

### [ ORIGINAL ARTICLE ]

## SARS-CoV-2 Infection upon Leaving the Tokyo 2020 Olympic and Paralympic Games

Mitsuyoshi Urashima<sup>1</sup>, Hiroyuki Takao<sup>2,3</sup>, Teppei Sakano<sup>2,4</sup>, Kohei Takeshita<sup>2</sup>, Masaki Yoshida<sup>5</sup>, Yasushi Nakazawa<sup>5</sup>, Makoto Kawai<sup>6</sup> and Yuichi Murayama<sup>2,3</sup>

#### **Abstract:**

**Objective** Just before the Tokyo 2020 Olympic and Paralympic Games in Japan, the number of people infected with coronavirus disease 2019 (COVID-19), caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), started to increase at an unprecedented rate. This study investigated the effectiveness of vaccines in large-scale sporting events under difficult circumstances, such as during adherence to a bubble system and confinement inside the Olympic/Paralympic Village.

**Methods** In collaboration with medical clinics inside and outside the Village, a prospective cohort study was conducted among overseas participants using the results of polymerase chain reaction (PCR) tests for SARS-CoV-2 upon leaving Japan.

**Results** A total of 12,072 foreign participants were enrolled, 13 (0.11%) of whom had a positive PCR test result. None of these cases were broadcasters or members of the press, were tested outside the Olympic Village, or had a history of COVID-19 infection. The effectiveness of full vaccination and vaccination at least once ( $\geq$ 14 days ago) was 74% [95% confidence interval (CI): 6-93%] and 81% (95% CI: 30-95%), respectively. Three breakthrough infections with the Delta variant were observed in 6,485 fully vaccinated participants (0.05%). The positivity rate was 0.09% among adherents to the bubble system and 0.28% among non-adherents, but this difference was not significant.

**Conclusion** These findings indicate that even huge sporting events such as the Olympic and Paralympic Games can proceed while pandemics are ongoing in the host country by combining countermeasures such as vaccination, frequent testing, social distancing, and adherence to a bubble system.

Key words: SARS-CoV-2, COVID-19, personal health record app, Olympic Games, bubble system, PCR

(Intern Med 61: 3659-3666, 2022) (DOI: 10.2169/internalmedicine.0724-22)

#### Introduction

The Tokyo 2020 Olympic and Paralympic Games were postponed for one year after coronavirus disease 2019 (COVID-19), which is caused by infection with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), was declared a pandemic in March 2020. The intervening year enabled the development of effective vaccines against SARS-CoV-2 infection but also saw the emergence of the Delta variant, which is more infectious (1), more severe (2), and less effectively suppressed by vaccination (3) than previous variants. The number of people infected with the Delta variant increased at an unprecedented rate just before the start of the Tokyo 2020 Olympic Games. Although tens of thousands of athletes, members of the press and broadcasters (press/broadcasters), and officials and other individuals (officials/others) traveled to Japan from all over the world, including from countries in which COVID-19 was highly prevalent, vaccination was not required.

Correspondence to Dr. Mitsuyoshi Urashima, urashima@jikei.ac.jp

<sup>&</sup>lt;sup>1</sup>Division of Molecular Epidemiology, the Jikei University School of Medicine, Japan, <sup>2</sup>Division of Innovation for Medical Information Technology, the Jikei University School of Medicine, Japan, <sup>3</sup>Department of Neurosurgery, the Jikei University School of Medicine, Japan, <sup>4</sup>Allm, Inc., Japan, <sup>5</sup>Department of Infectious Diseases and Infection Control, the Jikei University School of Medicine, Japan and <sup>6</sup>Division of Cardiology, Department of Internal Medicine, the Jikei University School of Medicine, Japan

Received: July 25, 2022; Accepted: August 30, 2022; Advance Publication by J-STAGE: October 5, 2022

To prevent the further spread of COVID-19, the Games were basically held without spectators. Participants were tested frequently for SARS-CoV-2 and required to practice social distancing and hygiene (4) and adopt the "bubble system," in which accommodations, transportation, and competition venues were enclosed in a large "bubble" to separate the participants of the Games from lay residents of Japan. Furthermore, athletes and officials were confined to the Olympic and Paralympic Village, whereas the press/broadcasters stayed at hotels outside the Village. Consequently, the press/broadcasters may have had more opportunities to come into contact with residents of Japan. By contrast, it was thought that, in order to ensure they did their best in the competition, the athletes would take actions to avoid COVID-19 infection as much as possible, including adhering strictly to the bubble system. Therefore, it was assumed that the press/broadcasters might be at a higher risk of infection than the athletes.

Upon leaving Japan, many participants needed proof of a negative SARS-CoV-2 polymerase chain reaction (PCR) test issued by a physician for international travel or entry their home country. Using these PCR data, the present study investigated the effectiveness of vaccines in allowing largescale sporting events to be held under difficult circumstances, such as during adherence to a bubble system and confinement inside the Olympic/Paralympic Village.

#### **Materials and Methods**

#### Study design

This prospective cohort study was conducted between July 23, 2021 (the day of the opening ceremony) and September 15, 2021. One medical clinic mainly for athletes and officials/others located inside the Village and four other clinics mainly for the press/broadcasters outside the Village collaborated in this study. Each participant downloaded a free personal health record app (MySOS; Allm, Tokyo, Japan) (5) designed specifically as an official health and location monitoring app for overseas entrants. The questionnaire responses and PCR results were collected electronically over the 55-day study period.

