Born into an isolating world: family-centred care for babies born to mothers with COVID-19

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Summary

Background **The benefits of facilitating breastmilk feeding and close contact between mother and neonate (family-centred care; FCC) in the perinatal period are well-established. The aim of this study was to determine how the delivery of FCC practices were impacted for neonates born to mothers with perinatal SARS-CoV-2 infection during the COVID-19 pandemic.**

Methods **Neonates born to mothers with confirmed SARS-CoV-2 infection during pregnancy were identified from the 'EsPnIC Covid paEdiatric NeonaTal REgistry' (EPICENTRE) multinational cohort between 10 March 2020 and 20 October 2021. The EPICENTRE cohort collected prospective data on FCC practices. Rooming-in and breastmilk feeding practice were the main outcomes, and factors influencing each were determined. Other outcomes included mother-baby physical contact prior to separation and the pattern of FCC components relative to time and local site guidelines.**

Findings **692 mother-baby dyads (13 sites, 10 countries) were analysed. 27 (5%) neonates were positive for SARS-CoV-2 (14 (52%) asymptomatic). Most sites had policies that encouraged FCC during perinatal SARS-CoV-2 infection for most of the reporting period. 311 (46%) neonates roomed-in with their mother during the admission. Rooming-in increased over time from 23% in March–June 2020 to 74% in January–March 2021 (boreal season). 330 (93%) of the 369 separated neonates had no FCC physical contact with their mother prior, and 319 (86%) were asymptomatic. Maternal breastmilk was used for feeding in 354 (53%) neonates, increasing from 23% to 70% between March–June 2020 and January–March 2021. FCC was most impacted when mothers had symptomatic COVID-19 at birth.**

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Interpretation This is the largest report of global FCC practice during the COVID-19 pandemic to date. The COVID-19 pandemic may have impacted FCC despite low perinatal transmission rates. Fortunately, clinicians appear to have adapted to allow more FCC delivery as the COVID-19 pandemic progressed.

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Keywords: Breastfeeding; Breastmilk; COVID-19; Family-centred care; Mother-baby contact; Pandemic; Perinatal care; Rooming-in; SARS-CoV-2; Skin-to-skin care

Research in context

Evidence before this study

Family-centred care (FCC) practices such as breastfeeding, co-habitation and skin-to-skin contact are critical to the well-being of mothers and neonates, even those needing intensive care. Most COVID-19 pandemic neonatal guidelines are based on expert consensus rather than evidence. Fortunately, neonatal SARS-CoV-2 infection is rare, and most neonates asymptomatic. Despite this, parental surveys suggest that FCC was significantly impacted for neonates born during the COVID-19 pandemic.

Added value of this study

We analysed detailed FCC data collected from 692 neonates born to mothers with SARS-CoV-2 during pregnancy in 13 NICU services in 10 countries participating in the international, prospective EsPnIC Covid paEdiatric NeonaTal (EPICENTRE) registry to determine real-world FCC practices. Neonatal SARS-CoV-2 infection was rare (5%). We found that although FCC practices were encouraged, separation of mother and neonate (54%) and avoidance of maternal breastmilk (47%) were common, even when neonates were asymptomatic. Separation and lack of maternal breastmilk feeding were associated with severity of maternal COVID-19 at delivery, caesarean section birth and preterm birth. This highlights the challenges the pandemic posed for the delivery of FCC. Fortunately, healthcare services evolved practice, with rooming-in and maternal breastmilk feeding rates increasing as the pandemic progressed.

Implications of all the available evidence

Although perinatal SARS-CoV-2 infection is low, the potential impact to neonates may arise from altered best-practice maternity care. FCC impacts should be considered when developing infection control guidelines. Despite our findings, we identified that FCC could be successfully applied when a mother is severely ill.

Introduction

The benefits of family-centred care (FCC) are well-established and an increasing focus of both postnatal and neonatal intensive care unit (NICU) practice. FCC practices facilitate early and close contact between parents and neonates via co-habitation ('rooming-in'), breastfeeding and skin-to-skin care (SSC). The advantages of breastfeeding are well-understood,[1] and rooming-in improves breastfeeding rates.[2] SSC involves the neonate spending periods on the parent's bare chest, even if they require NICU admission. This simple practice improves psychological and physiological outcomes in both the parent and neonate.[3] The COVID-19 pandemic introduced infection control practices that may have a relevant impact on the perinatal period, and substantial uncertainty remains in this area.

