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Supplementary appendix

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Pregnancy outcomes and vaccine effectiveness during the period of omicron as the variant of concern, INTERCOVID-2022: a multinational, observational study

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Supplementary Table 1: Baseline characteristics among pregnant women ‘diagnosed’ and ‘non-diagnosed’ with COVID-19.

	Women ‘diagnosed’ with COVID-19 (n=1,545) M ± SD or n (%)	Women ‘non- diagnosed’ with COVID-19 (n=3,073) M ± SD or n (%)
<i>Demographic and Socioeconomic Characteristics</i>		
Years of formal education	12.6 ± 4.8	12.7 ± 4.9
Worked outside the home	901 (62.2)	1,787 (63.3)
Married or cohabiting	1,309 (86.5)	2,576 (86.8)
Smoker during index pregnancy	116 (7.6)	177 (5.8)
Alcohol (≥1 units/week)	43 (3.0)	86 (3.0)
Recreational drugs	36 (2.3)	54 (1.8)
<i>Gynaecological and Obstetric History</i>		
Lowest haemoglobin, <27 weeks’ gestation (g/dl)	11.6 ± 1.3	11.6 ± 1.2
Hormonal contraceptives/ breastfeeding (2 months before pregnancy)	131 (8.8)	193 (6.5)
Fertility treatment	84 (5.5)	250 (8.3)
Previous pregnancy	1,068 (69.2)	2,053 (67.0)
Previous miscarriage	451 (29.3)	935 (30.5)
Previous birth	905 (58.7)	1,638 (53.4)
Previous baby <2.5kg or >4.5kg	71 (5.1)	185 (7.0)
Previous baby <37 weeks’ gestation	66 (4.8)	152 (5.7)
Previous stillbirth or neonatal death	41 (3.0)	70 (2.6)
<i>Pre-existing medical conditions/status</i>		
Maternal age, years	31.2 ± 6.0	31.5 ± 6.0
Maternal height, cm	162.6 ± 7.2	162.8 ± 7.6
Maternal weight, kg	69.7 ± 17.6	68.3 ± 17.0
Body mass index, kg/m ²	26.3 ± 6.0	25.8 ± 6.1
Diabetes	39 (2.5)	76 (2.5)
Overweight (BMI ≥ 25 kg/m ²)	759 (50.2)	1,390 (46.7)
Thyroid or other endocrine disease	149 (9.8)	351 (11.7)
Cardiac disease	27 (1.8)	69 (2.3)
Hypertension	49 (3.3)	81 (2.7)
Chronic respiratory disease	52 (3.5)	96 (3.2)
Kidney disease	7 (0.5)	27 (0.9)
Tuberculosis	3 (0.2)	12 (0.4)
Any pre-existing condition	276 (17.9)	614 (20.0)

Supplementary Table 2: Maternal and perinatal outcomes among women ‘diagnosed’ and ‘non-diagnosed’ with COVID-19 according to vaccination status and maternal risk factors.

