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Supplementary appendix 2

This appendix formed part of the original submission and has been peer reviewed. We post it as supplied by the authors.

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Supplementary appendix

		Page numbers
1	Table S1: Definitions	2
2	Table S2: Participant characteristics of the unmatched population	3
3	Table S3: Estimated vaccine effectiveness against laboratory confirmed symptomatic SARS-CoV-2 infection of the	4
!	unmatched population	

Table S1: Definitions

Term	Definition
Symptoms suggestive of COVID-19	An acute respiratory illness with fever and cough with onset within the preceding 10 days.
High-risk exposure	 Any of the following: Performed a respiratory Aerosol Generating Procedure (AGP) without ANY of the following – N95 mask, eye/face protection, gloves. If the patient's respiratory tract secretions, or saliva came in contact with non-intact skin Anyone in close proximity (within 1 meter) of the confirmed case without mask (BOTH case and contact) for a duration of more than 15 minutes. Household contact of a known positive case. Household contact of a known positive case. Household contact of a known positive case.
Previous SARS- CoV-2 infection	Presence of a positive microbiological test for SARS-CoV-2 (RT-PCR, CB-NAAT or rapid antigen test) more than 90 days prior to the current RT-PCR
Level of occupational exposure	
COVID-19 areas	Part of the normal chain of care for suspected and proven COVID-19 patients (eg. testing facility, emergency wards, holding wards for COVID-19 suspects pending test results and dedicated COVID-19 wards/ICUs/laboratories). Employees working here wear personal protective equipment (PPE) that include coverall, N-95 mask, goggles/face shield, gloves and shoecovers.
Non-COVID-19 areas	All other parts of the institute including wards/ICUs meant for the care of non-COVID-19 diseases, administrative and residential areas. Patients are admitted in non-COVID-19 wards/ICUs after testing negative for SARS-CoV-2 by RT-PCR or CB-NAAT. The detection of a COVID-19 patient or employee in non-COVID-19 areas requires immediate isolation of the case in a COVID-19 area, tracing of contacts and decontamination. Employees working here wear varying levels of PPE.

Table S2: Participant characteristics of the unmatched population

	Symptomatic SARS-CoV-2 RT-PCR positive participants (n =1617)	Symptomatic SARS-CoV-2 RT- PCR negative participants (n =1097)	P value	Unvaccinated participants (n =1282)	Participants vaccinated with only 1 dose of BBV152 (n =679)	P value (one dose vs. unvaccinated)	Participants vaccinated with 2 doses of BBV152 (n=753)	P value (two vs. unvaccina
Age, years <30 years 31-40 years 41-50 years 51-60 years 61-70 years >70 years	573 (35.4) 531 (32.8) 315 (19.5) 174 (10.8) 18 (1.1) 6 (0.4)	494 (45.0) 363 (33.1) 161 (14.7) 72 (6.6) 6 (0.5) 1 (0.1)	<0.0001	532 (41.5) 426 (33.2) 215 (16.8) 90 (7.0) 14 (1.1) 5 (0.4)	290 (42.7) 222 (32.7) 109 (16.1) 55 (8.1) 3	0.44	245 (32.5) 246 (32.7) 152 (20.2) 101 (13.4) 7 (0.9) 2 (0.3)	<0.0001
Gender Female Male	685 (42.4) 932 (57.6)	506 (46.1) 591 (53.9)	0.054	580 (45.2) 702 (54.8)	332 (48.9) 347 (51.1)	0.13	279 (37.1) 474 (62.9)	<0.0001
Previous SARS-CoV-2 infection	48 (3.0)	119 (10.8)	< 0.0001	76 (5.9)	47 (6.9)	0.38	44 (5.8)	0.99
Occupational exposure Works in COVID-19 area Works in non-COVID-19 area	243 (15.0) 1374 (85.0)	176 (16.0) 921 (84.0)	0.48	219 (17.1) 1063 (82.9)	96 (14.1) 583 (85.9)	0.093	104 (13.8) 649 (86.2)	0.052
10 day period of testing April 15–April 25 April 26–May 5 May 6-May 15	852 (52.7) 624 (38.6) 141 (8.7)	465 (42.4) 407 (37.1) 225 (20.5)	<0.001	680 (53.0) 454 (35.4) 148 (11.5)	303 (44.6) 287 (42.3) 89 (13.1)	0.0018	334 (44.4) 290 (38.5) 129 (17.1)	<0.0001
Vaccination Status Vaccinated with only one dose of BBV152 Vaccinated with two doses of BBV152	399 (24.7) 394 (24.3)	280 (25.5) 359 (32.7)	<0.0001					•
Unvaccinated Data are n(%).	824 (60.0)	458 (41.8)						