The study protocol was approved by the Ethics Committee of the Jikei University School of Medicine for Biomedical Research [No. 33-167(10779)]. Before the study began, informed consent was obtained electronically from all participants via the MySOS app. A website was created to provide opportunities for the participants to opt out of the study using every possible language. This study was performed in accordance with the principles of the Declaration of Helsinki.

#### Participants

The study included Games participants from countries outside of Japan who took a PCR test at the collaborating medical clinics inside or outside of the Village to obtain official proof of a negative PCR test just before leaving Japan. Those <20 years old were excluded.

#### Bubble concept

To protect athletes and para-athletes as well as their supporting personnel and officials from SARS-CoV-2 infection, the Tokyo 2020 Olympic and Paralympic Games were conducted within "bubbles" in which players, staff, and dignitaries were isolated within tight physical locations to limit their contact with outsiders, as implemented in the Football Club World Cup (6). During the Games, athletes and others were confined to their accommodations inside the Village and could only use a special transportation system and competition venues, which were shielded from general residents of Japan and press/broadcasters, who stayed at hotels outside the Village. In addition to staying in the "bubble," they were further required to test frequently for SARS-CoV-2, practice social distancing, good hygiene, and so on as risk mitigation strategies to decrease the likelihood of COVID-19 transmission.

#### Outcome

A reverse-transcriptase PCR test for SARS-CoV-2 was performed using the CronoSTAR<sup>TM</sup> 96 Real-Time PCR System (WakenBtech, Kusatsu, Japan) to determine the presence of the virus through identification of the nucleocapsid protein (N) gene. The cycle threshold (Ct) values of the PCR test were used as indicators of the copy number of SARS-CoV-2 RNA. According to the diagnostic criteria of the Ministry of Health, Labour and Welfare of Japan, a Ct value <40 was considered positive. The Delta variant was determined by the presence of the T478K mutation using Primer/Probe T478K (SARS-CoV-2) (TaKaRa Bio, Kusatsu, Japan). Breakthrough infection was defined as a positive PCR test result  $\geq$ 14 days after a second vaccination or after a single dose of the Ad26.COV2.S vaccine.

#### Questionnaire

Participants were asked to complete an electronic questionnaire including the following items through the MySOS app at the time of their PCR test (Fig. 1):

1) Choose one of the following categories: Athlete, Press/ Broadcaster, Official, Other

2) Do you have a history of COVID-19 infection?

3) If you have a history of infection, when were you infected?

4) Have you been vaccinated to help prevent COVID-19 infection?

5) If so, how many times?

6) Which of the following is the name of the vaccine manufacturer?

7) Please provide the date of your last vaccination.

8) Did you fully adhere to the rules of the bubble system and carry out all of your daily activities inside your bubble during the Games?

9) Have you been in contact with other participants in-

Neuro (Flord, Last) Gender Aut Date ar Berle Mallow Extension/Engine Parapert No.	Ith Certificate for COVID-19           GEORGE WASHINGTON           Male           41           ypp:           01/01/1980           Behrus
Gender Age Basic of Bashs (MAuna) Nationality/Region Paraport No.	Male 41 yio 101/01/1980
Gender Age Basic of Bashs (MAuna) Nationality/Region Paraport No.	Male 41 yio 101/01/1980
Date of Rich (dd/mod Nationality:Region Principal No.	(1)(01/01/1980
Nationality/Region Paraport No.	Belarm
1) Date of Kauminatonic	A123456b
	comen cilicition date (dalamitysys) (29/12/202
	person with COVID-19
	off while they were ill without YES / 20
the last two weeks.	Personal and the second sectors
	such as cough, shortorss of
	er, muscle pain, headache, sore stribez, or new loss of faste ar
smell.	
<ol> <li>Clinical Manifestati</li> </ol>	in BT. <u>36.0</u> Others to instr
	19 fexamined on the same day as the examination
Sample	Testing for COVID-28 Laboratory re
SNacopharyngeal swah	Of Nucleic sold amplification test (Real Time 87/PCR) Negative
	Nucleic acid amplification (Not detects)
Salva	test (LAMP)  Astigen test "Sample Tane 6
	(CLEIA)
	inice : rmation, the person named above is currently healthy :
unlikely infected with R	RS-CaV-2. Therefore, he or she is fit for flight/work at
	AKITA Hospital
Signature of Physician	AMIA KEN AKI
Name of Physician/Pr	ated): 81-3-6205-1020
	hund, stelli, for waveling, di and. and. ( These Mandacent ( These Mandacent) ( These Ma

**Figure 1.** MySOS interface. (A) Example screen for the digital reporting of health conditions. (B) Example of a digital health certificate for coronavirus disease 2019.

fected with COVID-19 within the last 2 weeks without appropriate preventive measures?

10) Have you had any clinical symptoms during your stay in Japan?

treated as missing data or as non-adherents to the bubble system. All data were analyzed using Stata 17.0 (StataCorp, College Station, USA).

