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Investigating service delivery and perinatal outcomes during the low prevalence first year of COVID-19 in a multiethnic Australian population: a cohort study

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Abstract

Objective Investigate the impact of the COVID-19 pandemic on perinatal outcomes in an Australian high migrant and low COVID-19 prevalent population to identify if COVID-19 driven health service changes and societal influences impact obstetric and perinatal outcomes.

Design Retrospective cohort study with pre COVID-19 period 1st January 2018-31st January 2020, and first year of global COVID-19 period 1st February 2020–31st January 2021. Multivariate logistic regression analysis was conducted adjusting for confounders including age, socioeconomic status, gestation, parity, ethnicity and BMI.

Setting Obstetric population attending three public hospitals including a major tertiary referral centre in Western Sydney, Australia.

Participants Women who delivered with singleton pregnancies over 20 weeks gestation. Ethnically diverse women, 66% overseas born. There were 34 103 births in the district that met inclusion criteria: before COVID-19 n=23 722, during COVID-19 n=10 381.

Main outcome measures Induction of labour, vaginal delivery, preterm birth, small for gestational age (SGA), composite neonatal adverse outcome, and full breastfeeding at hospital discharge.

Results During the first year of COVID-19 there was no change for induction of labour (aOR 0.97; 95% CI 0.92-1.02, p=0.26) and a 19% reduction in vaginal births (aOR 0.81; 95% CI 0.77-0.86, p<0.001). During the COVID-19 period we found a 15% reduction in spontaneous preterm birth (aOR 0.85; 95% CI 0.75-0.97, p=0.02) as well as a 10% reduction in SGA infants at birth (aOR 0.90; 95% CI 0.82-0.99, p=0.02). Composite adverse neonatal outcomes were marginally higher (aOR 1.08; 95% CI 1.00-1.15, p=0.04) and full breastfeeding rates at hospital discharge reduced by 15% (aOR 0.85; 95% CI 0.80-0.90, p<0.001).

Conclusion Despite a low prevalence of COVID-19, both positive and adverse obstetric outcomes were observed that may be related to changes in service delivery and interaction with health care providers. Further research is suggested to understand the drivers for these changes.

Keywords: COVID-19, Breastfeeding, Coronavirus, Pandemic, Preterm birth

Word count: 3259

Strengths and limitations of this study

- The analysis provides the opportunity to evaluate the indirect effects of COVID-19 against a background of low prevalence of COVID-19 in the community.
- The cohort comprised of a large ethnically diverse population with similar exposure of restriction experience and service delivery changes.
- Analysis for both iatrogenic and spontaneous preterm birth.
- Missing some COVID-19 related confounders is a limitation such as physical activity levels, prevalence of pregnancy population working from home, or missing planned overseas social support due to international border restrictions.
- A limitation of the study is multiple outcomes were compared however, our results are consistent with several other studies in different populations increasing the veracity of our findings.

INTRODUCTION

In the beginning of 2020, non-pharmaceutical interventions to reduce the spread of COVID-19 led to great changes in society such as lockdowns, enforced movement and travel restrictions.[1 2] There were also many changes to medical and maternity care around the world that are well documented, impacting direct care and social support.[3-6] Initial concerns of the impact of COVID-19 infection on pregnant women focused research on pregnancy outcomes for women who were infected and results varied, findings included increased COVID-19 infection risk in ethnic minorities, and a rise in both preterm and caesarean births.[7-10] More recently perinatal research has assessed the indirect impact of the pandemic,[11] particularly the impact of lockdowns.[12-14] Indirect impact will vary significantly between countries and within country due to diverse drivers such as lockdown experiences, social distancing measures, COVID-19 prevalence, societal compliance, economic and healthcare access.[4 6 15]

Studies of the indirect effects of COVID-19 on pregnancy outcome have shown inconsistent results. A reduction in preterm birth in the general population during the pandemic has been reported by some authors but not others.[12 16-18] Differences in study design and other factors have led some authors to conclude that there is insufficient evidence to determine if preterm birth has been reduced during COVID-19.[19]

Maternity care in Australia during the first year of the pandemic in 2020, experienced a disparate range of changes from very little to significant alterations in service delivery dependent on population and perceived risk in the community.[3] Little evidence exists for the impact of societal and service changes on a culturally diverse obstetric population who initially experienced minimal COVID-19 community transmission, a short lockdown period but experienced significant obstetric service and societal changes due to the pandemic.

In our study population, we hypothesise obstetric outcomes may have been impacted by the rapid changes in hospital service delivery as they shifted focus during the pandemic from patient centred care to preservation of service and staff.[20] Western Sydney with its multicultural population, is an ideal environment to examine the indirect effects of the response to the pandemic on perinatal outcomes given the setting of low COVID-19 case numbers at the time of the study, yet having considerable preventative measures implemented in the region. We aim to identify pandemic-related morbidity in our large multi-ethnic Australian population and uncover potential drivers for both improved and adverse maternity care outcomes.

METHODS

We conducted a retrospective cohort study using routinely collected obstetric, medical and administrative data for women seeking antenatal care in the Western Sydney Local Health District. We compared birth outcomes greater than or equal to 20 weeks of gestation in the two years prior to the COVID-19 pandemic to the first year of the COVID-19 pandemic. The study period is defined as pre COVID-19 1st January 2018 – 31st January 2020 to the first twelve months of the COVID-19 pandemic 1st February 2020 – 31st January 2021.

The state of New South Wales (NSW) has a population of approximately 8.2 million.[21] The three study hospitals serve a health district population of approximately one million people. A total of 39 pregnant women had a confirmed COVID-19 diagnosis in this state for the study period and fewer than 60 COVID-19 related deaths were recorded for the total population in NSW in the first year.[22] During the study period no pregnant women were admitted with COVID-19 to the study hospitals and the prevalence of COVID-19 in the local community was low (total 690 cases Supp Figure 1).[23]

The study period was determined by the time when public awareness grew in NSW of the impending pandemic with official government announcements and a sharp rise and dominance of media coverage concerning COVID-19 from early February 2020.[24] The study period was after the 30th January 2020 WHO announcement declaring 2019-nCoV virus (COVID-19) as a public health emergency of international concern.[25] Public health order restrictions commenced 16th March 2020 with restrictions on gathering of over 500 people in NSW to reduce the spread of COVID-19. The restrictions escalated on the 30th March 2020, to 'hard lockdown' issuing of public health orders "that a person must not, without reasonable excuse, leave the person's place of residence'.[25] The restrictions were present for approximately 7 weeks easing 15th May, 2020.

The short hard lockdown in NSW, was primarily enforced in greater Sydney, accompanied by increased restrictions and COVID-safe practices including all health facilities women and their families accessed. The restrictions for local maternity services included hospital entrance screening of all patients, staff and visitors including temperature checks, asking about recent travel and symptoms of COVID-19. Within the antenatal service, there was also an introduction of telehealth for the Diabetes in Pregnancy clinics, restrictions on visitors such as allowing only patients in waiting rooms, no support person during ultrasound and only one support person with no changing-over in the birth unit. During this time there were frequent changes to service delivery and some confusion regarding rules for patients reported by staff at the tertiary referral study Hospital.[20]

Community activities returned to near normal by July 2020 in NSW, however international and state borders continued to be disrupted with ongoing outbreaks emerging. Restrictions to visitors and other COVID-19 risk mitigation policies remained present for the maternity services throughout the study period. COVID-19 vaccinations were not available in Australia during the study period.

Western Sydney Local Health District human research ethics committee provided ethical approval for this study using deidentified routinely collected administrative data (WSLHD HREC QA2101-15).

Definitions

Routinely collected maternity data for singleton pregnancies greater than 20 weeks gestation was retrieved from the electronic maternal database. Terminations of pregnancy were not included in the database. Gestational age was determined and calculated in the electronic maternity system utilising the rules: use of last menstrual period (LMP) if regular, date was amended after available early ultrasound 6 week - 13+6 weeks gestation. If ultrasound dating varies from LMP by more than 5 days, if irregular or uncertain LMP then ultrasound expected date of delivery (EDD) was used.

Socioeconomic status (SES) in our study was derived from the postcode address of participants during pregnancy as determined for that area by the last Australian census information (2016), informing the Index of Relative Socioeconomic Disadvantage (IRSD). The index is based on households in that area using information on variables that include income, English fluency, education and employment status. A lower index score represents greater disadvantage.[26]

Outcomes of interest

Outcomes of interest were selected based on literature review, state obstetric benchmarking outcomes and outcomes that plausibly may be impacted by service delivery changes. Literature has reported criteria changes in some healthcare setting for induction of labour and overall induction rates changing, therefore we included any induction via any method at all gestations in our outcomes of interest. We defined all vaginal births as one outcome inclusive of breech vaginal births. All preterm births were defined as less than 37 weeks gestation. Spontaneous preterm was defined as vaginal preterm births without an induction or caesarean section preterm births with a history of preterm labour. Iatrogenic preterm births were those initiated by care providers, defined as either a planned caesarean section with no preterm labour or an induction prior to 37 weeks gestation. Small for gestational age (SGA) is birth weight less than 10th centile assessed by the Fenton growth chart.[27] Combined adverse neonatal outcome included any of the following; stillbirth, admission to special care/neonatal intensive care (NICU), Apgar score under 7 at 5 minutes, or newborn resuscitation with intubation.

Data analysis and statistical methods

Demographic and obstetric characteristics of women were compared before and during the first year of COVID-19 using the chi-squared, Fisher's exact, or t-test where appropriate. Univariate logistic regression was applied to each characteristic to estimate unadjusted odds ratios. Then, three adjusted models were devised and implemented using multivariate logistic regression. Model 1 adjusted for maternal age, socioeconomic status, gestational age (except for the preterm birth outcome), parity, ethnicity, BMI, smoking status and mental health status. Model 2 adjusted for model of pregnancy care and the variables from Model 1. Model 3 adjusted for additional covariates that are clinically relevant for specific outcomes. For the vaginal birth outcome, birthweight and induction of labour were added to the covariates from Models 1 and 2. For the preterm birth outcome, a composite gestational diabetes /hypertension variable was added to the covariates from Models 1 and 2. For the breastfeeding outcome, mode of delivery, length of stay <24 hours, and preterm birth were added to the covariates form Models 1 and 2. For each model, an adjusted odds ratio with a 95% confidence interval was reported. P values less than 0.05 were considered statistically significant. The cohort was restricted to records with complete data on outcomes of interest. Missing indicator variables were utilised for covariates in the multivariate analyses. All statistical analyses were completed using Stata Special Edition Version 14.2 (StataCorp).

Patient public involvement statement

This retrospective cohort study had no patient public involve in the design or analysis or dissemination of results.

RESULTS

Baseline characteristics

There were 34 103 singleton births for the three district hospitals meeting inclusion criteria. The principle tertiary referral centre had the greatest number of births in the cohort (n=17 005; 49.9%), with the large secondary hospital comprising of 36.6% (n=12 467) of the cohort. The pre COVID-19 period had a total of 23 722 singleton births and during the first year of COVID-19 (period 1st February 2020–31st January 2021) there were 10 381 singleton births.

Women who birthed in the first year of COVID-19 were more likely to be Australian born (35.1% vs 32.9%), overweight or obese (45.8% vs 44.5%), under 35 years old (59.7% vs 50.6%), have a history of a mental illness (15% vs 13%), to present for their first comprehensive antenatal visit at <10 weeks gestation (80.8% vs 64.4%) and less likely to be privately insured (5.9% vs 6.9%) compared to the preceding two years (Table 1). Women were admitted antenatally less often (10.1% vs 12.1%) and women who elected to have an early discharge postpartum at <24 hours, were higher from 15.5% during the pre-COVID period to 19.1% in the first year of COVID-19. Other demographic and pregnancy characteristics are documented in Table 1.