Table S3: Estimated vaccine effectiveness against laboratory confirmed symptomatic SARS-CoV-2 infection of the unmatched population

	Symptomatic SARS-CoV-2 RT-PCR positive	Symptomatic SARS-CoV-2 RT-PCR negative	Unadjusted OR (95% CI)	Unadjusted p value	Adjusted OR (95% CI)*	Adjusted p value*	Vaccine effectiveness (95% CI)
Unvaccinated	824	458	1 (ref)		1 (ref)		
Only one dose of BBV152 Tested at least 7 days after first dose Tested less than 7 days after first dose Tested at least 21 days after 1st dose	359 40 181	244 36 115	0.82 (0.67-0.99) 0.62 (0.39-0.98) 0.87(0.67-1.13)	0.047 0.042 0.31	0.86 (0.70-1.06) 0.57 (0.36-0.92) 0.95(0.72-1.25)	0.16 0.020 0.71	14 (-6 to 30) 43 (8 to 64) 5 (-25 to 28)
Two doses of BBV152							
Tested at least 14 days after second dose Tested less than 14 days after second dose Tested at least 28 days after second dose Tested at least 42 days after second dose	319 75 205 73	298 61 196 94	0.59 (0.49-0.72) 0.68 (0.48-0.98) 0.58 (0.47-0.73) 0.43 (0.31-0.60)	<0.0001 0.037 <0.0001 <0.0001	0.56 (0.45-0.68) 0.69 (0.48-1.00) 0.57 (0.45-0.73) 0.45 (0.31-0.64)	<0.0001 0.052 <0.0001 <0.0001	44 (32 to 55) 31 (0 to 52) 43 (27 to 55) 55 (36 to 69)
Two doses of BBV152 with second dose at least 14 days before testing, by 10-day period of testing							
April 15–April 25 April 26–May 5 May 6-May 15	155 128 36	102 118 78	0.78 (0.58-1.04) 0.49 (0.36-0.67) 0.66 (0.39-1.10)	0.094 <0.0001 0.11	0.65 (0.47-0.89) 0.45 (0.32-0.63) 0.61 (0.35-1.04)	0.0067 <0.0001 0.068	35 (11 to 53) 55 (37 to 68) 39 (-4 to 65)
Unvaccinated, by 10-day period of testing April 15–April 25 April 26–May 5 May 6-May 15	450 313 61	230 141 87					
Female participants Two doses of BBV152 with second dose at least 14 days before testing	107	121	0.49 (0.36-0.67)	<0.0001	0.44 (0.32-0.62)	<0.0001	56 (38 to 68)
Unvaccinated Males Two doses of BBV152 with second dose at least 14 days before testing	212	177	0.66 (0.51-0.85)	0.0014	0.61 (0.47-0.81)	0.0004	39 (19 to 53)
Unvaccinated	452	250					
Excluding those with previous SARS-CoV-2 infection Two doses of BBV152 with second dose at least 14 days before testing	315	268	0.61 (0.49-0.74)	<0.0001	0.58 (0.47-0.71)	<0.0001	42 (29 to 53)
Unvaccinated	796	410					

Data are n unless otherwise stated. OR= odds ratio.

* Adjusted for age, gender, previous SARS-CoV-2 infection, occupational exposure and 10-day period of testing.