**Results** 

#### Vaccination status

"Full vaccination" was defined as follows: two doses, in any combination, of BNT162b2 (Pfizer-BioNTech) (7), mRNA-1273 (Moderna) (8), ChAdOx1 nCoV-19 vaccine (AstraZeneca) (9), Gam-COVID-Vac (Sputnik V) (10), CoronaVac (Sinovac) (11), or NVX-CoV2373 (Novavax) (12) or at least one dose of the Ad26.COV2.S vaccine (Johnson & Johnson, Janssen) (13); and  $\geq$ 14 days between the last vaccination and the PCR test. "At least one vaccination" was defined as one or two doses of any of the vaccines listed above and  $\geq$ 14 days between the last vaccination and the PCR test. The participants who checked "others" were not included in either "Full vaccination" or "At least one vaccination".

#### Statistical analyses

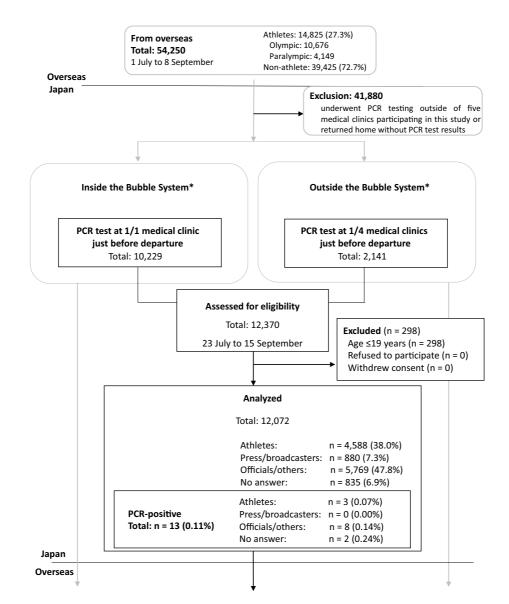
The effects of variables on the incidence of a positive PCR test result were estimated using % risk differences (RDs) and risk ratios (RRs) with 95% confidence intervals (CIs). When both sides of the 95% CI of the RD were more or less than 0, or if the 95% CI of the RR did not include 1, the risk estimate was considered significant. Vaccine effectiveness was calculated as 1-RR (×100). A sensitivity analysis was conducted to compare vaccine effectiveness including "no answer" as missing data. In an additional sensitivity analysis to evaluate the potential effect of adhering to the bubble system, participants who did not answer this question were

#### Study population

A flow diagram of the study population is shown in Fig. 2. A total of 54,250 people from 194 countries entered Japan between July 1 and September 8, 2021, for the purpose of participating in the Games. Of these, 12,370 agreed to complete the risk assessments for this study and took a PCR test between July 23 and September 15, 2021, just before leaving Japan. Another 41,880 underwent PCR testing outside of the 5 medical clinics participating in this study or returned home without PCR test results. After excluding those <20 years old, data from 12,072 participants were ultimately analyzed [athletes: 4,588 (38.0%); press/broadcasters: 880 (7.3%); officials/others: 5,769 (47.8%); "no answer": 835 (6.9%)].

#### Characteristics of the study participants by category

The characteristics of the study participants by category are shown in Table 1. The athletes were the youngest, and the officials/others were the oldest. The ratio of women to men was highest among the athletes, and the length of stay was longest among the press/broadcasters. The number of days between the last vaccination and PCR test was shortest in the athletes and longest in the press/broadcasters. Most athletes took their PCR test inside the Village, whereas most of the press/broadcasters took their test outside the Village. None of the press/broadcasters had close contact with some-



**Figure 2.** Patient flow. The study participants are indicated by black lines and the others by gray lines. PCR: polymerase chain reaction. \*Bubble system means that, during the Games, athletes and others were isolated from general residents of Japan and press/broadcasters, who stayed at hotels outside the Village, via confinement to accommodations inside the Village, a special transportation system that only they could use, and separate competition venues.

one diagnosed with COVID-19. No marked differences in the ratios of participants with and without clinical symptoms were found among the three categories. The press/broadcasters showed better adherence to the bubble system (99.4%) than did the officials/others (95.7%) and athletes (95.6%). No significant differences in the frequency of previous COVID-19 infection were found among the three categories. The rates of full vaccination and at least one vaccination were highest among the press/broadcasters and lowest among the athletes. The most commonly used vaccine was BNT162b2, followed by CoronaVac and ChAdOx1 nCoV-19.

# Characteristics of the participants with a positive test result

Thirteen participants (0.11%) had a positive PCR test re-

sult (Table 2), with the Delta variant found in 7 (53.8%). Breakthrough infection occurred in 3 (#7, #10, and #11) of 6,485 fully vaccinated participants (0.05%) who received their second vaccination 61, 46, and 21 days before the PCR test date, respectively. All three breakthrough infections were caused by the Delta variant. Three of the 13 positive cases had received a vaccine not listed in the questionnaire.