Pregnancy complications and outcomes

There were no differences in overall median gestation age at birth between the two time periods (Table 2). We did observe that the rate of preterm birth was lower during COVID-19 compared to the preceding period (7.2% vs 8.1%). We also observed a higher proportion of births at or after 41 weeks gestation during the first year of COVID-19 (10.0% vs 9.0%). We identified a reduction in all vaginal births (66.6% vs 69.6%) including reduced vaginal breech births (0.7% vs 0.9%). This corresponded with the caesarean section rate increasing during the first year of the COVID-19 pandemic (33.4% vs 30.5%) (Table 2). There was an overall higher rate of induction of labour (35.3% vs 29.9%) and a lower rate of SGA births (6.9% vs 7.8%). We found no change for adverse birth outcomes including for stillbirth (0.9% vs 1.0%) or admissions to special care/neonatal intensive care (16.8% vs 16.2%) (Table 2).

In adjusted analysis no difference was identified for labour inductions during the COVID-19 period compared to the pre-COVID period (aOR 0.97; 95% CI 0.92-1.02). There were 19% fewer vaginal births during the pandemic first year in our health district (aOR 0.81; 95% CI 0.77-0.86) (Table 3). The rate of spontaneous preterm births was reduced by 15% (aOR 0.85; 95% CI 0.78-0.95) and no change was found for iatrogenic preterm births (aOR 0.94; 95% CI 0.80-1.09) (Table 3). Adjusted models also uncovered a 10% reduction for SGA infants at birth during the COVID-19 period (aOR 0.90; 95% CI 0.82-0.99). We found a marginal increase for a combined adverse neonatal outcome during the COVID-19 period (aOR 1.08; 95% CI 1.00-1.15) (Table 3).

In our study population, the first year of the pandemic impacted breastfeeding when compared to the previous two years. When adjusted for several confounders including birthweight, mode of delivery, and prematurity, we found a 15% reduction for women fully breastfeeding their infant at discharge (aOR 0.85; 95% CI 0.80-0.90) (Table 3). Interestingly, there was a higher rate during the COVID-19 period in both breastfeeding within one hour (61.9% vs 60.5%, p=0.02) after birth and maternal/infant skin to skin contact at birth (76.7% vs 69.4%, p=0.02) (Table 2).

DISCUSSION

In a health district with low COVID-19 prevalence but affected by public health measures and process changes to service delivery, we found no differences in the rate of induction of labour, a reduction in spontaneous preterm and SGA births with no change in iatrogenic preterm births during the first year of COVID-19. There was also a significant reduction in vaginal birth and women fully breastfeeding at hospital discharge during this period compared to the previous two years. We identified a marginal increase in the rate of severe adverse neonatal composite outcome.

A strength of the study is the population experienced similar exposure to COVID-19 restrictions and maternity care service delivery changes. The multiethnic population with an even distribution between SES quintiles strengthens the generalisability of our findings to other populations. There may have been other confounders we were not able to capture that may impact on obstetric outcomes such as level of physical activity. Potentially some women may have benefited from more time to exercise with associated reduced infection risk through exercise-mediated protective immune response[28], while other women who felt unwell may have had the opportunity to rest at home.

It is difficult to capture individual responses to the threat of COVID-19 despite low prevalence in the community for this cohort. However, recent qualitative research at one study hospital found clinicians felt some groups of women benefited from the COVID-19 restrictions with less stress and protected family time. However, migrant women were seen to have experienced isolation and anxiety due to loss of significant practical and social support from overseas relatives unable to visit due to COVID-19 related international border closures.[20 29] The impact of the loss of expected support from relatives due to COVID-19 travel restrictions was not measured in our study and is a limitation.

Similar to other studies, we document a reduction in preterm birth.[12 17 18 30] The lack of delineation between iatrogenic and spontaneous preterm birth in some research has been an issue when comparing results and attempts to identify potential drivers.[19] A strength of our study is we were able to present the data and identified that only spontaneous preterm birth was reduced for the study period. However recent updated preterm birth meta-analysis by Yang et al found in unadjusted analysis preterm birth was reduced for both spontaneous and iatrogenic only in single centre studies, but not in national studies.[6] Local district level data and population characteristics may have less variation in obstetric service delivery confounders and other factors that increase the uniformity of experience for women and may account for the difference between large national level data and some single centre research. Local, more granular data for obstetric outcomes during the COVID-19 pandemic may assist in understanding drivers for improved and adverse obstetric outcomes. Shah et al in a Canadian population study, found no reduction in preterm births however, they did demonstrate preterm birth variation over time and between districts.[31] Our study covers the complete first year of the pandemic, reducing the possibility of a result based on a chance normal short-term variation.

It has been postulated that the causative mechanism for a reduction in preterm births during the COVID-19 period is reduced infection and maternal physical activity throughout lockdown.[32] In our population, these potential causative factors for a reduction in spontaneous preterm birth, may have existed in our health district during the short lockdown and likely persisted beyond the lockdown period. Some infection mitigation behaviours may have been driven by our high migrant population who received advice from overseas relatives in areas experiencing high rates of COVID-19. Encouraging suitable exercise[28] and simple hygiene measures such as appropriate hand washing, are public health measures that may reduce infection. Hand hygiene historically has been poorly done and with increased awareness and compliance, may assist with decreasing preterm births.[33 34]

We found women were presenting earlier to their family doctors for a first pregnancy visit and referral to tertiary hospital care. This may have been due to anxiety about the pregnancy and the unknown risk of COVID-19 infection to a fetus. The benefits of this early health provider contact may be correct dietary, provide opportunity for early aspirin prescription and other pregnancy care that may contribute to some of the improved pregnancy outcomes including preterm birth for this cohort.

Similar to our study, a prospective Italian study found a 28% reduction in full breastfeeding at discharge in a region with high COVID-19 prevalence.[35] We identified that during the COVID-19 period there was an improvement in practices that support breastfeeding immediately after birth; maternal-infant skin to skin contact and breastfeeding within the first hour. Birth unit protocols changed during the COVID-19 period, with only one support person allowed at the birth. The improvement in skin to skin and breastfeeding in the first hour may potentially be due to midwives identifying that woman were feeling more isolated and provided more one-to one support in the birth room improving these important breastfeeding outcomes. There may be several factors that contribute to less exclusive breastfeeding at discharge in our study despite adjustment which included time of postnatal stay. Due to reduced visitors, women may have felt they needed to bring formula into the hospital in case they had difficulty with breastfeeding, therefore it was available and more likely to be used. There may also have been reduced opportunities for staff to provide postnatal breastfeeding support due to concerns of COVID-19 infection risk by both staff and patients, staffing shortages and increased staff workload during the COVID-19 period. It is well acknowledged the introduction of formula and bottle feeding in the early postnatal period has significant consequences for infant long-term health and reduces total length of breastfeeding.[36-38] Providing adequate lactation support antenatally, at birth and postnatally with staff shortages during the pandemic is problematic but important for both short-term and long-term metabolic maternal and infant health.[36 39 40]

Although recent literature has focused on the impact of COVID-19 disease and pregnancy, the indirect impact of the world-wide pandemic may not be fully realised for many years. There is increasing evidence of the impact of exposure to disasters including pandemics, on long term health consequences. A recent systematic review concluded fetal and maternal exposure to natural disasters including pandemics resulted in increased cardiometabolic risk in both.[41] Understanding a pandemic population with a low prevalence of COVID-19 but subject to changes in maternity care and societal stress, may assist in future investigations of drivers for cardiometabolic health.

CONCLUSIONS

The benefit to women, their families and the community of reduced SGA and preterm birth is long lasting, the drivers for this change may be difficult to identify. However, the results from this study in a cohort primarily exposed only to COVID-19 related service and societal changes, provides unique opportunity to generate evidence of these changes on pregnancy complications. The significant reduction in breastfeeding at discharge may be more easily addressed now identified. Funding appropriate intervention strategies is imperative both in the antenatal and postnatal periods to improve breastfeeding outcomes. Revealing all drivers for obstetric changes during the pandemic may be difficult to ascertain, further research in this high migrant cohort with higher prevalence of COVID-19 cases may reveal evidence for more specific drivers.

Author contributions

Study designed by SJM, TM, SC, TIA and DP. JE performed the statistical analysis. SJM interpreted the data and wrote the initial and final manuscript drafts with supervision from DP. Invaluable support was given by JE, TM, VWL, NWC, SC, JM, TIA and DP for final interpretation of findings, and critical revision of the article.

Competing interest statement

All authors declare they have no conflicts of interest for the research presented in this manuscript.

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Data sharing statement

Institutional restrictions apply to the availability of these data, and so are not publicly available. Data are however available from the corresponding author upon reasonable request and with permission of WSLHD Human Research and Ethics Committee.

References

1. Suryanarayanan P, Tsou CH, Poddar A, et al. AI-assisted tracking of worldwide non-pharmaceutical interventions for COVID-19. *Sci Data* 2021;**8**(1):94. doi: 10.1038/s41597-021-00878-y
2. Haug N, Geyrhofer L, Londei A, et al. Ranking the effectiveness of worldwide COVID-19 government interventions. *Nat Hum Behav* 2020;**4**(12):1303-12. doi: 10.1038/s41562-020-01009-0
3. Bradfield Z, Wynter K, Hauck Y, et al. Experiences of receiving and providing maternity care during the COVID-19 pandemic in Australia: A five-cohort cross-sectional comparison. *PLoS One* 2021;**16**(3):e0248488. doi: 10.1371/journal.pone.0248488
4. Cutler DM, Summers LH. The COVID-19 Pandemic and the $16 Trillion Virus. *JAMA* 2020;**324**(15):1495-96. doi: 10.1001/jama.2020.19759
5. Pak A, Adegboye OA, Adekunle AI, et al. Economic Consequences of the COVID-19 Outbreak: the Need for Epidemic Preparedness. *Frontiers in Public Health* 2020;**8**(241) doi: 10.3389/fpubh.2020.00241
6. Yang J, D'Souza R, Kharrat A, et al. Coronavirus disease 2019 pandemic and pregnancy and neonatal outcomes in general population: A living systematic review and meta-analysis (updated Aug 14, 2021). *Acta Obstet Gynecol Scand* 2021 doi: 10.1111/aogs.14277
7. Acosta AM, Garg S, Pham H, et al. Racial and Ethnic Disparities in Rates of COVID-19–Associated Hospitalization, Intensive Care Unit Admission, and In-Hospital Death in the United States From March 2020 to February 2021. *JAMA Network Open* 2021;**4**(10):e2130479-e79. doi: 10.1001/jamanetworkopen.2021.30479
8. Agyemang C, Richters A, Jolani S, et al. Ethnic minority status as social determinant for COVID-19 infection, hospitalisation, severity, ICU admission and deaths in the early phase of the pandemic: a meta-analysis. *BMJ Global Health* 2021;**6**(11):e007433. doi: 10.1136/bmjgh-2021-007433
9. Matar R, Alrahmani L, Monzer N, et al. Clinical Presentation and Outcomes of Pregnant Women With Coronavirus Disease 2019: A Systematic Review and Meta-analysis. *Clin Infect Dis* 2021;**72**(3):521-33. doi: 10.1093/cid/ciaa828
10. Papapanou M, Papaioannou M, Petta A, et al. Maternal and Neonatal Characteristics and Outcomes of COVID-19 in Pregnancy: An Overview of Systematic Reviews. *Int J Environ Res Public Health* 2021;**18**(2) doi: 10.3390/ijerph18020596
11. Du M, Yang J, Han N, et al. Association between the COVID-19 pandemic and the risk for adverse pregnancy outcomes: a cohort study. *BMJ Open* 2021;**11**(2):e047900. doi: 10.1136/bmjopen-2020-047900
12. Been JV, Burgos Ochoa L, Bertens LCM, et al. Impact of COVID-19 mitigation measures on the incidence of preterm birth: a national quasi-experimental study. *The Lancet Public Health* 2020;**5**(11):e604-e11. doi: https://doi.org/10.1016/S2468-2667(20)30223-1
13. Gallo LA, Gallo TF, Borg DJ, et al. A decline in planned, but not spontaneous, preterm birth rates in a large Australian tertiary maternity centre during COVID-19 mitigation measures. *Aust N Z J Obstet Gynaecol*;**n/a**(n/a) doi: https://doi.org/10.1111/ajo.13406
14. Rolnik DL, Matheson A, Liu Y, et al. Impact of COVID-19 pandemic restrictions on pregnancy duration and outcome in Melbourne, Australia. *Ultrasound Obstet Gynecol* 2021;**58**(5):677-87. doi: https://doi.org/10.1002/uog.23743
15. Nam SH, Nam JH, Kwon CY. Comparison of the Mental Health Impact of COVID-19 on Vulnerable and Non-Vulnerable Groups: A Systematic Review and Meta-Analysis of Observational Studies. *Int J Environ Res Public Health* 2021;**18**(20) doi: 10.3390/ijerph182010830
16. Bian Z, Qu X, Ying H, et al. Are COVID-19 mitigation measures reducing preterm birth rate in China? *BMJ Glob Health* 2021;**6**(8) doi: 10.1136/bmjgh-2021-006359
17. Chmielewska B, Barratt I, Townsend R, et al. Effects of the COVID-19 pandemic on maternal and perinatal outcomes: a systematic review and meta-analysis. *Lancet Glob Health* 2021;**9**(6):e759-e72. doi: 10.1016/s2214-109x(21)00079-6