	N	RR (95% CI)					
		Maternal Morbidity and Mortality Index ^b	Severe Neonatal Morbidity Index ^c	Severe Perinatal Morbidity and Mortality Index ^d	Preterm birth (<37 weeks' gestation)	Preeclampsia or eclampsia or HELLP syndrome	Maternal referral to higher care or ICU admission, or death
All Pregnant Women	4,618						
<i>No pre-existing conditions</i>							
‘Non-diagnosed’	2,459	1 (Reference)	1 (Reference)	1 (Reference)	1 (Reference)	1 (Reference)	1 (Reference)
‘Diagnosed’	1,269	1.18 (1.02, 1.36)	1.26 (0.86, 1.85)	1.30 (1.05, 1.61)	1.15 (0.97, 1.36)	1.31 (0.95, 1.81)	1.51 (0.99, 2.33)
<i>Pre-existing conditions</i>							
‘Non-diagnosed’	614	1 (Reference)	1 (Reference)	1 (Reference)	1 (Reference)	1 (Reference)	1 (Reference)
‘Diagnosed’	274	1.09 (0.85, 1.39)	1.09 (0.55, 2.16)	0.98 (0.64, 1.49)	1.04 (0.76, 1.42)	1.08 (0.70, 1.65)	1.00 (0.35, 2.85)
<i>Normal weight</i>							
‘Non-diagnosed’	1,585	1 (Reference)	1 (Reference)	1 (Reference)	1 (Reference)	1 (Reference)	1 (Reference)
‘Diagnosed’	753	0.98 (0.81, 1.20)	0.79 (0.44, 1.44)	0.84 (0.61, 1.15)	0.95 (0.75, 1.20)	1.03 (0.64, 1.67)	0.87 (0.47, 1.59)
<i>Overweight or obese</i>							
‘Non-diagnosed’	1,390	1 (Reference)	1 (Reference)	1 (Reference)	1 (Reference)	1 (Reference)	1 (Reference)
‘Diagnosed’	759	1.29 (1.10, 1.51)	1.41 (0.91, 2.18)	1.45 (1.13, 1.86)	1.24 (1.01, 1.52)	1.39 (1.01, 1.90)	2.25 (1.32, 3.83)
Unvaccinated Pregnant Women							
<i>No pre-existing conditions</i>	1,732						
‘Non-diagnosed’	902	1 (Reference)	1 (Reference)	1 (Reference)	1 (Reference)	1 (Reference)	1 (Reference)
‘Diagnosed’	518	1.43 (1.15, 1.78)	1.74 (0.84, 3.63)	1.52 (1.09, 2.11)	1.25 (0.97, 1.60)	2.02 (1.22, 3.35)	3.51 (1.95, 6.33)
<i>Pre-existing conditions</i>							
‘Non-diagnosed’	198	1 (Reference)	1 (Reference)	1 (Reference)	1 (Reference)	1 (Reference)	1 (Reference)
‘Diagnosed’	114	1.03 (0.69, 1.54)	0.39 (0.09, 1.64)	0.56 (0.28, 1.12)	1.03 (0.62, 1.69)	0.62 (0.28, 1.40)	1.75 (0.46, 6.67)
<i>Normal weight</i>							
‘Non-diagnosed’	494	1 (Reference)	1 (Reference)	1 (Reference)	1 (Reference)	1 (Reference)	1 (Reference)
‘Diagnosed’	271	1.23 (0.89, 1.69)	0.57 (0.16, 1.97)	0.84 (0.50, 1.42)	1.01 (0.70, 1.46)	1.68 (0.75, 3.77)	2.33 (1.04, 5.20)
<i>Overweight or obese</i>							
‘Non-diagnosed’	560	1 (Reference)	1 (Reference)	1 (Reference)	1 (Reference)	1 (Reference)	1 (Reference)
‘Diagnosed’	342	1.44 (1.13, 1.84)	1.61 (0.76, 3.41)	1.47 (1.00, 2.15)	1.36 (1.02, 1.81)	1.48 (0.89, 2.45)	3.95 (1.99, 7.85)

^a Adjusted for maternal age and country. Models stratified by overweight/obesity are additionally adjusted by pre-existing medical conditions. Models stratified by pre-existing medical conditions are additionally adjusted for overweight/obesity. Models for preterm birth additionally adjusted for past history of preterm birth.

^b Maternal morbidity and mortality index includes at least one of the following complications during pregnancy: vaginal bleeding, pregnancy-induced hypertension, preeclampsia, eclampsia, HELLP, preterm labour, or infections requiring antibiotics; or maternal referral for higher care ICU admission or death.

^c Severe neonatal morbidity index includes at least one of the following morbidities: bronchopulmonary dysplasia, hypoxic-ischaemic encephalopathy, sepsis, anaemia requiring transfusion, patent ductus arteriosus, intraventricular haemorrhage, necrotising enterocolitis, or retinopathy of prematurity.

^d Severe perinatal morbidity and mortality index includes any of the morbidities listed in the Severe neonatal morbidity index; or intrauterine or neonatal death, or NICU stay ≥ 7 days.