Guidelines for the management of neonates born to infected mothers were initially formulated in the context of many unknowns and often varied.[4] Whilst many guidelines exist, most were designed using expert consensus, and there is a lack of published reports of implementation and outcomes.[5] Furthermore, the mother-to-fetus SARS-CoV-2 transmission, initially unknown, is now understood to rarely occur.[6] No studies to date have described FCC practices during the COVID-19 pandemic using a large, international cohort of neonates born to SARS-CoV-2 positive mothers. The only existing data is limited to a survey of parental experiences of the impact of the pandemic restrictions on FCC.[7] In March 2020, the Murdoch Children's Research Institute (MCRI) and the European Society of Paediatric and Neonatal Intensive Care (ESPNIC) established EPICENTRE (EsPnIC Covid paEdiatric NeonaTal REgistry), a multicentre, observational, cohort registry of neonatal and paediatric SARS-CoV-2 positive patients.[8] EPICENTRE contains prospectively collected clinical data on SARS-CoV-2 positive neonates and children requiring intensive care, as well as all neonates born to mothers with proven SARS-CoV-2 infection during pregnancy. During the design of the registry, the EPICENTRE steering committee included questions about FCC practices. This unique dataset provides the first real-word data on FCC practices for neonates born to SARS-CoV-2 infected mothers throughout the pandemic.

We hypothesise that 1) the implementation of infection control measures during the COVID-19 pandemic had a negative impact on FCC, and 2) as the risks of perinatal transmission became better understood, the delivery of FCC improved. The aim of this study was to report the FCC practices for neonates born to SARS-CoV-2 positive mothers that were implemented in participating EPICENTRE sites.

Methods

Study design and setting

The EPICENTRE protocol has been published in full previously (Online Supplementary Material).[8] The Murdoch Children's Research Institute (MCRI), Melbourne, Australia, was the coordinating site for EPICENTRE. This was a prospective, multicentre, international, observational, cohort study. Voluntary participation in the registry was initially offered to several NICUs and paediatric intensive care units (PICUs) worldwide. Sites were invited to participate by general announcements from ESPNIC between April and July 2020, as well as by direct contact from steering committee members. Prior to opening EPICENTRE, a data management plan for co-enrolled participants was established.[8] Co-enrolment in other registries was permitted providing details were recorded for each co-enrolled participant. Data were collected between 17 March 2020 (first registrant) and 20 October 2021 (data lock-out). Local ethical committee, Institutional Review Board approval and informed parental consent (written or oral) were obtained in each participating centre where required by local regulation. All maternal and neonatal data were deidentified and relevant local privacy regulations applied.

Ethics statement

The study was approved by the Human Research and Ethics Committee of the Royal Children's Hospital, Melbourne, Australia on 11 May 2020 (HREC 64264) in accordance with National Health and Medical Research Council guidelines and is reported as per STROBE guidelines.

Participants

Neonates born to a mother with a proven SARS-CoV-2 infection at any time during the pregnancy were enrolled in the study. Maternal infection at any time in pregnancy was included because the impact of SARS-CoV-2 infection on the fetus was unknown early in the pandemic. SARS-CoV-2 maternal[9] and neonatal[10] infections were determined using World Health Organization criteria. EPICENTRE was designed to be inclusive, especially with regards to maternal and neonatal comorbidities including preterm birth and congenital malformations. As such, neonates were only excluded if parental consent was refused (if required).

Outcomes

The main outcomes were the rates of rooming-in and maternal breastmilk feeding practice. Other outcomes included mother-baby physical contact prior to separation (if occurred) and the pattern of FCC practices relative to phase of pandemic and local site guidelines.