18. Kirchengast S, Hartmann B. Pregnancy Outcome during the First COVID 19 Lockdown in Vienna, Austria. *Int J Environ Res Public Health* 2021;**18**(7) doi: 10.3390/ijerph18073782
19. Goldenberg RL, McClure EM. Have Coronavirus Disease 2019 (COVID-19) Community Lockdowns Reduced Preterm Birth Rates? *Obstet Gynecol* 2021;**137**(3):399-402. doi: 10.1097/AOG.0000000000004302
20. Melov SJ, Galas N, Swain J, et al. Exploring the COVID-19 pandemic experience of maternity clinicians in a high migrant population and low COVID-19 prevalence country: a qualitative study. *Women and Birth* 2021 doi: https://doi.org/10.1016/j.wombi.2021.10.011
21. Key Facts about NSW; Available from: https://www.nsw.gov.au/about-nsw/key-facts-about-nsw#toc-population
22. NSW Govenment. COVID-19 weekly surveillance in NSW, Epidemiology week 4, Ending 30 January 2021; Available from: https://www.health.nsw.gov.au/Infectious/covid-19/Documents/covid-19-surveillance-report-20210130.pdf
23. NSW Government. NSW COVID-19 data;Available from: https://data.nsw.gov.au.
24. Nolan D, Hanna C, McGuinness K and McCallum K . Covering COVID-19: How Australian Media reported the Coronavirus pandemic in 2020. News & Media Research Centre, University of Canberra, 2021 DOI:10.25916/01t1-6649
25. World Health Organisation. Statement on the second meeting of the International Health Regulations (2005) Emergency Committee regarding the outbreak of novel coronavirus (2019-nCoV) 2020; Available from: https://www.who.int/news/item/30-01-2020-statement-on-the-second-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-(2019-ncov).
26. Australian Bureau of Statistics. Census of Population and Housing: Socio-Economic Indexes for Areas (SEIFA), Australia, 2016 Canberra: Australian Government; 2018; Available from: https://www.abs.gov.au/ausstats/abs@.nsf/Lookup/by%20Subject/2033.0.55.001~2016~Main%20Features~IRSD~19
27. Fenton TR, Nasser R, Eliasziw M, et al. Validating the weight gain of preterm infants between the reference growth curve of the fetus and the term infant. *BMC Pediatr* 2013;**13**:92. doi: 10.1186/1471-2431-13-92
28. Scheffer DdL, Latini A. Exercise-induced immune system response: Anti-inflammatory status on peripheral and central organs. *Biochim Biophys Acta Mol Basis Dis* 2020;**1866**(10):165823-23. doi: 10.1016/j.bbadis.2020.165823
29. Melov SJ, Hitos K. Venous thromboembolism risk and postpartum lying-in: Acculturation of Indian and Chinese women. *Midwifery* 2018;**58**:13-18. doi: 10.1016/j.midw.2017.11.006
30. Einarsdóttir K, Swift EM, Zoega H. Changes in obstetric interventions and preterm birth during COVID-19: A nationwide study from Iceland. *Acta Obstet Gynecol Scand* 2021;**100**(10):1924-30. doi: https://doi.org/10.1111/aogs.14231
31. Shah PS, Ye XY, Yang J, et al. Preterm birth and stillbirth rates during the COVID-19 pandemic: a population-based cohort study. *CMAJ* 2021;**193**(30):E1164-e72. doi: 10.1503/cmaj.210081
32. Hedermann G, Hedley PL, Bækvad-Hansen M, et al. Danish premature birth rates during the COVID-19 lockdown. *Arch Dis Child Fetal Neonatal Ed* 2021;**106**(1):93-95. doi: 10.1136/archdischild-2020-319990
33. Freeman MC, Stocks ME, Cumming O, et al. Hygiene and health: systematic review of handwashing practices worldwide and update of health effects. *Trop Med Int Health* 2014;**19**(8):906-16. doi: 10.1111/tmi.12339
34. Wolf J, Johnston R, Freeman MC, et al. Handwashing with soap after potential faecal contact: global, regional and country estimates. *Int J Epidemiol* 2019;**48**(4):1204-18. doi: 10.1093/ije/dyy253
35. Latorre G, Martinelli D, Guida P, et al. Impact of COVID-19 pandemic lockdown on exclusive breastfeeding in non-infected mothers. *Int Breastfeed J* 2021;**16**(1):36. doi: 10.1186/s13006-021-00382-4

36. Victora CG, Bahl R, Barros AJ, et al. Breastfeeding in the 21st century: epidemiology, mechanisms, and lifelong effect. *Lancet* 2016;**387**(10017):475-90. doi: 10.1016/s0140-6736(15)01024-7
37. Ávila-Ortiz MN, Castro-Sánchez AE, Martínez-González EA, et al. Factors associated with abandoning exclusive breastfeeding in Mexican mothers at two private hospitals. *Int Breastfeed J* 2020;**15**(1):73. doi: 10.1186/s13006-020-00316-6
38. Batista CLC, Ribeiro VS, Nascimento M, et al. Association between pacifier use and bottle-feeding and unfavorable behaviors during breastfeeding. *J Pediatr (Rio J)* 2018;**94**(6):596-601. doi: 10.1016/j.jped.2017.10.005
39. Melov SJ, White L, Simmons M, et al. The BLIiNG study - Breastfeeding length and intensity in gestational diabetes and metabolic effects in a subsequent pregnancy: A cohort study. *Midwifery* 2022;**107**:103262. doi: 10.1016/j.midw.2022.103262
40. Tschiderer L, Seekircher L, Kunutsor SK, et al. Breastfeeding Is Associated With a Reduced Maternal Cardiovascular Risk: Systematic Review and Meta-Analysis Involving Data From 8 Studies and 1 192 700 Parous Women. *J Am Heart Assoc* 2022;**11**(2):e022746. doi: 10.1161/jaha.121.022746
41. De Rubeis V, Lee J, Anwer MS, et al. Impact of disasters, including pandemics, on cardiometabolic outcomes across the life-course: a systematic review. *BMJ Open* 2021;**11**(5):e047152. doi: 10.1136/bmjopen-2020-047152

Table 1. Women with a singleton pregnancy: maternal demographic characteristics and pregnancy outcomes first year of COVID-19 compared to pre-COVID in a NSW metropolitan health district
Pre-COVID-19 = 1st January 2018 – 31st January 2020 COVID-19 = 1st February 2020 – Jan 31st 2021

Characteristics	**Pre-COVID-19 n = 23,722 N (%)**	**COVID-19 n = 10,381 N (%)**	**P value**
Clinical & demographic characteristics			
Maternal age group years			
<20	38 (0.2)	46 (0.4)	<0.001
20-24	614 (2.6)	452 (3.1)	
25-34	11 335(47.8)	5 835 (56.2)	
35-39	8 939 (37.7)	3 335 (32.1)	
>39	2 796 (11.8)	713 (6.9)	
Ethnicity			
South Asian	6047 (25.5)	2 950 (28.4)	<0.001
Caucasian/European	3 307 (13.9)	1 886 (18.1)	
South-East Asian	3249 (13.7)	1 357 (13.1)	
Middle Eastern	8116 (34.2)	3827 (36.9)	
Aboriginal Torres Strait Islander	338 (1.4)	188 (1.8)	
Unknown/missing§	2665 (11.2)	173 (1.7)	
Australian born	7 809 (32.9)	3 648 (35.1)	<0.001
SES disadvantage			
Quintile 1 (most disadvantaged)	5 367 (22.7)	2 361 (22.8)	0.04
Quintile 2	5 721 (24.1)	2 568 (24.8)	
Quintile 3	3 508 (14.8)	1 494 (14.4)	
Quintile 4	3 291 (13.9)	1 528 (14.7)	
Quintile 5 (least disadvantaged)	5 809 (24.6)	2 416 (23.3)	
BMI (kg/m2) at booking			
<18.50	1 116 (4.7)	417 (4.5)	0.02
18.5–24.9	11 981 (50.5)	5 207 (50.2)	
25.0–29.9	6 317 (26.3)	2 875 (27.3)	
≥30.0	4 308 (18.2)	1 922 (18.5)	
Nulliparous	10 331 (43.6)	4 475 (43.1)	0.45
Assisted conception	1 050 (4.4)	471 (4.5)	0.65
Current smoking at booking	1 380 (5.8)	619 (6.0)	0.60
Disclosed domestic violence	340 (1.5)	141 (1.5)	0.69
Diagnosed mental illness	3 083 (13.0)	1 552 (15.0)	<0.001
History of hypertension	844 (3.6)	327 (3.2)	0.06
History of diabetes (T1DM T2DM)	265 (1.3)	114 (1.3)	0.93
History of gestational diabetes	1,555 (6.6)	738 (7.1)	0.06
Health service characteristics			
< 10 weeks gestation first comprehensive assessment	15,221 (64.4)	8,360 (80.8)	<0.001
Model of care			
Low risk hospital	15,210 (64.1)	6,768 (65.2)	0.00
Hospital complex medical	6 775 (28.6)	3,096 (29.4)	
Private maternity	1 635 (6.9)	611 (5.9)	
No antenatal care	102 (0.4)	38 (0.4)	
Antenatal admission to hospital	2 863 (12.1)	1 044 (10.1)	<0.001
Postnatal maternal length of stay < one day	3 674 (15.5)	2 000 (19.1)	<0.001
Postnatal maternal length of stay (days, median IQR)	2.02 (1.51)	2.00 (1.68)	<0.001

SES = Socio Economic Status (Index of Relative Socio-economic Disadvantage)

Low risk hospital: Midwifery care and shared antenatal care (General Practitioner/family doctor); Hospital complex medical care: Hospital based medical and high-risk clinic; Private maternity care: Obstetrician & privately practicing midwife
§ missing due to ethnicity as routine collection introduced mid-2018