CI=confidence interval; ICU= intensive care unit; NICU=neonatal ICU; HELLP=haemolysis, elevated liver enzymes and low platelet count

VE=vaccine effectiveness

Supplementary Table 3a. Pregnancy and neonatal complications, perinatal events and neonatal morbidities among women ‘diagnosed’ and ‘non-diagnosed’ with COVID-19.

Outcome	Women ‘diagnosed’ with COVID-19 (n=1,545)	Women ‘non-diagnosed’ with COVID-19 (n=3,073)	Relative Risk (95% CI)
	N (%)	N (%)	(95% CI)
Vaginal bleeding	82 (5.5)	148 (4.9)	1.10 (0.85, 1.44)
Pregnancy-induced hypertension	85 (5.6)	177 (5.9)	0.96 (0.74, 1.23)
Preeclampsia/eclampsia/HELLP	83 (5.5)	135 (4.5)	1.23 (0.94, 1.60)
Haemoglobin <10g/dl at >27 weeks’ gestation	101 (10.3)	180 (9.7)	1.07 (0.85, 1.34)
Preterm labour	56 (3.7)	125 (4.2)	0.89 (0.66, 1.22)
Infection requiring antibiotics	200 (13.3)	299 (10.0)	1.33 (1.13, 1.58)
Admitted to ICU or referred to higher care	40 (2.6)	54 (1.6)	1.48 (0.99, 2.22)
Number of days in ICU (mean, SD)	5.1 ± 5.2	2.5 ± 2.7	2.07 (1.33, 3.23) ^a
Maternal death	3 (0.2)	2 (0.1)	3.00 (0.50, 17.93)
Fetal distress	11 (7.4)	198 (6.6)	1.12 (0.89, 1.40)
Spontaneous initiation of labour	790 (51.8)	1,607 (53.0)	0.98 (0.92, 1.04)
Induced labour	375 (24.6)	758 (25.0)	0.98 (0.88, 1.10)
Caesarean section	616 (40.4)	1,156 (38.0)	1.06 (0.99, 1.15)
Pre-labour rupture of membranes	277 (18.6)	591 (20.0)	0.93 (0.82, 1.06)
Gestational age at birth, weeks (mean, SD)	38.6 ± 2.8	38.7 ± 2.7	-0.13 (-0.29, 0.04) ^b
Preterm birth (<37 weeks’ gestation)	219 (14.3)	393 (12.8)	1.11 (0.95, 1.30)
Spontaneous preterm birth	69 (4.5)	119 (3.9)	1.16 (0.86, 1.55)
Medically-indicated preterm birth	150 (9.8)	274 (9.0)	1.09 (0.90, 1.32)

CI=confidence interval; HELLP=haemolysis, elevated liver enzymes, low platelet count; ICU=intensive care unit.

^a Incidence Rate Ratio and 95% CI.

^b β and 95% CI

Supplementary Table 3b. Pregnancy and neonatal complications, perinatal events and neonatal morbidities among unvaccinated women ‘diagnosed’ and ‘non-diagnosed’ with COVID-19.