#### Factors associated with SARS-CoV-2 infection

The results of the risk analysis for the participants with a positive PCR test result are shown in Table 3. No positive cases were found for the press/broadcasters, those tested outside the Village, or those with a history of COVID-19 infection, all of which were significant. Although no significant differences were observed, the frequency of PCR-positive cases was 0.09% among the participants of the

#### Table 1. Participant Characteristics by Category.

	Total n (%)=12,072 (100)	Athlete n (%)=4,588 (38.0)	Press/broadcaster n (%)=880 (7.3)	Official/other n (%)=5,769 (47.8)	No answer n (%)=835 (6.9)
Age at PCR test					
Median (IQR), years	37 (28-49)	28 (24-33)	42 (35-51)	46 (37-55)	38 (30-48)
Minimum-maximum, years	20-103	20-71	22-75	20-103	20-80
Age ≥37 years, n (%)	5,825 (48.3)	576 (12.6)	572 (65.0)	4,242 (73.5)	435 (52.1)
Sex, n (%)					
Female	3,751 (31.1)	1,932 (42.1)	183 (20.8)	1,358 (23.5)	278 (33.3)
Male	8,295 (68.7)	2,652 (57.8)	695 (79.0)	4,411 (76.5)	537 (64.3)
Missing	26 (0.22)	4 (0.09)	2 (0.23)	0 (0.00)	20 (2.40)
Days between arrival and PCR test, median (IQR), days	15 (11-21)	13 (10-18)	21 (18-25)	15 (11-22)	13 (12-24)
Days between last vaccination day and PCR test day, median (IQR), days	62 (36-95)	59 (35-88)	69 (46-110)	63 (34-101)	66 (50-73)
PCR test inside the Village, n (%)	9,997 (82.8)	4,449 (97.0)	29 (3.30)	4,917 (85.2)	602 (72.1)
Close contact, n (%)	),))/ (02.0)	-,,()7.0)	2) (5.50)	4,717 (05.2)	002 (72.1)
Yes	26 (0.22)	13 (0.28)	0 (0.00)	12 (0.21)	1 (0.12)
No	11,775 (97.5)	4,548 (99.1)	880 (100)	5,744 (99.6)	603 (72.2)
Missing	271 (2.24)	27 (0.59)	0 (0.00)	13 (0.23)	231 (27.7)
Clinical symptoms, n (%)	271 (2.24)	27 (0.57)	0 (0.00)	15 (0.25)	231 (27.7)
Yes	13 (0.11)	5 (0.11)	1 (0.11)	6 (0.10)	1 (0.12)
No	11,785 (97.6)	4,556 (99.3)	879 (99.9)	5,747 (99.6)	603 (72.2)
Missing	274 (2.27)	27 (0.59)	0 (0.00)	16 (0.28)	231 (27.7)
Adherent to bubble system, n (%)	274 (2.27)	27 (0.57)	0 (0.00)	10 (0.20)	251 (27.7)
Yes	10,802 (89.5)	4,385 (95.6)	875 (99.4)	5,521 (95.7)	21 (2.51)
No	358 (2.97)	134 (2.92)	5 (0.57)	218 (3.78)	1(0.12)
Missing	912 (7.55)	69 (1.50)	0 (0.00)	30 (0.52)	813 (97.4)
History of COVID-19 infection, n (%)	<i>y</i> 12 (1.55)	0) (1.50)	0 (0.00)	50 (0.52)	015 (77.1)
Yes	282 (2.34)	120 (2.62)	26 (2.95)	136 (2.36)	0 (0.00)
No	11,790 (97.7)	4,468 (97.4)	854 (97.1)	5,633 (97.6)	835 (100)
Full vaccination (≥14 days)*, n (%)	11,770 (7717)	i, ioo (2711)	001 (2711)	0,000 () (10)	000 (100)
Yes	6,485 (53.7)	2,497 (54.4)	561 (63.8)	3,422 (59.3)	5 (0.60)
No	4,646 (38.5)	2,011 (43.8)	319 (36.3)	2,308 (40.0)	8 (0.96)
Missing	941 (7.79)	80 (1.74)	0 (0.00)	39 (0.68)	822 (98.4)
At least one vaccination ( $\geq 14 \text{ days}$ ) <sup>†</sup> , n (%)	<i>y</i> (1 ( <i>1</i> , <i>y</i> )	00 (1171)	0 (0100)	0) (0.00)	022 (2011)
Yes	7,357 (60.9)	2,868 (62.5)	632 (71.8)	3,851 (66.8)	6 (0.72)
No	3,774 (31.3)	1,640 (35.8)	248 (28.2)	1,879 (32.6)	7 (0.84)
Missing	941 (7.79)	80 (1.74)	0 (0.00)	39 (0.68)	822 (98.4)
BNT162b2 (Pfizer-BioNTech)	, ()		0 (0100)	., ()	0() 01.1)
Two doses	3,104 (25.7)	1,276 (27.8)	289 (32.8)	1,538 (26.7)	1 (0.12)
One or two doses	3,170 (26.3)	1,304 (28.4)	291 (33.1)	1,573 (27.3)	2 (0.24)
CoronaVac (Sinovac)		· · · · ·			× /
Two doses	1,384 (11.5)	615 (13.4)	87 (9.89)	680 (11.8)	2 (0.24)
One or two doses	1,487 (12.3)	651 (14.2)	90 (10.2)	744 (12.9)	2 (0.24)
ChAdOx1 nCoV-19 vaccine (AstraZeneca)	,				
Two doses	1,355 (11.2)	408 (8.89)	136 (15.5)	809 (14.0)	2 (0.24)
One or two doses	1,691 (14.0)	524 (11.4)	173 (19.7)	992 (17.2)	2 (0.24)
mRNA-1273 (Moderna)					× /
Two doses	484 (4.01)	147 (3.20)	49 (5.57)	287 (4.97)	1 (0.12)
One or two doses	522 (4.32)	165 (3.60)	55 (6.25)	301 (5.22)	1 (0.12)
Gam-COVID-Vac (Sputnik V)					
Two doses	322 (2.67)	129 (2.81)	2 (0.23)	191 (3.31)	0 (0.00)
One or two doses	415 (3.44)	169 (3.68)	3 (0.34)	234 (4.21)	0 (0.00)
Ad26.COV2.S vaccine (Johnson & Johnson.					
Janssen)					
Two doses	5 (0.04)	2 (0.04)	0 (0.00)	3 (0.05)	0 (0.00)
One or two doses	502 (4.16)	213 (4.64)	32 (3.64)	257 (4.45)	0 (0.00)
NVX-CoV2373 (Novavax)	× -/	× - /		· -/	· · · /
Two doses	4 (0.03)	2 (0.04)	0 (0.00)	2 (0.03)	0 (0.00)
One or two doses	5 (0.04)	3 (0.07)	0 (0.00)	2 (0.03)	0 (0.00)
Other <sup>‡</sup>	- \/	()	</td <td><!--</td--><td>()</td></td>	</td <td>()</td>	()
Two doses	985 (8.16)	336 (7.32)	185 (21.0)	458 (7.94)	6 (0.72)
One or two doses	1,006 (8.33)	339 (7.39)	185 (21.0)	475 (8.23)	7 (0.84)