Table 2. Pregnancy outcomes in a low-prevalence COVID-19 high-migrant Australian urban population:

Pre-COVID = 1st January 2018 – 31st January 2020 COVID-19 =1st February 2020 – Jan 31st 2021

Pregnancy complications	Pre-COVID-19 N=23 722 N (%)	COVID-19 n = 10 381 N (%)	P value
Timing of birth			
Gestational age (weeks) median (IQR)	39.2 (1.8)	39.2 (1.8)	0.25
<28 weeks	301 (1.3)	128 (1.2)	<0.001
28-32 weeks	232 (1.0)	84 (0.8)	
<37 weeks	1 439 (6.1)	539 (5.2)	
37+ weeks	21 748 (91.7)	9 630 (92.8)	
Mode of delivery			
Vaginal birth	13 931 (58.8)	5 819 (56.1)	<0.001
Instrumental	2 340 (9.9)	1 016 (9.8)	
Vaginal breech	204 (0.9)	76 (0.7)	
Caesarean section	7 224 (30.5)	3 465 (33.4)	
Onset of labour			
Induction	7 095 (29.9)	3 666 (35.3)	<0.001
Birth weight			
Appropriate for gestational age	20 071 (85.1)	28 884 (85.5)	0.39
Large for gestational age	1 676 (7.1)	784 (7.6)	0.11
Small for gestational age	1 832 (7.8)	713 (6.9)	0.01
Adverse birth outcomes			
Stillbirth	227 (1.0)	95 (0.9)	0.71
Apgar <7 at 5mins	662 (2.8)	257 (2.5)	0.10
Intubation resuscitation at birth	262 (1.1)	100 (1.0)	0.24
Admission to NICU	3 851 (16.2)	1 743 (16.8)	0.23
Neonatal feeding			
Skin to skin at birth	16 454 (69.4)	7 961 (76.7)	0.02
Feeding within 1 hour	14 353 (60.5)	6 424 (61.9)	0.02
Fully breastfeeding at discharge	15 620 (65.8)	6 410 (62.1)	<0.001

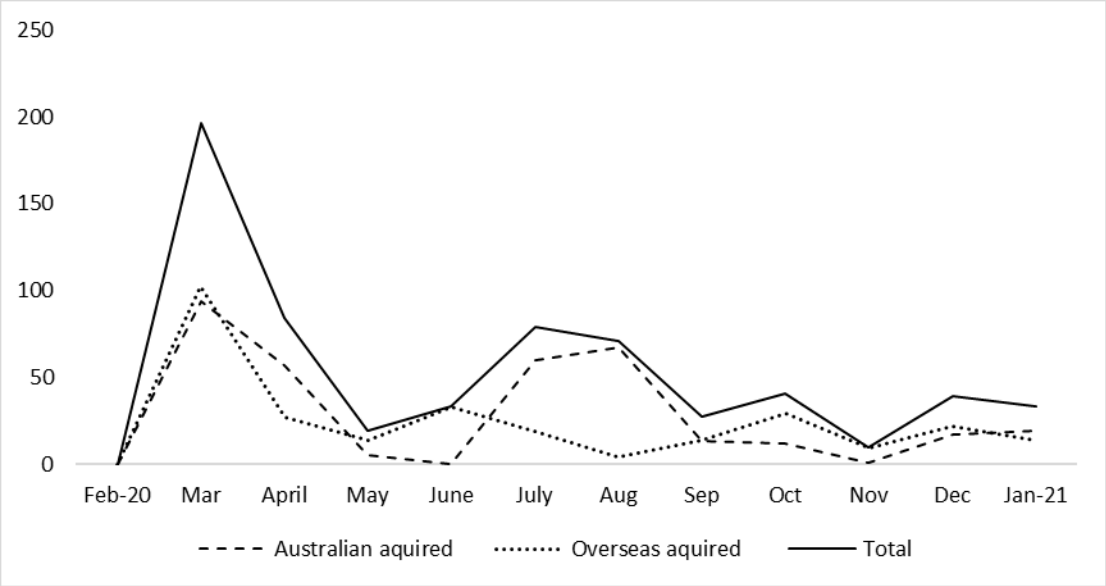
Table 3.
Odds ratio for maternal and neonatal pregnancy outcomes during the first year of COVID-19 compared to the previous two years in an Australian metropolitan health district
COVID = 1st February 2020 – Jan 31st 2021(n=10 381) Pre-COVID = 1st January 2018 – 31st January 2020 (n=23 722)

Outcome	Sample Size	Unadj. OR	P	Model 1 OR	P	Model 2 OR	P	Model 3 OR	P
Induction of labour	34,082	0.90 (0.86,0.94)	<0.001	0.97 (0.92,1.02)	0.30	0.97 (0.92,1.02)	0.26	-	-
Vaginal birth	34,065	0.89 (0.85,0.93)	<0.001	0.82 (0.78,0.86)	<0.001	0.82 (0.78,0.86)	<0.001	0.81 (0.77,0.86)	<0.001
Preterm birth	34,080	0.86 (0.79,0.94)	0.00	0.91 (0.83,0.99)	0.05	0.91 (0.83,0.99)	0.03	0.88 (0.80,0.97)	0.01
Spontaneous preterm birth	34,080	0.76 (0.67,0.85)	<0.001	0.88 (0.77,0.99)	0.04	0.88 (0.77,0.99)	0.04	0.85 (0.75,0.97)	0.02
Small for gestational age at birth	33,880	0.88 (0.81,0.96)	0.01	0.90 (0.82,0.99)	0.03	0.90 (0.82,0.99)	0.02	-	-
Composite adverse neonatal outcome	33,632	1.03 (0.97,1.09)	0.38	1.08 (1.00,1.15)	0.03	1.08 (1.00,1.15)	0.04	-	-
Full breastfeeding at hospital discharge	31,113	0.86 (0.81,0.90)	<0.001	0.85 (0.80,0.90)	<0.001	0.85 (0.81,0.90)	<0.001	0.85 (0.80,0.90)	<0.001

Composite adverse neonatal includes any: stillbirth, admission to NICU, Apgar score under 7 at 5 minutes, or newborn resuscitation with intubation.
Variables adjusted for in each model:
Model 1: Includes maternal age, Socioeconomic status SEIFA disadvantage quintile, gestational age, parity, ethnicity, BMI (numeric), smoking status, and mental health status.
Model 2: Model 1 variables and model of pregnancy care variable.
For preterm birth outcome the models are not adjusted for gestational age.
Model 3: Includes Model 1 and 2 covariates and additional covariates as listed below.
Vaginal birth: birthweight and induction of labour.
Preterm birth: composite maternal complications variable (gestational diabetes or hypertensive disorders of pregnancy).
Breastfeeding: birthweight, mode of delivery, length of stay <24 hours and gestational age/preterm.

Supplementary Figure 1

Total COVID-19 cases during study period 1st Feb 2020 – Jan 31st 2021 Western Sydney Local Health District, NSW Australia; total cases 632 (open source data https://data.nsw.gov.au)



STROBE Statement—Checklist of items that should be included in reports of ***cohort 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	✓ 4-5
Objectives	3	State specific objectives, including any prespecified hypotheses	✓ 4-5
Methods			
Study design	4	Present key elements of study design early in the paper	✓ 6
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. Describe methods of follow-up	✓ 7-8
		(*b*) For matched studies, give matching criteria and number of exposed and unexposed	-
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	✓ 7-8
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	✓ 6-7
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	✓ 6-8
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	✓ 8-9
		(*b*) Describe any methods used to examine subgroups and interactions	✓ 8-9
		(*c*) Explain how missing data were addressed	✓ 9
		(*d*) If applicable, explain how loss to follow-up was addressed	-
		(*e*) Describe any sensitivity analyses	-
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	✓ 10 Tables
		(b) Give reasons for non-participation at each stage	✓ 10 Tables
		(c) Consider use of a flow diagram	-
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	✓ 10 Tables

		(b) Indicate number of participants with missing data for each variable of interest	✓ tables
		(c) Summarise follow-up time (eg, average and total amount)	-
Outcome data	15*	Report numbers of outcome events or summary measures over time	✓ 10-11 Tables

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 (*b*) Report category boundaries when continuous variables were categorized (*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	✓ Tables 10-11
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	✓ Tables 10-11
Discussion			
Key results	18	Summarise key results with reference to study objectives	✓ 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	✓ 12-13
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	✓ 13-15
Generalisability	21	Discuss the generalisability (external validity) of the study results	✓ 14-15
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	✓ 3

*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 http://www.strobe-statement.org.

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Investigating service delivery and perinatal outcomes during the low prevalence first year of COVID-19 in a multiethnic Australian population: a cohort study

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Investigating service delivery and perinatal outcomes during the low prevalence first year of COVID-19 in a multiethnic Australian population: a cohort study

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Abstract

Objective Investigate the impact of the COVID-19 pandemic on perinatal outcomes in an Australian high migrant and low COVID-19 prevalent population to identify if COVID-19 driven health service changes and societal influences impact obstetric and perinatal outcomes.

Design Retrospective cohort study with pre COVID-19 period 1st January 2018-31st January 2020, and first year of global COVID-19 period 1st February 2020–31st January 2021. Multivariate logistic regression analysis was conducted adjusting for confounders including age, area-level socioeconomic status, gestation, parity, ethnicity and BMI.

Setting Obstetric population attending three public hospitals including a major tertiary referral centre in Western Sydney, Australia.

Participants Women who delivered with singleton pregnancies over 20 weeks gestation. Ethnically diverse women, 66% overseas born. There were 34 103 births in the district that met inclusion criteria: before COVID-19 n=23 722, during COVID-19 n=10 381.

Main outcome measures Induction of labour, caesarean section delivery, iatrogenic and spontaneous preterm birth, small for gestational age (SGA), composite neonatal adverse outcome, and full breastfeeding at hospital discharge.

Results During the first year of COVID-19 there was no change for induction of labour (aOR 0.97; 95% CI 0.92-1.02, p=0.26) and a 25% increase in caesarean section births (aOR 1.25; 95% CI 1.19-1.32, p<0.001). During the COVID-19 period we found no change in iatrogenic preterm births (aOR 0.94; 95% CI 0.80-1.09) but a 15% reduction in spontaneous preterm birth (aOR 0.85; 95% CI 0.75-0.97, p=0.02) and a 10% reduction in SGA infants at birth (aOR 0.90; 95% CI 0.82-0.99, p=0.02). Composite adverse neonatal outcomes were marginally higher (aOR 1.08; 95% CI 1.00-1.15, p=0.04) and full breastfeeding rates at hospital discharge reduced by 15% (aOR 0.85; 95% CI 0.80-0.90, p<0.001).

Conclusion Despite a low prevalence of COVID-19, both positive and adverse obstetric outcomes were observed that may be related to changes in service delivery and interaction with health care providers. Further research is suggested to understand the drivers for these changes.

Keywords: COVID-19, Breastfeeding, Coronavirus, Pandemic, Preterm birth
Word count: 3259

Strengths and limitations of this study

- The analysis provides the opportunity to evaluate the indirect effects of COVID-19 against a background of low COVID-19 prevalence in the local health district with a total of six women with COVID-19 during pregnancy for the study period.
- The cohort comprised of a large ethnically diverse population with similar exposure of restriction experience and service delivery changes.
- Analysis for both iatrogenic and spontaneous preterm birth.
- Missing some COVID-19 related confounders is a limitation such as physical activity levels, prevalence of pregnancy population working from home, or missing planned overseas social support due to international border restrictions.
- A limitation of the study is multiple outcomes were compared however, our results are consistent with several other studies in different populations increasing the veracity of our findings.

