present key elements of study design early in the paper	6-8
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6-7
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants	6-7
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	6-8
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	6-8
Bias	9	Describe any efforts to address potential sources of bias	6-7
Study size	10	Explain how the study size was arrived at	6-8
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	7-8
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	7-8
		(b) Describe any methods used to examine subgroups and interactions	N/A
		(c) Explain how missing data were addressed	7-8
		(d) If applicable, describe analytical methods taking account of sampling strategy	7-8
		(e) Describe any sensitivity analyses	N/A
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	8-9
		(b) Give reasons for non-participation at each stage	N/A
		(c) Consider use of a flow diagram	N/A
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	8-9
		(b) Indicate number of participants with missing data for each variable of interest	N/A
Outcome data	15*	Report numbers of outcome events or summary measures	8-9
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	8-9

		(b) Report category boundaries when continuous variables were categorized	N/A
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	8-9
Discussion			
Key results	18	Summarise key results with reference to study objectives	10-12
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	12
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	10-12
Generalisability	21	Discuss the generalisability (external validity) of the study results	10-13
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	14

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.