<sup>1</sup>Full vaccination was defined as follows: two doses of BNT162b2 (Pfizer-BioNTech), mRNA-1273 (Moderna), ChAdOx1 nCoV-19 vaccine (AstraZeneca), NVX-CoV2373 (Novavax), CoronaVac (Sinovac), or Gam-COVID-Vac (Sputnik V), and at least one dose of Ad26.COV2.S vaccine (Johnson & Johnson, Janssen), and ≥14 days since the last vaccination and PCR test in Japan. <sup>†</sup>At least one vaccination (≥14 days): one or two doses of BNT162b2 (Pfizer-BioNTech), mRNA-1273 (Moderna), ChAdOx1 nCoV-19 vaccine (AstraZeneca), NVX-CoV2373 (Novavax), CoronaVac (Sinovac), Gam-COVID-Vac (Sputnik V), or Ad26.COV2.S vaccine (Johnson & Johnson, Janssen), and ≥14 days since the astronavac (Sinovac), Gam-COVID-Vac (Sputnik V), or Ad26.COV2.S vaccine (Johnson & Johnson, Janssen), and ≥14 days since the astronavac (Sinovac), Gam-COVID-Vac (Sputnik V), or Ad26.COV2.S vaccine (Johnson & Johnson, Janssen), and ≥14 days since the astronavac (Sinovac), Gam-COVID-Vac (Sputnik V), or Ad26.COV2.S vaccine (Johnson & Johnson, Janssen), and ≥14 days since the astronavac (Sinovac), Gam-COVID-Vac (Sputnik V), or Ad26.COV2.S vaccine (Johnson & Johnson, Janssen), and ≥14 days since the astronavac (Sinovac), Gam-COVID-Vac (Sputnik V), or Ad26.COV2.S vaccine (Johnson & Johnson, Janssen), and ≥14 days since the astronavac (Sinovac), Gam-COVID-Vac (Sputnik V), or Ad26.COV2.S vaccine (Johnson & Johnson, Janssen), and ≥14 days since the astronavac (Sinovac), Gam-COVID-Vac (Sputnik V), or Ad26.COV2.S vaccine (Johnson & Johnson, Janssen), and ≥14 days since the astronavac (Sinovac) (Sputnik V), or Ad26.COV2.S vaccine (Johnson & Johnson, Janssen), and ≥14 days since the astronavac (Sinovac) (Sputnik V), or Ad26.COV2.S vaccine (Johnson & Johnson, Janssen), and ≥14 days since the astronavac (Sputnik V), or Ad26.COV2.S vaccine (Johnson & Johnson, Janssen), and ≥14 days since the astronavac (Sputnik V), or Ad26.COV2.S vaccine (Johnson & Johnson, Janssen), and ≥14 days since the astronavac (Sputnik V), or Ad26.COV2.S vaccine (Johnson & Johnson V), or Ad26.COV2.S vaccine (Joh

the first vaccination and PCR test in Japan.

<sup>‡</sup>Other: other types of vaccines against severe acute respiratory syndrome-coronavirus 2 were added to the vaccines listed above. In addition, those for whom <14 days had passed from the last vaccination to the PCR test were included. PCR: polymerase chain reaction, IQR: interquartile range, COVID-19: coronavirus disease 2019