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A competing interest statement

All authors declare they have no conflicts of interest for the research presented in this manuscript.

Author contributions

Study designed by SJM, TM, SC, TIA and DP. JE performed the statistical analysis. SJM interpreted the data and wrote the initial and final manuscript drafts with supervision from DP. Invaluable support was given by JE, TM, VWL, NWC, SC, JM, TIA and DP for final interpretation of findings, and critical revision of the article.

Data Availability statement

Institutional restrictions apply to the availability of these data, and so are not publicly available. Data are however available from the corresponding author upon reasonable request and with permission of WSLHD Human Research and Ethics Committee.

INTRODUCTION

In the beginning of 2020, non-pharmaceutical interventions to reduce the spread of COVID-19 led to great changes in society such as lockdowns, enforced movement and travel restrictions.[1 2] There were also many changes to medical and maternity care around the world that are well documented, impacting direct care and social support.[3-6] Initial concerns of the impact of COVID-19 infection on pregnant women focused research on pregnancy outcomes for women who were infected and results varied, findings included increased COVID-19 infection risk in ethnic minorities, and a rise in both preterm and caesarean births.[7-10] More recently perinatal research has assessed the indirect impact of the pandemic,[11] particularly the impact of lockdowns.[12-14] Indirect impact will vary significantly between countries and within country due to diverse drivers such as lockdown experiences, social distancing measures, COVID-19 prevalence, societal compliance, economic and healthcare access.[4 6 15]

Studies of the indirect effects of COVID-19 on pregnancy outcome have shown inconsistent results. A reduction in preterm birth in the general population during the pandemic has been reported by some authors but not others.[12 16-18] Differences in study design and other factors have led some authors to conclude that there is insufficient evidence to determine if preterm birth has been reduced during COVID-19.[19]

Maternity care in Australia during the first year of the pandemic in 2020 experienced a disparate range of changes from very little to significant alterations in service delivery, dependent on population and perceived risk in the community.[3 20] Little evidence exists for the impact of societal and service changes on a culturally diverse obstetric population who initially experienced minimal COVID-19 community transmission, a short lockdown period but experienced significant obstetric service and societal changes due to the pandemic.

In our study population, we hypothesise obstetric outcomes may have been impacted by the rapid changes in hospital service delivery as they shifted focus during the pandemic from patient centred care to preservation of service and staff.[21] Western Sydney with its multicultural population is an ideal environment to examine the indirect effects of the response to the pandemic on perinatal outcomes given the setting of low COVID-19 case numbers. There was a total of 632 cases recorded of COVID-19 in the local health district for the study period. However, considerable preventative measures were implemented in the region including access to telehealth, ability to work from home, restrictions in healthcare settings such as mask wearing and health-screening questions on entry to all hospitals.[22]

We aim to identify indirect and pandemic-related morbidity in our large multi-ethnic Australian population and uncover potential drivers for both improved and adverse maternity care outcomes.

METHODS

We conducted a retrospective cohort study using routinely collected obstetric, medical and administrative data for women seeking antenatal care in the Western Sydney Local Health District. We compared birth outcomes greater than or equal to 20 weeks of gestation in the two years prior to the COVID-19 pandemic to the first year of the COVID-19 pandemic. The study period is defined as pre COVID-19 1st January 2018 – 31st January 2020 to the first twelve months of the COVID-19 pandemic 1st February 2020 – 31st January 2021.

The state of New South Wales (NSW) has a population of approximately 8.2 million.[23] The three study hospitals serve a health district population of approximately one million people. For the study period a total of 39 pregnant women had a confirmed COVID-19 diagnosis in NSW, six of these were in the study health district and none of these were admitted to hospital for COVID-19 complications. There were fewer than 60 COVID-19 related deaths recorded for the total population in NSW in the first year.[24] The prevalence of COVID-19 in the local community was also low (total 632 cases Supp Figure 1).[25]

The study period was determined by the time when public awareness grew in NSW of the impending pandemic with official government announcements and a sharp rise and dominance of media coverage concerning COVID-19 from early February 2020.[26] The study period was after the 30th January 2020 WHO announcement declaring 2019-nCoV virus (COVID-19) as a public health emergency of international concern.[27] Public health order restrictions commenced 16th March 2020 with restrictions on gathering of over 500 people in NSW to reduce the spread of COVID-19. The restrictions escalated on the 30th March 2020, to 'hard lockdown' issuing of public health orders "that a person must not, without reasonable excuse, leave the person's place of residence'.[27] The restrictions were present for approximately 7 weeks easing 15th May, 2020.

The short hard lockdown in NSW, was primarily enforced in greater Sydney, accompanied by increased restrictions and COVID-safe practices including all health facilities women and their families accessed. The restrictions for local maternity services included hospital entrance screening of all patients, staff and visitors including temperature checks, asking about recent travel and symptoms of COVID-19. Within the antenatal service, there was also an introduction of telehealth for the Diabetes in Pregnancy clinics, restrictions on visitors such as allowing only patients in waiting rooms, no support person during ultrasound and only one support person with no changing-over in the birth unit. The potential changes in background stress for women during the peripartum due to these restrictions, reduced social support and service delivery changes may potentially impact perinatal outcomes.[28] During this time there were frequent changes to service delivery and some confusion regarding rules for patients reported by staff at the tertiary referral study Hospital.[21]

Women in the public health sector in NSW are triaged to their nearest public hospital for pregnancy care according to their home address and pregnancy complications. Therefore, during the pandemic period there would be limited changes in referrals pathways for the district obstetric population.

Community activities returned to near normal by July 2020 in NSW, however international and state borders continued to be disrupted with ongoing outbreaks emerging. Restrictions to visitors and other COVID-19 risk mitigation policies remained present for the maternity services throughout the study period. COVID-19 vaccinations were not available in Australia during the study period.

Western Sydney Local Health District human research ethics committee provided ethical approval for this study using deidentified routinely collected administrative data (WSLHD HREC QA2101-15).

Definitions

Routinely collected maternity data for singleton pregnancies greater than 20 weeks gestation was retrieved from the electronic maternal database. Terminations of pregnancy were not included in the database. Gestational age was determined and calculated in the electronic maternity system utilising the rules: use of last menstrual period (LMP) if regular, date was amended after available early ultrasound 6 week - 13+6 weeks gestation. If ultrasound dating varies from LMP by more than 5 days, if irregular or uncertain LMP then ultrasound expected date of delivery (EDD) was used.

Area-level socioeconomic status (SES) in our study was derived from the postcode address of participants during pregnancy as determined for that area by the last Australian census information (2016), informing the Index of Relative Socioeconomic Disadvantage (IRSD). The index is based on households in that area using information on variables that include income, English fluency, education and employment status. A lower index score represents greater disadvantage.[29]

Outcomes of interest

Outcomes of interest were selected based on literature review, state obstetric benchmarking outcomes and outcomes that plausibly may be impacted by service delivery changes. Literature has reported criteria changes in some healthcare setting for induction of labour and overall induction rates changing, therefore we included any induction via any method at all gestations in our outcomes of interest. We defined all vaginal births as one outcome inclusive of breech vaginal births. All preterm births were defined as less than 37 weeks gestation. Spontaneous preterm was defined as vaginal preterm births without an induction or caesarean section preterm births with a history of preterm labour. Iatrogenic preterm births were those initiated by care providers, defined as either a planned caesarean section with no preterm labour or an induction prior to 37 weeks gestation. Small for gestational age (SGA) is birth weight less than 10^{th} centile assessed by the Fenton growth chart.[30] Combined adverse neonatal outcome included any of the following; stillbirth, admission to special care/neonatal intensive care (NICU), Apgar score under 7 at 5 minutes, or newborn resuscitation with intubation.

Data analysis and statistical methods

Demographic and obstetric characteristics of women were compared before and during the first year of COVID-19 using the chi-squared, Fisher's exact, or t-test where appropriate. Univariate logistic regression was applied to each characteristic to estimate unadjusted odds ratios. Then, three adjusted models were devised and implemented using multivariate logistic regression. Model 1 was for maternal characteristics and adjusted for maternal age, area-level socioeconomic status, gestational age (except for the preterm birth outcome), parity, ethnicity, BMI, smoking status and mental health status. Model 2 adjusted for model of pregnancy care and the variables from Model 1. Model 3 adjusted for additional covariates that are clinically relevant for specific outcomes. For the caesarean section birth outcome, birthweight and induction of labour were added to the covariates from Models 1 and 2. For the preterm birth outcome, a composite gestational diabetes/hypertension variable was added to the covariates from Models 1 and 2. For the breastfeeding outcome, mode of delivery, length of stay <24 hours, and preterm birth were added to the covariates form Models 1 and 2. For each model, an adjusted odds ratio with a 95% confidence interval was reported. P values less than 0.05 were considered statistically significant. The cohort was restricted to records with complete data on outcomes of interest. Missing indicator variables were utilised for covariates in the multivariate analyses. All statistical analyses were completed using Stata Special Edition Version 14.2 (StataCorp).

Patient public involvement statement

This retrospective cohort study had no patient public involve in the design or analysis or dissemination of results.

RESULTS

Baseline characteristics

The pre COVID-19 period had a total of 23 722 singleton births and during the first year of COVID-19 (period 1st February 2020–31st January 2021) there were 10 381 singleton births. The principle tertiary referral centre had the greatest number of births in the cohort (n=17 005; 49.9%), with the large secondary hospital comprising of 36.6% (n=12 467) of the cohort.

Women who birthed in the first year of COVID-19 were more likely to be Australian born (35.1% vs 32.9%), overweight or obese (45.8% vs 44.5%), under 35 years old (59.7% vs 50.6%), have a history of a mental illness (15% vs 13%), to present for their first comprehensive antenatal visit at <10 weeks gestation (80.8% vs 64.4%) and less likely to be privately insured (5.9% vs 6.9%) compared to the preceding two years (Table 1). Women were admitted antenatally less often (10.1% vs 12.1%) and women who elected to have an early discharge postpartum at <24 hours, were higher from 15.5% during the pre-COVID period to 19.1% in the first year of COVID-19. Other demographic and pregnancy characteristics are documented in Table 1.

Pregnancy complications and outcomes

There were no differences in overall median gestation age at birth between the two time periods (Table 2). We did observe that the rate of preterm birth was lower during COVID-19 compared to the preceding period (7.2% vs 8.1%). We also observed a higher proportion of births at or after 41 weeks gestation during the first year of COVID-19 (10.0% vs 9.0%). We identified a reduction in all vaginal births (66.6% vs 69.6%) including reduced vaginal breech births (0.7% vs 0.9%). This corresponded with the caesarean section rate increasing during the first year of the COVID-19 pandemic (33.4% vs 30.5%) (Table 2). There was an overall higher rate of induction of labour (35.3% vs 29.9%) and a lower rate of SGA births (6.9% vs 7.8%). We found no change for adverse birth outcomes including for stillbirth (0.9% vs 1.0%) or admissions to special care/neonatal intensive care (16.8% vs 16.2%) (Table 2).

In adjusted analysis no difference was identified for labour inductions during the COVID-19 period compared to the pre-COVID period (aOR 0.97; 95% CI 0.92-1.02). There was a 25% increase in caesarean section births during the pandemic first year in our health district (aOR 1.25; 95% CI 1.19-1.32) (Table 3). The rate of spontaneous preterm births was reduced by 15% (aOR 0.85; 95% CI 0.78-0.95) and no change was found for iatrogenic preterm births (aOR 0.94; 95% CI 0.80-1.09) (Table 3). Adjusted models also uncovered a 10% reduction for SGA infants at birth during the COVID-19 period (aOR 0.90; 95% CI 0.82-0.99). We found a marginal increase for a combined adverse neonatal outcome during the COVID-19 period (aOR 1.08; 95% CI 1.00-1.15) (Table 3).