Data sources and measurement

Eligible mother-baby dyads were identified from admission records, medical records and/or laboratory investigations at each site. Data were entered electronically into a data collection form built into a REDCap database hosted by the MCRI.[11] Data collected included maternal and neonatal demographic characteristics, birth details, maternal and neonatal clinical condition at birth and during the postnatal period and available SARS-CoV-2 results (RT-PCR and serology) for mothers and neonates. We also collected data on FCC practices. These included rooming-in or separation, and maternal breastmilk as the sole nutritional method, combined feeding (maternal breastmilk and donor milk/formula/intravenous therapy), or maternal breastmilk exclusion. For neonates who were separated from their mothers during the postnatal hospital admission, the location of neonatal care and what maternal physical contact the neonate had prior to separation was documented. FCC practices were then coded based upon the available local guidelines at the time. Where published country or site policies were unavailable, site coordinators were contacted directly via email. Where guidelines remained unclear, they were coded as unknown for that point in time. All sites had active policies of promoting and encouraging all aspects of FCC prior to the pandemic. Data on maternal co-morbidities beyond pregnancy and COVID-19, such as age and body mass index, were not collected due to the neonatal focus of the study and privacy limitations in some jurisdictions requiring prospective permission. In balancing the needs to ensure complete data capture amongst sites and rapidly and easily implement the registry at the onset of the pandemic, we elected to omit these data. Data were assessed for quality by each site coordinator and the MCRI study coordination team. This included review of available admission data for missing mother-baby dyads. If data on missing mother-baby dyads could not be provided this was recorded and site excluded from analysis.

Statistical analysis

This is a convenience sample size of all participants we were able to enrol during the study period. Descriptive statistics were calculated and presented as proportions for discrete variables. Continuous data distribution was analysed with a Shapiro–Wilk test and expressed as mean (standard deviation) or median (25th percentile, 75th percentile) for normally and non-normally distributed data, respectively. To compare the temporal pattern of FCC practices during the pandemic, data were divided into three monthly periods based on the northern hemisphere (boreal) seasons. Maternal and neonatal characteristics in each FCC practice group were described with the point estimate of the risk difference (difference in the proportion of an outcome between two groups; see Online Supplement for details), chi-squared test, Fisher exact test or Mann–Whitney test as appropriate. The primary outcomes of rooming-in and maternal breastmilk feeding were analysed with logistic regression using maternal and neonatal covariates of clinical or biological relevancy with a significant risk difference and ($p < 0.05$). These were vaginal delivery, COVID-19 as the primary reason for maternal admission and/or decision to deliver, maternal symptoms at delivery (asymptomatic at delivery, recovered from COVID-19 and moderate-severe COVID-19 disease), gestational age at birth <37 weeks and neonatal symptoms during admission (asymptomatic, respiratory failure). Data were not clustered by site during analysis. Statistical analysis was performed in Prism V9.0.0 (GraphPad Software Inc., California, USA).

Role of the funding source

The funding source had no role in study design, data collection, analysis and interpretation, and in the writing of the report. The corresponding (GD), second (EJP) and senior author (DGT) had full access to all data in the study and all authors had responsibility in submitting the paper for publication.

Results

Of the 55 sites globally that expressed initial interest, 30 NICU and PICU sites completed regulatory requirements to enter the study. Of these, 14 sites from 11 countries entered data on FCC practices. 1 site (1 mother-baby dyad) was excluded due to missing data. Complete data from 692 mother-baby dyads from 13 sites from 10 countries (Online Supplementary Table S1) were finally available for analysis.

Maternal demographic characteristics are summarised in Table 1. The primary reason for hospital admission was COVID-19 in 162 (24%) mothers, and the decision to deliver being based on maternal SARS-CoV-2 status in 122 (18%). Most mothers (431 [65%]) were asymptomatic for COVID-19 during the admission, but only 112 (17%) mothers were deemed to have recovered from COVID-19 by delivery. The remaining 552 (83%) mothers were symptomatic and/or had a positive SARS-CoV-2 test within the 14 days before delivery.

Most babies were term, and 48% assigned female (Table 2). The duration of admission was a median (25th, 75th quartile) 4 (2,8) days. A total of 471 (69%) neonates were asymptomatic for any cause throughout the admission, whilst 146 (21%) required a period of respiratory support and/or supplemental oxygen therapy for respiratory failure, and 6 neonates died before discharge. 576 (83%) neonates were tested for SARS-CoV-2 during their admission, and 27 (5%) had at least one positive PCR or serology result. Of the SARS-CoV-2 positive neonates, 14 (52%) were asymptomatic, 11 (41%) were born preterm (9 requiring respiratory support and/or supplemental oxygen therapy), and 1 neonate had myocarditis.