No.	Ct value	Delta	Age (years)	Sex	Country	Category	Close contact	Adhered to bubble system	Vaccine	Date of last vaccina- tion	Date of entry into Japan	Vaccine to PCR test (days)	Entry to PCR test (days)	Subse- quent medical treatment
1	26.9	1	30s	Female	Africa	Athlete	Yes	Yes	None		2021/7/28		11	Yes
2	31.5	0	30s	Female	Africa	Official	No	Yes	Other	2021/6/11	2021/7/25	50	6	Yes
3	32.1	1	50s	Male	Africa	Official	No	Yes	None		2021/7/14		27	No
4	32.5	0	30s	Male	Middle East	Official	No	Yes	Other	2021/7/18	2021/7/31	23	10	No
5	33.9	0	30s	Male	Europe	Official	No	No	None		2021/7/18		16	No
6	34.8	0	30s	Male	Europe	n.a.	No	n.a.	n.a.	n.a.	n.a.	n.a.		No
7	35.9	1	30s	Male	Europe	Athlete	No	Yes	Moderna	2021/6/7	2021/7/13	61	25	Yes
8	36.2	0	40s	Male	South America	Other	No	Yes	None		2021/8/18		18	Yes
9	36.2	1	40s	Female	Carib- bean	Other	No	Yes	Other	2021/7/30	2021/8/24	34	9	Yes
10	37.5	1	20s	Female	Middle East	Athlete	No	Yes	Pfizer	2021/6/9	2021/7/14	46	11	No
11	38.1	1	60s	Female	Africa	Official	No	Yes	Astra- Zeneca	2021/7/13	2021/7/22	21	12	No
12	38.4	1	20s	Female	Central Asia	n.a.	No	n.a.	n.a.	n.a.	n.a.	n.a.		Yes
13	38.8	0	30s	Male	Middle East	Official	No	Yes	None		2021/7/14		11	No

#### Table 2. Characteristics of the Participants with a Positive SARS-CoV-2 PCR Test Result.

SARS-CoV-2: severe acute respiratory syndrome-coronavirus 2, PCR: polymerase chain reaction, Ct: cycle threshold, n.a.: no answer

Table 3.	Risk of a Po	sitive SARS-Co	V-2 PCR Test	<b>Result by Variable.</b>
----------	--------------	----------------	--------------	----------------------------

Variable	No. of PCR test-positive cases (%)		% Risk difference (95%CI)	Risk ratio (95%CI)	
Category	Yes	No			
Athlete	3 (0.07)	10 (0.13)	-0.07 (-0.18 to 0.04)	0.49 (0.13 to 1.78)	
Press/broadcaster	0 (0.00)	13 (0.12)	-0.12 (-0.18 to -0.05)*	-	
Official/other	8 (0.14)	5 (0.08)	0.06 (-0.06 to 0.18)	1.75 (0.57 to 5.34)	
No answer	2 (0.24)	11 (0.10)	0.14 (-0.19 to 0.48)	2.45 (0.54 to 11.02)	
Behavior					
PCR test clinic location					
Inside the Olympic and Paralympic Village	13 (0.13)	0 (0.00)	0.13 (0.06 to 0.20)*	-	
Adherence to the bubble system					
Including "no answer" as non-adherent	10 (0.09)	3 (0.24)	-0.14 (-0.42 to 0.13)	0.39 (0.11 to 1.42)	
Excluding "no answer"	10 (0.09)	1 (0.28)	-0.19 (-0.74 to 0.36)	0.33 (0.04 to 2.58)	
COVID-19 infection					
History of COVID-19 infection June 2021 and before	0 (0.00)	13 (0.11)	-0.11 (-0.17 to -0.05)*		
Vaccination					
Full vaccination (≥14 days)					
Including "no answer" as unvaccinated	3 (0.05)	10 (0.18)	-0.13 (-0.26 to -0.01)*	0.26 (0.07 to 0.94)*	
Excluding "no answer"	3 (0.05)	8 (0.17)	-0.13 (-0.26 to 0.00)*	0.27 (0.07 to 1.01)	
At least one vaccination (≥14 days)					
Including "no answer" as unvaccinated	3 (0.04)	10 (0.21)	-0.17 (-0.31 to -0.03)*	0.19 (0.05 to 0.70)*	
Excluding "no answer"	3 (0.04)	8 (0.21)	-0.17 (-0.33 to -0.02)*	0.19 (0.05 to 0.72)*	

\*Statistically significant (p<0.05)

SARS-CoV-2: severe acute respiratory syndrome-coronavirus 2, PCR: polymerase chain reaction, CI: confidence interval, COVID-19: coronavirus disease 2019

than that among the non-adherents (0.24%) when "no answer" was included as non-adherent and when it was ex-

Games who adhered to the bubble system, which was lower cluded (0.28%). The effectiveness rates for full vaccination and at least 1 vaccination (≥14 days) were 74% (95% CI: 6-93%) and 81% (95% CI: 30-95%), respectively. Little difference was seen between the effectiveness of full and at least one vaccination, even when "no answer" was excluded.

#### Discussion

The results of the present study showed that the effectiveness rates of full vaccination and at least 1 vaccination ( $\geq$ 14 days) were 74% (95% CI: 6-93%) and 81% (95% CI: 30-95%), respectively. In the United Kingdom, the effectiveness of full vaccination with BNT162b2 and ChAdOx1 nCoV-19 has been reported to be 94% and 75% against the Alpha variant and 88% and 67% against the Delta variant, respectively (3). Similarly, in the United States, the effectiveness of full mRNA and Ad26.COV2.S vaccination has been reported to be 89% and 68%, respectively (14). Although the 95% CI showed a wide range in the present study, we consider the point estimates of vaccine effectiveness to be consistent with the results reported in previous studies.