Outcome	Women ‘diagnosed’ with COVID-19 (n=632)	Women ‘non-diagnosed’ with COVID-19 (n=1,100)	Relative Risk (95% CI)
	N (%)	N (%)	(95% CI)
Vaginal bleeding	35 (5.8)	52 (4.9)	1.17 (0.77, 1.78)
Pregnancy-induced hypertension	29 (4.8)	58 (5.5)	0.87 (0.56, 1.35)
Preeclampsia/eclampsia/HELLP	37 (6.1)	42 (4.0)	1.54 (1.00, 2.37)
Haemoglobin <10g/dl at >27 weeks’ gestation	55 (14.0)	79 (12.4)	1.13 (0.82, 1.55)
Preterm labour	25 (4.1)	48 (4.6)	0.91 (0.56, 1.45)
Infection requiring antibiotics	76 (12.5)	88 (8.3)	1.50 (1.12, 2.01)
Admitted to ICU or referred for higher care	35 (5.6)	20 (1.8)	3.07 (1.79, 5.27)
Number of days in ICU (mean, SD)	5.5 ± 5.5	2.2 ± 1.8	2.47 (1.48, 4.14) ^a
Maternal death	3 (0.5)	1 (0.1)	5.26 (0.55, 50.51)
Fetal distress	58 (9.6)	69 (6.5)	1.47 (1.05, 2.05)
Spontaneous initiation of labour	333 (53.7)	610 (56.5)	0.95 (0.87, 1.04)
Induced labour	145 (23.4)	214 (19.8)	1.18 (0.98, 1.42)
Caesarean section	254 (40.8)	405 (37.3)	1.09 (0.97, 1.23)
Pre-labour rupture of membranes	117 (19.4)	215 (20.8)	0.94 (0.77, 1.15)
Gestational age at birth, weeks (mean, SD)	38.5 ± 2.9	38.6 ± 2.6	-0.14 (-0.41, 0.13) ^b
Preterm birth (<37 weeks’ gestation)	104 (16.6)	155 (14.2)	1.17 (0.93, 1.47)
Spontaneous preterm birth	32 (5.1)	50 (4.6)	1.12 (0.72, 1.72)
Medically-indicated preterm birth	72 (11.5)	105 (9.6)	1.20 (0.90, 1.59)

CI=confidence interval; HELLP=haemolysis, elevated liver enzymes, low platelet count; ICU=intensive care unit.

^a Incidence Rate Ratio and 95% CI.

^b β and 95% CI

Supplementary Table 4. Baseline characteristics among vaccinated and unvaccinated women.

	Vaccinated women (n=2,886)	Unvaccinated women (n=1,732)
<i>Demographic and Socioeconomic Characteristics</i>		
Years of formal education	13.3 ± 4.9	11.4 ± 4.7
Worked outside the home	1,840 (68.7)	848 (53.3)
Married or cohabiting	2,468 (88.0)	1,417 (84.5)
Smoker during index pregnancy	166 (5.8)	127 (7.4)
Alcohol (≥1 units/week)	102 (3.8)	27 (1.7)
Recreational drugs	62 (2.2)	28 (1.6)
<i>Gynaecological and Obstetric History</i>		
Lowest haemoglobin, <27 weeks' gestation (g/dl)	11.7 ± 1.2	11.4 ± 1.4
Hormonal contraceptives/ breastfeeding (2 months before pregnancy)	239 (8.5)	85 (5.2)
Fertility treatment	246 (8.6)	88 (5.2)
Previous pregnancy	1,893 (65.7)	1,228 (71.1)
Previous miscarriage	860 (29.9)	526 (30.5)
Previous birth	1,515 (52.6)	1,028 (59.6)
Previous baby <2.5kg or >4.5kg	152 (6.1)	104 (6.8)
Previous baby <37 weeks' gestation	138 (5.5)	80 (5.3)
Previous stillbirth or neonatal death	69 (2.8)	42 (2.8)
<i>Pre-existing medical conditions/status</i>		
Maternal age, years	32.0 ± 5.8	30.3 ± 6.0
Maternal height, cm	162.8 ± 7.6	162.5 ± 7.2
Maternal weight, kg	68.1 ± 17.5	69.9 ± 16.8
Body mass index (BMI), kg/m ²	25.7 ± 6.2	26.4 ± 5.8
Diabetes	80 (2.8)	35 (2.0)
Overweight (BMI ≥ 25 kg/m ²)	1,247 (44.2)	902 (54.1)
Thyroid or other endocrine disease	331 (11.6)	169 (10.0)
Cardiac disease	68 (2.4)	28 (1.7)
Hypertension	92 (3.2)	38 (2.3)
Chronic respiratory disease	74 (2.6)	74 (4.4)
Kidney disease	26 (0.9)	8 (0.5)
Tuberculosis	13 (0.5)	2 (0.1)
Any significant morbidity	578 (20.0)	312 (18.0)

Supplementary Table 5: Pregnancy complications, perinatal events and neonatal morbidities among vaccinated and unvaccinated women, excluding those with pre-existing medical conditions.