Rooming-in practices

311 (46%) neonates roomed-in with their mother during the admission, with 292 mother-baby dyads both being asymptomatic (Fig. 1). A total of 369 (54%) neonates were separated from their mother, the majority were asymptomatic and isolated in a NICU or Special Care

Maternal characteristics	All mothers (n = 671)
Reason for admission	COVID-19 disease, 162 (24%) Delivery, 423 (64%) Perinatal complication, 24 (4%) Missing data, 7
Mode of delivery	Caesarean section, 339 (51%) Vaginal, 330 (49%) Missing data, 2
Decision to deliver based on maternal SARS-CoV-2 status	Yes, 122 (18%) No, 540 (81%) Unknown, 3 (0.5%) Missing data, 6
Active COVID-19 at delivery	552 (83%) Missing data, 7
Symptoms at delivery	None, 437 (66%) Mild[a], 103 (16%) Moderate[b], 28 (4%) Severe[c], 94 (14%) Missing data, 8
Symptoms during admission	None, 431 (65%) Mild[a], 107 (16%) Moderate[b], 29 (4%) Severe[c], 96 (14%) Missing data, 7

[a]Mild maternal symptoms included fever, rhinitis, sore throat and/or cough. [b]Moderate symptoms included pneumonia and/or respiratory distress without ventilation or oxygen. [c]Severe symptoms were requiring non-invasive ventilation, invasive ventilation, acute respiratory distress syndrome, myocarditis, sepsis and/or shock. Symptom classification as per World Health Organization classification of COVID-19 clinical severity.[9]

***Table 1:* Maternal characteristics.**

Neonatal characteristics	All infants (n = 692)
Gestational age at birth (completed weeks)	38 (36, 39)[a]
	Missing data, 12
Birth weight (g)	2924 (783)[b]
	Missing data, 12
Female	333 (48%)
Plurality	Singleton, 640 (93%)
	Twin, 48 (7%)
	Triplet or more, 2 (0.3%)
	Missing data, 2
Ethnicity	African American, 64 (9%)
	Asian, 39 (6%)
	Caucasian, 358 (52%)
	Hispanic, 19 (3%)
	Other, 126 (18%)
	Not stated, 85 (12%)
	Missing data, 1
Duration of admission (days)	4 (2,8)[a]
	Missing data, 20
Apgar score at 5 min	9 (1)[b]
	Missing data, 134
Resuscitation at birth	None, 513 (76%)
	Non-invasive ventilation, 61 (9%)
	Positive pressure inflations, 57 (8%)
	Oxygen, 64 (9%)
	Chest compressions, 7 (1%)
	Adrenaline, 5 (1%)
	Intubation, 59 (9%)
	Missing data, 15
Clinical condition during hospitalisation until discharge or confirmed recovery	Asymptomatic, 471 (69%)
	Respiratory failure requiring respiratory support ± oxygen therapy, 146 (21%)
	Jaundice, 19 (3%)
	Sepsis, 18 (3%)
	Feeding difficulties, 17 (2%)
	Lethargy, 8 (1%)
	Apnoea, 4 (1%)
	Fever or temperature instability, 4 (1%)
	Gastrointestinal symptoms, 4 (1%)
	Tachycardia, 3 (0.4%)
	Other, 51 (7%)
	Missing data, 11
Discharge outcome	Home, 643 (95%)
	Transfer, 27 (4%)
	Death, 6 (1%)
	Missing data, 16
Confirmed SARS-CoV-2 positive	27 (5%)
	Missing data, 116
SARS-CoV-2 positive neonatal symptoms	Asymptomatic, 14 (52%)
	Respiratory failure requiring respiratory support ± oxygen therapy, 9 (33%)
	Anaemia, 1 (4%)
	Bradycardia, 1 (4%)
	Feeding difficulties, 1 (4%)
	Fetal demise, 1 (4%)
	Hypocalcaemia, 1 (4%)
	Hypotonia, 1 (4%)
	Jaundice, 1 (4%)
	Lethargy, 1 (4%)
	Myocarditis, 1 (4%)
	Per rectal bleeding, 1 (4%)
	Sepsis, 1 (4%)

(Table 2 continued on next column)

(Continued from previous column)

[a]Median (25th percentile, 75th percentile). [b]Mean (SD).