Breakthrough infection occurred in 3 fully vaccinated participants (0.05%), which is much lower than the 2.6% reported in fully vaccinated healthcare workers in the United Kingdom (15). Furthermore, breakthrough infection was observed in 3 of the 13 participants with a positive PCR test result (23.1%), which is also lower than the 346 breakthrough infections (74%) in a total of 469 COVID-19 cases that occurred following multiple large public events in the United States (16). During the Delta variant epidemic, in addition to vaccination, it may be important to use basic preventive measures, such as masks, frequent testing, social distancing, and the bubble system.

As an unexpected finding, no press/broadcasters (0.00%) were infected, compared with 3 of the athletes (0.07%), 8 of the officials/others (0.14%), and 2 of those who did not offer their designation (0.24%). In addition, no one who took a PCR test outside of the Village was infected. More than 99% of the press/broadcasters adhered to the bubble system, compared with <96% of the others. Vaccination coverage was the highest among the press/broadcasters and lowest among the athletes. In addition, the press/broadcasters were most commonly vaccinated with the BNT162b2, mRNA-1273, or ChAdOx1 nCoV-19 vaccine. Most of the press/ broadcasters may have stayed alone in a private hotel room outside the Village, in contrast to the standard three athletes per room in the Village (17). The conditions of the press/ broadcasters listed above may have synergistically reduced the infection rate to zero. A previous study conducted prior to development of the vaccine investigated the SARS-CoV-2 infection rate among United States Marine Corps recruits who had undergone two weeks of quarantine at home followed by a second supervised two weeks of quarantine at a closed college campus that involved mask wearing, social distancing, and daily temperature and symptom monitoring (18). Approximately 2% tested positive for SARS-CoV-2, even under strictly enforced quarantine. Shared rooms and shared platoon membership were suspected to be the risk factors for transmission, similar to the situation of athletes

living in the Village.

The Games were held in the midst of the unprecedented spread of COVID-19 in Japan. However, based on the epidemic curve, it is unlikely that the infection situation in Tokyo deteriorated significantly during the Games; in fact, it decreased after the end of the Olympics. Before the Games, a state of emergency was declared, and restaurants were prohibited from serving alcohol. Although percent changes in retail and recreation decreased only slightly, many Japanese may have gone home after work and watched the Games at home on television. In Japan, older adults who wished to be vaccinated were able to do so by the end of July, and almost half of the total Japanese population had been vaccinated at least once by the peak of the epidemic curve, i.e. 13 August 2021. It may be that the combination of watching the Games at home and vaccination were well synchronized to limit the spread of infection. However, there are numerous other possible mechanisms. For example, many people may have been unknowingly exposed to SARS-CoV-2 during the epidemic and had enhanced levels of trained innate immunity (19). In contrast, the cumulative number of PCR testpositive cases among residents of Tokyo during the present study period was 175,888 (1.25%), compared with 13 (0.11%) in the study population. Although not strictly a proper comparison, the bubble system may have protected the participants of the Games from the Japanese epidemic, and vice versa.

We conducted this study using MySOS, a personal health record app that uses the communication concept of social networking services, such as WhatsApp, LINE, or iMessage. It was originally developed for use in emergency care before being adopted by the Ministry of Health, Labour and Welfare of Japan as a health monitoring app for overseas entrants to the Games. All overseas entrants were asked to use the app to report their location and any health conditions during the quarantine period. Many medical institutions have also adopted MySOS for issuing digital PCR test reports, vaccination certificates, and diagnosis reports. Prior to the Olympic and Paralympic Games, the utility of MySOS was also evaluated for large-scale events in Japan, such as professional baseball games and music events, with the aim of preventing COVID-19 clusters.

Several limitations associated with the present study warrant mention. First, we analyzed 12,072 Games participants who took a PCR test to prove that they were negative upon leaving Japan, and this grouping may have included bias in evaluating the overall infection rate during the Games. The Tokyo Organising Committee of the Olympic and Paralympic Games reported the status of the entire group of 54,250 overseas participants who took a PCR test at the airport or inside and outside the Village in Tokyo (20). Second, the present results may have been biased toward underestimating the risk of infection compared with the study of the entire group of 54,250 overseas participants. The participants with a positive PCR test result might not have been required to obtain a negative certificate upon leaving Japan if the physician had already issued a certificate of cure after isolation and treatment. In addition, some countries changed their reentry policy during the period of the Olympic Games from a PCR test to an antigen test that does not require a physician's signature. Third, as the number of PCR test-positive cases was only 13, the 95% CI was wide, and a multivariate analysis could not be performed. Fourth, "no answer" was seen at various rates depending on the question item, which may have introduced biases. Fifth, the infectious disease epidemic curve in this study was drawn based on the reporting date rather than the onset date. This may have complicated the estimation of factors affecting the number of daily new confirmed cases of COVID-19. Sixth, due to the observational nature of the study, the conclusion is no more than a hypothesis, and the findings should not be generalized or applied to other countries or other large sporting events.

#### Conclusion

The results of the present study suggest that even huge sporting events, such as the Olympic and Paralympic Games, can proceed while pandemics are ongoing in the host country by combining countermeasures such as vaccination, frequent testing, social distancing, and adherence to a bubble system.

#### Author's disclosure of potential Conflicts of Interest (COI).

Teppei Sakano: Employment, Allm. Yuichi Murayama: Inventor of My SOS app. Hiroyuki Takao: Research funding, Allm; Inventor of My SOS app.