Outcome	Unvaccinated women	Vaccinated women	Relative Risk	First vaccination during	Relative Risk
	(n=1,420)	(n=2,308)	(95% CI) ^a	pregnancy	(95% CI) ^b
	N (%)	N (%)	(95% CI)	(n=1,478)	
Vaginal bleeding	72 (5.1)	119 (5.2)	1.01 (0.76, 1.35)	65 (4.4)	0.86 (0.62, 1.20)
Pregnancy-induced hypertension	61 (4.3)	121 (5.3)	1.22 (0.90, 1.64)	83 (5.6)	1.30 (0.94, 1.80)
Preeclampsia/eclampsia/HELLP	54 (3.8)	90 (3.9)	1.02 (0.73, 1.42)	60 (4.1)	1.06 (0.74, 1.53)
Haemoglobin <10g/dl at >27 weeks' gestation	110 (13.0)	114 (7.9)	0.60 (0.47, 0.78)	71 (7.3)	0.56 (0.42, 0.74)
Preterm labour	60 (4.2)	80 (3.5)	0.82 (0.59, 1.14)	42 (2.8)	0.67 (0.46, 0.99)
Infection requiring antibiotics	141 (10.0)	271 (11.8)	1.18 (0.97, 1.43)	183 (12.4)	1.24 (1.01, 1.53)
Admitted to ICU or referred to higher care	44 (3.1)	31 (1.4)	0.43 (0.27, 0.68)	20 (1.4)	0.44 (0.26, 0.74)
Number of days in ICU (mean, SD)	4.1 ± 4.1	3.1 ± 3.2	0.76 (0.46, 1.24) ^c	2.9 ± 2.5	0.73 (0.43, 1.21) ^c
Maternal death	3 (0.2)	1 (0.0)	0.20 (0.02, 1.97)	No cases	-- ^d
Fetal distress	105 (7.4)	135 (5.9)	0.79 (0.62, 1.01)	91 (6.2)	0.83 (0.63, 1.09)
Spontaneous initiation of labour	796 (56.5)	1,243 (54.1)	0.96 (0.90, 1.02)	800 (54.3)	0.96 (0.90, 1.03)
Induced labour	287 (20.4)	580 (25.3)	1.24 (1.09, 1.41)	379 (25.7)	1.26 (1.10, 1.45)
Caesarean section	535 (37.9)	855 (37.3)	0.98 (0.90, 1.07)	545 (37.0)	0.98 (0.89, 1.07)
Pre-labour rupture of membranes	277 (20.0)	438 (19.3)	0.96 (0.84, 1.10)	291 (20.0)	1.00 (0.86, 1.15)
Congenital abnormality	50 (3.6)	69 (3.0)	0.85 (0.59, 1.21)	37 (2.5)	0.71 (0.46, 1.07)
Gestational age at birth, weeks (mean, SD)	38.7 ± 2.7	38.8 ± 2.7	0.09 (-0.09, 0.27) ^c	39.0 ± 2.1	0.34 (0.16, 0.51) ^c
Preterm birth (<37 weeks' gestation)	202 (14.3)	266 (11.6)	0.81 (0.68, 0.96)	139 (9.4)	0.66 (0.54, 0.81)
Spontaneous preterm birth	67 (4.8)	83 (3.6)	0.76 (0.55, 1.04)	47 (3.2)	0.67 (0.46, 0.97)
Medically-indicated preterm birth	135 (9.6)	183 (8.0)	0.83 (0.67, 1.03)	92 (6.2)	0.65 (0.50, 0.84)

CI=confidence interval; HELLP=haemolysis, elevated liver enzymes, low platelet count; ICU=intensive care unit.