In our study population, the first year of the pandemic impacted breastfeeding when compared to the previous two years. When adjusted for several confounders including birthweight, mode of delivery, and prematurity, we found a 15% reduction for women fully breastfeeding their infant at discharge (aOR 0.85; 95% CI 0.80-0.90) (Table 3). There was no difference in effect size between model 1 and the fully adjusted model that included birthweight, mode of delivery, length of stay <24 hours and gestational age/preterm variable. Notably, there was a higher rate during the COVID-19 period in both breastfeeding within one hour (61.9% vs 60.5%, p=0.02) after birth and maternal/infant skin to skin contact at birth (76.7% vs 69.4%, p=0.02) (Table 2).

DISCUSSION

In a health district with low COVID-19 prevalence but affected by public health measures and process changes to service delivery, we found no differences in the rate of induction of labour, a reduction in spontaneous preterm and SGA births with no change in iatrogenic preterm births during the first year of COVID-19. There was also a significant increase in caesarean section births and a reduction in women fully breastfeeding at hospital discharge during this period compared to the previous two years. We identified a marginal increase in the rate of severe adverse neonatal composite outcome. In the study population only six women were recorded to have experienced COVID-19 infection during pregnancy therefore the outcome changes identified in this study are likely related to the indirect effects of COVID-19.

A strength of the study is the population experienced similar exposure to COVID-19 restrictions and maternity care service delivery changes. The multiethnic population with an even distribution between national SES quintiles strengthens the generalisability of our findings to other high-income populations with universal health coverage such as the United Kingdom. A more homogenous population may provide a possible explanation of changes to be specific cultural drivers however the diversity of the study population supports the explanation to likely be societal and service delivery related. A limitation is the difficulty of identifying all changing population drivers however adjustment was made for known factors.

There may have been other confounders we were not able to capture that may impact on obstetric outcomes such as level of physical activity. Potentially some women may have benefited from more time to exercise with associated reduced infection risk through exercise-mediated protective immune response[31], while other women who felt unwell may have had the opportunity to rest at home. There may potentially be a uniquely cumulative improved immune environment for pregnant women during the COVID-19 period. Underlying factors such as consistent diet stabilising the microbiome and less maternal inflammatory triggers or burden from exposure to environmental and infectious factors may be the reason for improved spontaneous preterm birth rate and SGA outcomes.

It is difficult to capture individual responses to the threat of COVID-19 despite low prevalence in the community for this cohort. However, recent qualitative research at one study hospital found clinicians felt some groups of women benefited from the COVID-19 restrictions with less stress and protected family time. However, migrant women were seen to have experienced isolation and anxiety due to loss of significant practical and social support from overseas relatives unable to visit due to COVID-19 related international border closures.[21 32] The impact of the loss of expected support from relatives due to COVID-19 travel restrictions was not measured in our study and is a limitation.

Similar to other studies, we document a reduction in preterm birth.[12 17 18 33] The lack of delineation between iatrogenic and spontaneous preterm birth in some research has been an issue when comparing results and attempts to identify potential drivers.[19] A strength of our study is we were able to present the data and identified that only spontaneous preterm birth was reduced for the study period. However recent updated preterm birth meta-analysis by Yang et al found in unadjusted analysis preterm birth was reduced for both spontaneous and iatrogenic only in single centre studies, but not in national studies.[6] Local district level data and population characteristics may have less variation in obstetric service delivery confounders and other factors that increase the uniformity of experience for women and may account for the difference between large national level data and some single centre research. Local, more granular data for obstetric outcomes during the COVID-19 pandemic may assist in understanding drivers for improved and adverse obstetric outcomes. The stable iatrogenic preterm birth rate is a positive finding and reflects no change in clinical management for this important obstetric outcome. This may partly be associated with the ongoing understanding of the adverse outcomes associated with late preterm births and recent national initiatives such as 'every week counts' that has occurred over the study period.[34]

Shah et al in a Canadian population study, found no reduction in preterm births however, they did demonstrate preterm birth variation over time and between districts.[35] Our study covers the complete first year of the pandemic, reducing the possibility of a result based on a chance normal short-term variation.

It has been postulated that the causative mechanism for a reduction in preterm births during the COVID-19 period is reduced infection and maternal physical activity throughout lockdown.[36] In our population, these potential causative factors for a reduction in spontaneous preterm birth, may have existed in our health district during the short lockdown and likely persisted beyond the lockdown period. Some infection mitigation behaviours may have been driven by our high migrant population who received advice from overseas relatives in areas experiencing high rates of COVID-19. Encouraging suitable exercise[31] and simple hygiene measures such as appropriate hand washing, are public health measures that may reduce infection. Hand hygiene historically has been poorly done and with increased awareness and compliance, may assist with decreasing preterm births.[37 38]

We found women were presenting earlier to their family doctors for a first pregnancy visit and referral to tertiary hospital care. This may have been due to anxiety about the pregnancy and the unknown risk of COVID-19 infection to a fetus. The benefits of this early health provider contact may be correct dietary advice, provide opportunity for early aspirin prescription and other pregnancy care that may contribute to some of the improved pregnancy outcomes including preterm birth and SGA for this cohort. It is possible that the drivers for the reduction of spontaneous preterm birth and SGA are similar and multifactorial. They may include the opportunity for partners and pregnant women to work from home with the associated reduction in stress.

The increase in caesarean section births in this study is a concerning finding that may indicate changes in clinical decision making during the COVID-19 period of a lower threshold trigger for immediate delivery. However other factors may also be involved such as less surveillance during pregnancy with maternal reluctance to present or be in hospitals as demonstrated by the increase in early discharge. Another human factor that may be involved in the rise in caesarean section birth is the difficulty of midwives in birth unit to develop a rapport with the women in their care to adequately assess their non-verbal cues, recent studies have identified midwives report a loss of 'women-centred care' during the COVID-19 pandemic.[20 21] Clinician may rely more on electronic 'socially distant' continuous cardiotocography (CTG) monitoring for fetal assessment. Evidence suggests increased CTG monitoring leads to higher caesarean section rates.[39 40] The increase in caesarean section births also have known immediate and long-term associated morbidity for women and their infants, therefore measures to counter the rise in caesarean births are recommended.[41]

There was a marginal increase in the composite adverse neonatal outcome largely driven by the increase in neonatal admissions. Although it is beyond the scope of this study to determine the causes for the increased admission, there was no alteration in admission criteria for the neonatal or special care nursery during the study period. However, the increase in caesarean birth may have contributed through the associated known increased risk of NICU admission with a caesarean section birth.[41 42]

Similar to our study, a prospective Italian study found a 28% reduction in full breastfeeding at discharge in a region with high COVID-19 prevalence.[43] We identified that during the COVID-19 period there was an improvement in practices that support breastfeeding immediately after birth; maternal-infant skin to skin contact and breastfeeding within the first hour. Birth unit protocols changed during the COVID-19 period, with only one support person allowed at the birth. The improvement in skin to skin and breastfeeding in the first hour may potentially be due to midwives identifying that woman were feeling more isolated and provided more one-to one support in the birth room improving these important breastfeeding outcomes. There may be several factors that contribute to less exclusive breastfeeding at discharge in our study. Intuitively the reduction in breastfeeding should be linked with the increase in early discharge however the 25% reduction in full breastfeeding was present for both model 2 and the final model that adjusted for variables including early discharge. Other factors are therefore more likely influencing this outcome. Due to reduced visitors, women may have felt they needed to bring formula into the hospital in case they had difficulty with breastfeeding, therefore it was available and more likely to be used. There may also have been reduced opportunities for staff to provide postnatal breastfeeding support due to concerns of COVID-19 infection risk by both staff and patients, staffing shortages and increased staff workload during the COVID-19 period. It is well acknowledged the introduction of formula and bottle feeding in the early postnatal period has significant consequences for infant long-term health and reduces total length of breastfeeding.[44-46] Providing adequate lactation support antenatally, at birth and postnatally with staff shortages during the pandemic is problematic but important for both short-term and long-term metabolic maternal and infant health.[44 47 48]

Although recent literature has focused on the impact of COVID-19 disease and pregnancy, the indirect impact of the world-wide pandemic may not be fully realised for many years. There is increasing evidence of the impact of exposure to disasters including pandemics, on long term health consequences. A recent systematic review concluded fetal and maternal exposure to natural disasters including pandemics resulted in increased cardiometabolic risk in both.[49] Understanding a pandemic population with a low prevalence of COVID-19 but subject to changes in maternity care and societal stress, may assist in future investigations of drivers for cardiometabolic health.

CONCLUSIONS

In a low COVID-19 prevalent population this study found no change in inductions of labour or iatrogenic preterm births. However, an increase in caesarean section births, a reduction in SGA and spontaneous preterm births was identified. The benefit to women, their families and the community of reduced SGA and preterm birth is long lasting, including improved cardiometobolic lifetime risk for both women and their infants.[42] The drivers for these changes in perinatal outcomes during the COVID-19 first year may be difficult to identify but may be a reduction in maternal inflammatory triggers. However, the results from this study in a cohort primarily exposed only to COVID-19 related service and societal changes, provides unique opportunity to generate evidence of these changes on pregnancy complications. The significant reduction in breastfeeding at discharge may be more easily addressed now identified. Funding appropriate intervention strategies is imperative both in the antenatal and postnatal periods to improve breastfeeding outcomes. Revealing all drivers for obstetric changes during the pandemic may be difficult to ascertain, further research in this high migrant cohort with higher prevalence of COVID-19 cases may reveal evidence for more specific drivers.