#### **Financial Support**

This research was supported by the Visual Industry Promotion Organization and the Jikei University School of Medicine.

#### Acknowledgement

The authors would like to thank Dr. Hiroe Kobashi and others at the Infectious Disease Department, Team Medical Clinics, for their assistance with the data collection inside and outside the Olympic and Paralympic Village. The authors would also like to thank Ms. Kayoko Takao of the Innovation for Medical Information Technology, the Jikei University School of Medicine (Tokyo, Japan) for translating the documents, including the consent explanation and questionnaires.

#### References

- Delta variant: what we know about the science [Internet]. [cited 2022 Jul 14]. Available from: https://stacks.cdc.gov/view/cdc/1086 71
- **2.** Twohig KA, Nyberg T, Zaidi A, et al.; COVID-19 Genomics UK (COG-UK) Consortium. Hospital admission and emergency care attendance risk for SARS-CoV-2 delta (B.1.617.2) compared with alpha (B.1.1.7) variants of concern: a cohort study. Lancet Infect

Dis 22: 35-42, 2022.

- Lopez Bernal J, Andrews N, Gower C, et al. Effectiveness of COVID-19 vaccines against the B.1.617.2 (delta) variant. N Engl J Med 385: 585-594, 2021.
- **4.** Tokyo 2020 Playbooks [Internet]. [cited 2022 Jul 14]. Available from: https://olympics.com/ioc/tokyo-2020-playbooks
- MySOS [Internet]. [cited 2021 May 19]. Available from: https://w ww.allm.net/en/mysos-en/
- Massey A, Lindsay S, Seow D, Gordon J, Lowe DJ. Bubble concept for sporting tournaments during the COVID-19 pandemic: Football Club World Cup. BMJ Open Sport Exerc Med 7: e001126, 2021.
- Polack FP, Thomas SJ, Kitchin N, et al. Safety and efficacy of the BNT162b2 mRNA COVID-19 vaccine. N Engl J Med 383: 2603-2615, 2020.
- Baden LR, El Sahly HM, Essink B, et al. Efficacy and safety of the mRNA-1273 SARS-CoV-2 vaccine. N Engl J Med 384: 403-416, 2021.
- **9.** Voysey M, Clemens SAC, Madhi SA, et al. Safety and efficacy of the ChAdOx1 nCoV-19 vaccine (AZD1222) against SARS-CoV-2: an interim analysis of four randomised controlled trials in Brazil, South Africa, and the UK. Lancet **397**: 99-111, 2021.
- 10. Logunov DY, Dolzhikova IV, Shcheblyakov DV, et al. Safety and efficacy of an rAd26 and rAd5 vector-based heterologous primeboost COVID-19 vaccine: an interim analysis of a randomised controlled phase 3 trial in Russia. Lancet **397**: 671-681, 2021.
- Jara A, Undurraga EA, González C, et al. Effectiveness of an inactivated SARS-CoV-2 vaccine in Chile. N Engl J Med 385: 875-884, 2021.
- Heath PT, Galiza EP, Baxter DN, et al. Safety and efficacy of NVX-CoV2373 COVID-19 vaccine. N Engl J Med 385: 1172-1183, 2021.
- Sadoff J, Gray G, Vandebosch A, et al. Safety and efficacy of single-dose Ad26.COV2.S vaccine against COVID-19. N Engl J Med 384: 2187-2201, 2021.
- 14. Thompson MG, Stenehjem E, Grannis S, et al. Effectiveness of COVID-19 vaccines in ambulatory and inpatient care settings. N Engl J Med 385: 1355-1371, 2021.
- Bergwerk M, Gonen T, Lustig Y, et al. COVID-19 breakthrough infections in vaccinated health care workers. N Engl J Med 385: 1474-1484, 2021.
- 16. Brown CM, Vostok J, Johnson H, et al. Outbreak of SARS-CoV-2 infections, including COVID-19 vaccine breakthrough infections, associated with large public gatherings - Barnstable County, Massachusetts, July 2021. MMWR Morb Mortal Wkly Rep 70: 1059-1062, 2021.
- 17. Sparrow AK, Brosseau LM, Harrison RJ, Osterholm MT. Protecting Olympic participants from COVID-19 - the urgent need for a risk-management approach. N Engl J Med 385: e2, 2021.
- Letizia AG, Ramos I, Obla A, et al. SARS-CoV-2 transmission among Marine recruits during quarantine. N Engl J Med 383: 2407-2416, 2020.
- Mantovani A, Netea MG. Trained innate immunity, epigenetics, and COVID-19. N Engl J Med 383: 1078-1080, 2020.
- 20. Games of the XXXII Olympiad. Tokyo 2020 Paralympic Games. Tokyo Metropolitan Government Report [Internet]. [cited 2022 Aug 19]. Available from: https://www.2020games.metro.tokyo.lg.j p/TOKYO2020\_TMG\_Report\_en\_A3.pdf

The Internal Medicine is an Open Access journal distributed under the Creative Commons Attribution-NonCommercial-NoDerivatives 4.0 International License. To view the details of this license, please visit (https://creativecommons.org/licenses/ by-nc-nd/4.0/).

© 2022 The Japanese Society of Internal Medicine Intern Med 61: 3659-3666, 2022