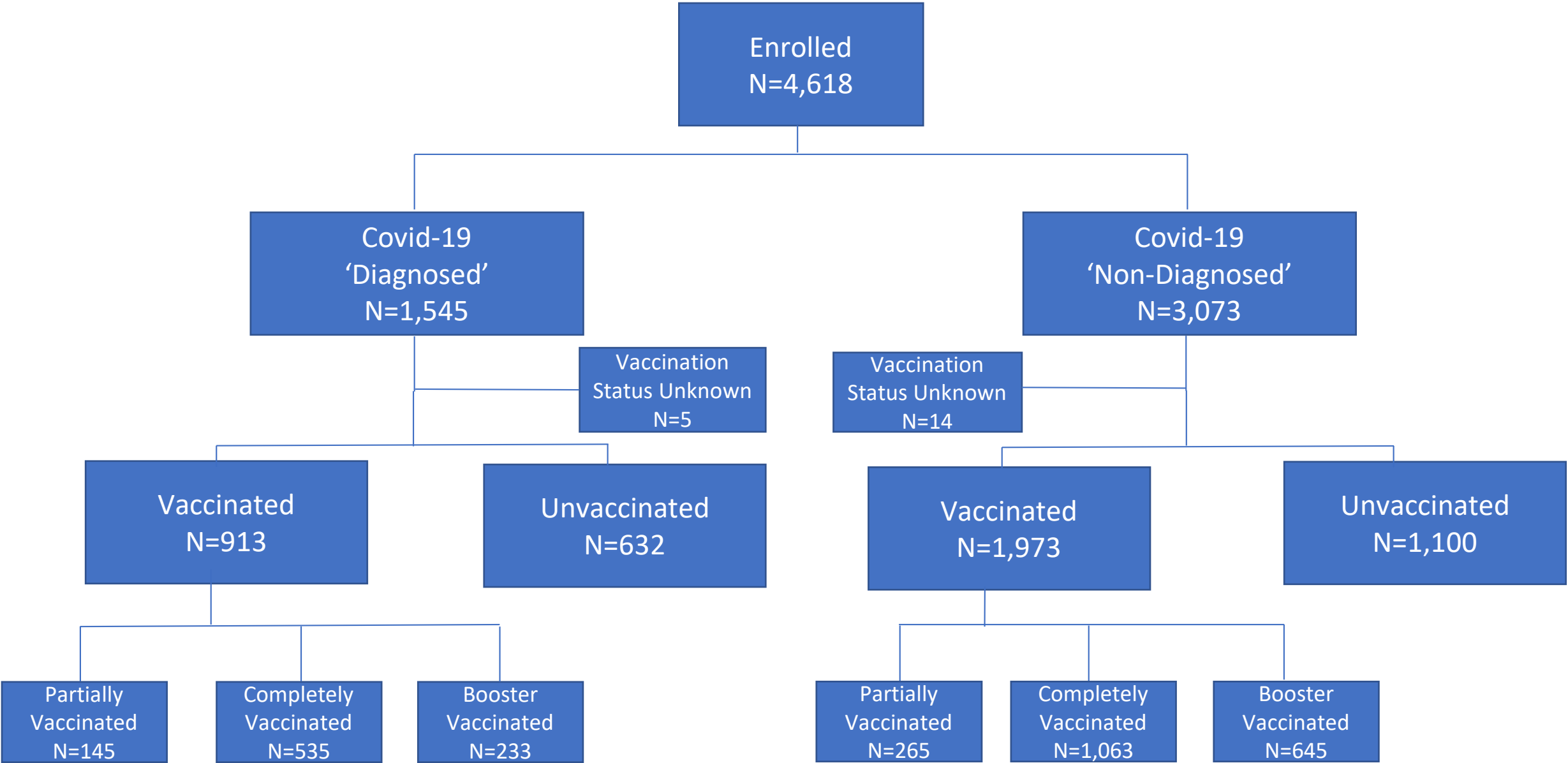
^a Relative risk indicates change in outcome associated with being vaccinated, as opposed to being unvaccinated (the reference group).

^b Relative risk indicates change in outcome associated with being vaccinated and receiving their first dose during pregnancy, as opposed to being unvaccinated (the reference group).

^c Incidence Rate Ratio and 95% CI.

^d No cases in the vaccinated group.

^e β and 95% CI



Supplementary Figure 1: Flowchart

Contributors and Members of the International Study on the Effects of Covid-19 in pregnancy on maternal and newborn outcomes (The INTERCOVID-2022 Study)

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