References

1. Suryanarayanan P, Tsou CH, Poddar A, et al. AI-assisted tracking of worldwide non-pharmaceutical interventions for COVID-19. *Sci Data* 2021;**8**(1):94. doi: 10.1038/s41597-021-00878-y
2. Haug N, Geyrhofer L, Londei A, et al. Ranking the effectiveness of worldwide COVID-19 government interventions. *Nat Hum Behav* 2020;**4**(12):1303-12. doi: 10.1038/s41562-020-01009-0
3. Bradfield Z, Wynter K, Hauck Y, et al. Experiences of receiving and providing maternity care during the COVID-19 pandemic in Australia: A five-cohort cross-sectional comparison. *PLoS One* 2021;**16**(3):e0248488. doi: 10.1371/journal.pone.0248488
4. Cutler DM, Summers LH. The COVID-19 Pandemic and the $16 Trillion Virus. *JAMA* 2020;**324**(15):1495-96. doi: 10.1001/jama.2020.19759
5. Pak A, Adegboye OA, Adekunle AI, et al. Economic Consequences of the COVID-19 Outbreak: the Need for Epidemic Preparedness. *Frontiers in Public Health* 2020;**8**(241) doi: 10.3389/fpubh.2020.00241
6. Yang J, D'Souza R, Kharrat A, et al. Coronavirus disease 2019 pandemic and pregnancy and neonatal outcomes in general population: A living systematic review and meta-analysis (updated Aug 14, 2021). *Acta Obstet Gynecol Scand* 2021 doi: 10.1111/aogs.14277
7. Acosta AM, Garg S, Pham H, et al. Racial and Ethnic Disparities in Rates of COVID-19–Associated Hospitalization, Intensive Care Unit Admission, and In-Hospital Death in the United States From March 2020 to February 2021. *JAMA Network Open* 2021;**4**(10):e2130479-e79. doi: 10.1001/jamanetworkopen.2021.30479
8. Agyemang C, Richters A, Jolani S, et al. Ethnic minority status as social determinant for COVID-19 infection, hospitalisation, severity, ICU admission and deaths in the early phase of the pandemic: a meta-analysis. *BMJ Global Health* 2021;**6**(11):e007433. doi: 10.1136/bmjgh-2021-007433
9. Matar R, Alrahmani L, Monzer N, et al. Clinical Presentation and Outcomes of Pregnant Women With Coronavirus Disease 2019: A Systematic Review and Meta-analysis. *Clin Infect Dis* 2021;**72**(3):521-33. doi: 10.1093/cid/ciaa828
10. Papapanou M, Papaioannou M, Petta A, et al. Maternal and Neonatal Characteristics and Outcomes of COVID-19 in Pregnancy: An Overview of Systematic Reviews. *Int J Environ Res Public Health* 2021;**18**(2) doi: 10.3390/ijerph18020596
11. Du M, Yang J, Han N, et al. Association between the COVID-19 pandemic and the risk for adverse pregnancy outcomes: a cohort study. *BMJ Open* 2021;**11**(2):e047900. doi: 10.1136/bmjopen-2020-047900
12. Been JV, Burgos Ochoa L, Bertens LCM, et al. Impact of COVID-19 mitigation measures on the incidence of preterm birth: a national quasi-experimental study. *The Lancet Public Health* 2020;**5**(11):e604-e11. doi: https://doi.org/10.1016/S2468-2667(20)30223-1
13. Gallo LA, Gallo TF, Borg DJ, et al. A decline in planned, but not spontaneous, preterm birth rates in a large Australian tertiary maternity centre during COVID-19 mitigation measures. *Aust N Z J Obstet Gynaecol*;**n/a**(n/a) doi: https://doi.org/10.1111/ajo.13406
14. Rolnik DL, Matheson A, Liu Y, et al. Impact of COVID-19 pandemic restrictions on pregnancy duration and outcome in Melbourne, Australia. *Ultrasound Obstet Gynecol* 2021;**58**(5):677-87. doi: https://doi.org/10.1002/uog.23743
15. Nam SH, Nam JH, Kwon CY. Comparison of the Mental Health Impact of COVID-19 on Vulnerable and Non-Vulnerable Groups: A Systematic Review and Meta-Analysis of Observational Studies. *Int J Environ Res Public Health* 2021;**18**(20) doi: 10.3390/ijerph182010830

16. Bian Z, Qu X, Ying H, et al. Are COVID-19 mitigation measures reducing preterm birth rate in China? *BMJ Glob Health* 2021;**6**(8) doi: 10.1136/bmjgh-2021-006359
17. Chmielewska B, Barratt I, Townsend R, et al. Effects of the COVID-19 pandemic on maternal and perinatal outcomes: a systematic review and meta-analysis. *Lancet Glob Health* 2021;**9**(6):e759-e72. doi: 10.1016/s2214-109x(21)00079-6
18. Kirchengast S, Hartmann B. Pregnancy Outcome during the First COVID 19 Lockdown in Vienna, Austria. *Int J Environ Res Public Health* 2021;**18**(7) doi: 10.3390/ijerph18073782
19. Goldenberg RL, McClure EM. Have Coronavirus Disease 2019 (COVID-19) Community Lockdowns Reduced Preterm Birth Rates? *Obstet Gynecol* 2021;**137**(3):399-402. doi: 10.1097/AOG.0000000000004302
20. Bradfield Z, Hauck Y, Homer CSE, et al. Midwives' experiences of providing maternity care during the COVID-19 pandemic in Australia. *Women Birth* 2022;**35**(3):262-71. doi: 10.1016/j.wombi.2021.02.007
21. Melov SJ, Galas N, Swain J, et al. Exploring the COVID-19 pandemic experience of maternity clinicians in a high migrant population and low COVID-19 prevalence country: a qualitative study. *Women and Birth* 2021 doi: https://doi.org/10.1016/j.wombi.2021.10.011
22. WSLHD. Year In Review 2019/2020: Protecting and growing our people: WSLHD; 2020 Available from: file:///C:/Users/seren/Downloads/NSW%20Health_WSLHD_Year%20in%20Review_2019-20.pdf.
23. Key Facts about NSW. NSW Government. Available from: https://www.nsw.gov.au/about-nsw/key-facts-about-nsw#toc-population
24. NSW Govenment. COVID-19 weekly surveillance in NSW, Epidemiology week 4, Ending 30 January 2021 Available from: https://www.health.nsw.gov.au/Infectious/covid-19/Documents/covid-19-surveillance-report-20210130.pdf
25. NSW Government. NSW COVID-19 data Available from: https://data.nsw.gov.au.
26. Nolan D, Hanna, C., McGuinness, K. and McCallum, K. . Covering COVID-19: How Australian Media reported the Coronavirus pandemic in 2020. In: Centre NMR, ed. Canberra: University of Canberra., 2021.
27. World Health Organisation. Statement on the second meeting of the International Health Regulations (2005) Emergency Committee regarding the outbreak of novel coronavirus (2019-nCoV) 2020 Available from: https://www.who.int/news/item/30-01-2020-statement-on-the-second-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-(2019-ncov).
28. Traylor CS, Johnson JD, Kimmel MC, et al. Effects of psychological stress on adverse pregnancy outcomes and nonpharmacologic approaches for reduction: an expert review. *American Journal of Obstetrics & Gynecology MFM* 2020;**2**(4):100229. doi: https://doi.org/10.1016/j.ajogmf.2020.100229
29. Australian Bureau of Statistics. Census of Population and Housing: Socio-Economic Indexes for Areas (SEIFA), Australia, 2016 Canberra: Australian Government; 2018 Available from: https://www.abs.gov.au/ausstats/abs@.nsf/Lookup/by%20Subject/2033.0.55.001~2016~Main%20Features~IRSD~19
30. Fenton TR, Nasser R, Eliasziw M, et al. Validating the weight gain of preterm infants between the reference growth curve of the fetus and the term infant. *BMC Pediatr* 2013;**13**:92. doi: 10.1186/1471-2431-13-92
31. Scheffer DdL, Latini A. Exercise-induced immune system response: Anti-inflammatory status on peripheral and central organs. *Biochim Biophys Acta Mol Basis Dis* 2020;**1866**(10):165823-23. doi: 10.1016/j.bbadis.2020.165823
32. Melov SJ, Hitos K. Venous thromboembolism risk and postpartum lying-in: Acculturation of Indian and Chinese women. *Midwifery* 2018;**58**:13-18. doi: 10.1016/j.midw.2017.11.006

33. Einarsdóttir K, Swift EM, Zoega H. Changes in obstetric interventions and preterm birth during COVID-19: A nationwide study from Iceland. *Acta Obstet Gynecol Scand* 2021;**100**(10):1924-30. doi: https://doi.org/10.1111/aogs.14231
34. Women and Babies Research KI. Every Week Counts: The University of Sydney; 2020 [Available from: https://everyweekcounts.com.au/.
35. Shah PS, Ye XY, Yang J, et al. Preterm birth and stillbirth rates during the COVID-19 pandemic: a population-based cohort study. *CMAJ* 2021;**193**(30):E1164-e72. doi: 10.1503/cmaj.210081
36. Hedermann G, Hedley PL, Bækvad-Hansen M, et al. Danish premature birth rates during the COVID-19 lockdown. *Arch Dis Child Fetal Neonatal Ed* 2021;**106**(1):93-95. doi: 10.1136/archdischild-2020-319990
37. Freeman MC, Stocks ME, Cumming O, et al. Hygiene and health: systematic review of handwashing practices worldwide and update of health effects. *Trop Med Int Health* 2014;**19**(8):906-16. doi: 10.1111/tmi.12339
38. Wolf J, Johnston R, Freeman MC, et al. Handwashing with soap after potential faecal contact: global, regional and country estimates. *Int J Epidemiol* 2019;**48**(4):1204-18. doi: 10.1093/ije/dyy253
39. Devane D, Lalor JG, Daly S, et al. Cardiotocography versus intermittent auscultation of fetal heart on admission to labour ward for assessment of fetal wellbeing. *Cochrane Database Syst Rev* 2017;**1**(1):Cd005122. doi: 10.1002/14651858.CD005122.pub5
40. Alfirevic Z, Devane D, Gyte GM, et al. Continuous cardiotocography (CTG) as a form of electronic fetal monitoring (EFM) for fetal assessment during labour. *Cochrane Database Syst Rev* 2017;**2**(2):Cd006066. doi: 10.1002/14651858.CD006066.pub3
41. Antoine C, Young BK. Cesarean section one hundred years 1920–2020: the Good, the Bad and the Ugly. *J Perinat Med* 2021;**49**(1):5-16. doi: doi:10.1515/jpm-2020-0305
42. Li Y, Zhang C, Zhang D. Cesarean section and the risk of neonatal respiratory distress syndrome: a meta-analysis. *Arch Gynecol Obstet* 2019;**300**(3):503-17. doi: 10.1007/s00404-019-05208-7
43. Latorre G, Martinelli D, Guida P, et al. Impact of COVID-19 pandemic lockdown on exclusive breastfeeding in non-infected mothers. *Int Breastfeed J* 2021;**16**(1):36. doi: 10.1186/s13006-021-00382-4
44. Victora CG, Bahl R, Barros AJ, et al. Breastfeeding in the 21st century: epidemiology, mechanisms, and lifelong effect. *Lancet* 2016;**387**(10017):475-90. doi: 10.1016/s0140-6736(15)01024-7
45. Ávila-Ortiz MN, Castro-Sánchez AE, Martínez-González EA, et al. Factors associated with abandoning exclusive breastfeeding in Mexican mothers at two private hospitals. *Int Breastfeed J* 2020;**15**(1):73. doi: 10.1186/s13006-020-00316-6
46. Batista CLC, Ribeiro VS, Nascimento M, et al. Association between pacifier use and bottle-feeding and unfavorable behaviors during breastfeeding. *J Pediatr (Rio J)* 2018;**94**(6):596-601. doi: 10.1016/j.jped.2017.10.005
47. Melov SJ, White L, Simmons M, et al. The BLIiNG study - Breastfeeding length and intensity in gestational diabetes and metabolic effects in a subsequent pregnancy: A cohort study. *Midwifery* 2022;**107**:103262. doi: 10.1016/j.midw.2022.103262
48. Tschiderer L, Seekircher L, Kunutsor SK, et al. Breastfeeding Is Associated With a Reduced Maternal Cardiovascular Risk: Systematic Review and Meta-Analysis Involving Data From 8 Studies and 1 192 700 Parous Women. *J Am Heart Assoc* 2022;**11**(2):e022746. doi: 10.1161/jaha.121.022746
49. De Rubeis V, Lee J, Anwer MS, et al. Impact of disasters, including pandemics, on cardiometabolic outcomes across the life-course: a systematic review. *BMJ Open* 2021;**11**(5):e047152. doi: 10.1136/bmjopen-2020-047152

Table 1. Women with a singleton pregnancy: maternal demographic characteristics and pregnancy outcomes first year of COVID-19 compared to pre-COVID in a NSW metropolitan health district
Pre-COVID-19 = 1st January 2018 – 31st January 2020 COVID-19 = 1st February 2020 – Jan 31st 2021

Characteristics	Pre-COVID-19 n = 23,722 N (%)	COVID-19 n = 10,381 N (%)	P value
Clinical & demographic characteristics			
Maternal age group years			
<20	38 (0.2)	46 (0.4)	<0.001
20-24	614 (2.6)	452 (3.1)	
25-34	11 335(47.8)	5 835 (56.2)	
35-39	8 939 (37.7)	3 335 (32.1)	
>39	2 796 (11.8)	713 (6.9)	
Ethnicity			
South Asian	6047 (25.5)	2 950 (28.4)	<0.001
Caucasian/European	3 307 (13.9)	1 886 (18.1)	
South-East Asian	3249 (13.7)	1 357 (13.1)	
Middle Eastern	8116 (34.2)	3827 (36.9)	
Aboriginal Torres Strait Islander	338 (1.4)	188 (1.8)	
Unknown/missing§	2665 (11.2)	173 (1.7)	
Australian born	7 809 (32.9)	3 648 (35.1)	<0.001
SES disadvantage			
Quintile 1 (most disadvantaged)	5 367 (22.7)	2 361 (22.8)	0.04
Quintile 2	5 721 (24.1)	2 568 (24.8)	
Quintile 3	3 508 (14.8)	1 494 (14.4)	
Quintile 4	3 291 (13.9)	1 528 (14.7)	
Quintile 5 (least disadvantaged)	5 809 (24.6)	2 416 (23.3)	
BMI (kg/m2) at booking			
<18.50	1 116 (4.7)	417 (4.5)	0.02
18.5–24.9	11 981 (50.5)	5 207 (50.2)	
25.0–29.9	6 317 (26.3)	2 875 (27.3)	
≥30.0	4 308 (18.2)	1 922 (18.5)	
Nulliparous	10 331 (43.6)	4 475 (43.1)	0.45
Assisted conception	1 050 (4.4)	471 (4.5)	0.65
Current smoking at booking	1 380 (5.8)	619 (6.0)	0.60
Disclosed domestic violence	340 (1.5)	141 (1.5)	0.69
Diagnosed mental illness	3 083 (13.0)	1 552 (15.0)	<0.001
History of hypertension	844 (3.6)	327 (3.2)	0.06
History of diabetes (T1DM T2DM)	265 (1.3)	114 (1.3)	0.93
History of gestational diabetes	1,555 (6.6)	738 (7.1)	0.06
Health service characteristics			
< 10 weeks gestation first comprehensive assessment	15,221 (64.4)	8,360 (80.8)	<0.001
Model of care			
Low risk hospital	15,210 (64.1)	6,768 (65.2)	<0.01
Hospital complex medical	6 775 (28.6)	3,096 (29.4)	
Private maternity	1 635 (6.9)	611 (5.9)	

No antenatal care	102 (0.4)	38 (0.4)	
Antenatal admission to hospital	2 863 (12.1)	1 044 (10.1)	<0.001
Postnatal maternal length of stay < one day	3 674 (15.5)	2 000 (19.1)	<0.001
Postnatal maternal length of stay (days, median IQR)	2.02 (1.51)	2.00 (1.68)	<0.001

SES = Socio Economic Status (Index of Relative Socio-economic Disadvantage)
Low risk hospital: Midwifery care and shared antenatal care (General Practitioner/family doctor); Hospital complex medical care: Hospital based medical and high-risk clinic; Private maternity care: Obstetrician & privately practicing midwife
§ missing due to ethnicity as routine collection introduced mid-2018

Table 2. Pregnancy outcomes in a low-prevalence COVID-19 high-migrant Australian urban population:
Pre-COVID = 1st January 2018 – 31stJanuary 2020 COVID-19 =1st February 2020 – Jan 31st 2021

Pregnancy complications	**Pre-COVID-19 N=23 722 N (%)**	**COVID-19 n = 10 381 N (%)**	**P value**
Timing of birth			
Gestational age (weeks) median (IQR)	39.2 (1.8)	39.2 (1.8)	0.25
<28 weeks	301 (1.3)	128 (1.2)	<0.001
28-32 weeks	232 (1.0)	84 (0.8)	
<37 weeks	1 439 (6.1)	539 (5.2)	
37+ weeks	21 748 (91.7)	9 630 (92.8)	
Mode of delivery			
Vaginal birth	13 931 (58.8)	5 819 (56.1)	<0.001
Instrumental	2 340 (9.9)	1 016 (9.8)	
Vaginal breech	204 (0.9)	76 (0.7)	
Caesarean section	7 224 (30.5)	3 465 (33.4)	
Onset of labour			
Induction	7 095 (29.9)	3 666 (35.3)	<0.001
Birth weight			
Appropriate for gestational age	20 071 (85.1)	28 884 (85.5)	0.39
Large for gestational age	1 676 (7.1)	784 (7.6)	0.11
Small for gestational age	1 832 (7.8)	713 (6.9)	0.01
Adverse birth outcomes			
Stillbirth	227 (1.0)	95 (0.9)	0.71
Apgar <7 at 5mins	662 (2.8)	257 (2.5)	0.10
Intubation resuscitation at birth	262 (1.1)	100 (1.0)	0.24
Admission to NICU	3 851 (16.2)	1 743 (16.8)	0.23
Composite adverse neonatal			
	4 261 (18.2)	1 907 (18.3)	0.41
Neonatal feeding			
Skin to skin at birth	16 454 (69.4)	7 961 (76.7)	0.02
Feeding within 1 hour	14 353 (60.5)	6 424 (61.9)	0.02
Fully breastfeeding at discharge	15 620 (65.8)	6 410 (62.1)	<0.001

Composite adverse neonatal includes any: stillbirth, admission to NICU, Apgar score under 7 at 5 minutes, or newborn resuscitation with intubation.

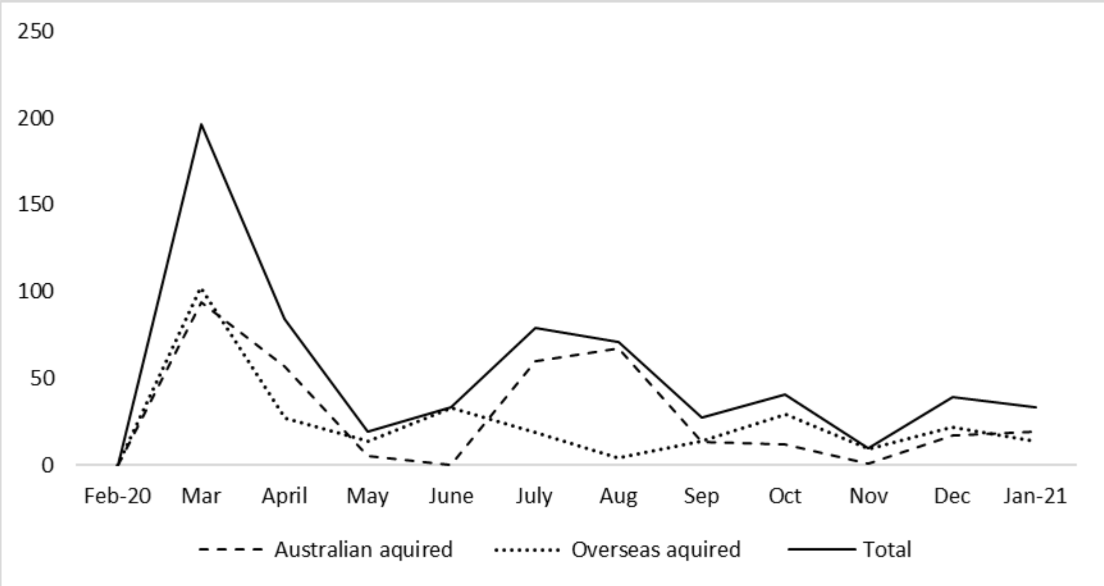
Table 3.
Odds ratio for maternal and neonatal pregnancy outcomes during the first year of COVID-19 compared to the previous two years in an Australian metropolitan health district
COVID = 1st February 2020 – Jan 31st 2021(n=10 381) Pre-COVID = 1st January 2018 – 31st January 2020 (n=23 722)

Outcome	Sample Size	Unadj. OR	P	Model 1 OR	P	Model 2 OR	P	Model 3 OR	P
Induction of labour	34,082	0.90 (0.86,0.94)	<0.001	0.97 (0.92,1.02)	0.30	0.97 (0.92,1.02)	0.26	-	-
Caesarean birth	34,063	1.14 (1.09,1.20)	<0.001	1.24 (1.17,1.30)	<0.001	1.23 (1.17,1.30)	<0.001	1.25 (1.19,1.32)	<0.001
Preterm birth	34,080	0.86 (0.79,0.94)	0.00	0.91 (0.83,0.99)	0.05	0.91 (0.83,0.99)	0.03	0.88 (0.80,0.97)	0.01
Spontaneous preterm birth	34,080	0.76 (0.67,0.85)	<0.001	0.88 (0.77,0.99)	0.04	0.88 (0.77,0.99)	0.04	0.85 (0.75,0.97)	0.02
Small for gestational age at birth	33,880	0.88 (0.81,0.96)	0.01	0.90 (0.82,0.99)	0.03	0.90 (0.82,0.99)	0.02	-	-
Composite adverse neonatal outcome	33,632	1.03 (0.97,1.09)	0.38	1.08 (1.00,1.15)	0.03	1.08 (1.00,1.15)	0.04	-	-
Full breastfeeding at hospital discharge	31,113	0.86 (0.81,0.90)	<0.001	0.85 (0.80,0.90)	<0.001	0.85 (0.81,0.90)	<0.001	0.85 (0.80,0.90)	<0.001

Composite adverse neonatal includes any: stillbirth, admission to NICU, Apgar score under 7 at 5 minutes, or newborn resuscitation with intubation.
Variables adjusted for in each model:
Model 1 Maternal characteristics: Includes maternal age, area-level socioeconomic status SEIFA disadvantage quintile, gestational age, parity, ethnicity, BMI (numeric), smoking status, and mental health status.
Model 2 Model of care: Model 1 variables and model of pregnancy care variable.
For preterm birth outcome the models are not adjusted for gestational age.
Model 3 Outcome of interest: Includes Model 1 and 2 covariates and additional covariates as listed below.
Caesarean section birth: birthweight and induction of labour.
Preterm birth: composite maternal complications variable (gestational diabetes or hypertensive disorders of pregnancy).
Breastfeeding: birthweight, mode of delivery, length of stay <24 hours and gestational age/preterm.

Supplementary Figure 1

Total COVID-19 cases during study period 1st Feb 2020 – Jan 31st 2021 Western Sydney Local Health District, NSW Australia; total cases 632 (open source data https://data.nsw.gov.au)



STROBE Statement—Checklist of items that should be included in reports of ***cohort 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	✓ 4-5
Objectives	3	State specific objectives, including any prespecified hypotheses	✓ 4-5
Methods			
Study design	4	Present key elements of study design early in the paper	✓ 6
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. Describe methods of follow-up	✓ 7-8
		(*b*) For matched studies, give matching criteria and number of exposed and unexposed	-
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	✓ 7-8
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	✓ 6-7
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	✓ 6-8
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	✓ 8-9
		(*b*) Describe any methods used to examine subgroups and interactions	✓ 8-9
		(*c*) Explain how missing data were addressed	✓ 9
		(*d*) If applicable, explain how loss to follow-up was addressed	-
		(*e*) Describe any sensitivity analyses	-
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	✓ 10 Tables
		(b) Give reasons for non-participation at each stage	✓ 10 Tables
		(c) Consider use of a flow diagram	-
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	✓ 10 Tables

		(b) Indicate number of participants with missing data for each variable of interest	✓ tables
		(c) Summarise follow-up time (eg, average and total amount)	-
Outcome data	15*	Report numbers of outcome events or summary measures over time	✓ 10-11 Tables

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 (*b*) Report category boundaries when continuous variables were categorized (*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	✓ Tables 10-11
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	✓ Tables 10-11
Discussion			
Key results	18	Summarise key results with reference to study objectives	✓ 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	✓ 12-13
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	✓ 13-15
Generalisability	21	Discuss the generalisability (external validity) of the study results	✓ 14-15
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	✓ 3

*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 http://www.strobe-statement.org.