Table 2: **Neonatal characteristics.**

Nursery (SCN) rather than a postnatal ward. Only 50 (14%) separated neonates exhibited symptoms of any cause (COVID-19 related or not). Of the separated neonates, only 25 (7%) had any reported physical contact with their mother prior to separation (breastfeeding 14, cuddle 9, touch 11, SSC 13; Online Supplementary Table S2). Separation due to a lack of postnatal ward capacity was rare (15 [2%]).

As the pandemic progressed, the percentage of neonates rooming-in with their mother increased from 23% (March–June 2020) to a peak of 74% (January–March 2021; Fig. 2). Most sites stated that they allowed rooming-in during the entire COVID-19 pandemic (4 sites policies unknown for at least one time epoch; Online Supplementary Table S3). 3 sites had a stated policy of separating all infants from mothers during the initial phase of the pandemic (March–June 2020). Interestingly, there was a decrease in rooming-in in July–September 2021 to 17%. Although the absolute number of neonates in this period was small (n = 60), there was a greater proportion of mothers with moderate or severe COVID-19, preterm neonates and neonates requiring respiratory support and/or oxygen therapy for respiratory failure compared to other time periods (Online Supplementary Table S4). Online Supplementary Table S5 summarises the geographic location of participating sites for each temporal phase of the pandemic.

The mothers of separated neonates were more likely to have had a caesarean section compared to mothers who were rooming-in with their neonates (244 [69%] versus 91 [30%], respectively; Table 3) and/or severe COVID-19 symptoms at delivery (88 [25%] versus 5 [2%]), respectively). Preterm neonates (182 [49%] versus 16 [5%]) and those with respiratory failure of any cause (144 [39%] versus 2 [1%]) were more likely to be separated. This was probably not related to SARS-CoV-2 neonatal infection as the number of SARS-CoV-2 positive neonates was similar between those separated and those rooming-in (14 [4%] versus 12 [4%]). Active

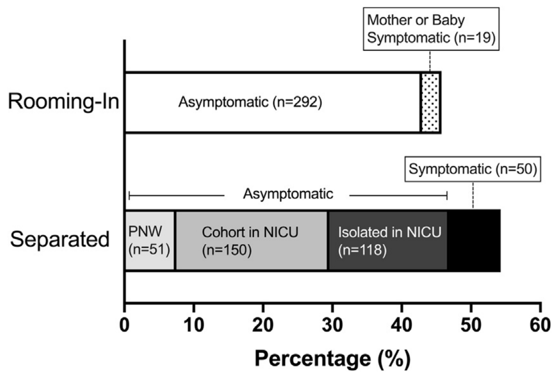

Fig. 1: Rooming Practices. 311 (46%) of neonates roomed-in with their mother and 369 (54%) were separated from mother during birth admission. Of those rooming-in, 292 mother-baby dyads were both asymptomatic (white bar) whilst the mother and/or neonate was symptomatic in 19 cases (dotted bar). Of the separated neonates, 319 were asymptomatic and isolated on the postnatal ward (light grey bar), in a cohort in the NICU or SCN (grey bar) or in a single room in the NICU or SCN (dark grey bar). 50 separated neonates were symptomatic in the NICU or SCN (black bar). Total neonates 680 (12 missing data).

maternal COVID-19, caesarean section, preterm birth and respiratory failure increased separation on logistic regression (Online Supplementary Table S6).

Feeding practices

354 (53%) neonates received breastmilk from their mother during the admission, with 163 (24%) fed with maternal breastmilk only, and the majority of these exclusively breastfed (143; Online Supplementary Table S7). The remaining 320 (47%) neonates who received no maternal breastmilk were predominately formula fed (295). The use of maternal breastmilk in feeding increased from 23% (March–June 2020) to 70% (January–March 2021; Fig. 3). 8 of the 10 participating countries had published guidelines for feeding methods for neonates born to SARS-CoV-2 positive mothers, all encouraging breastfeeding and/or EBM (Online Supplementary Table S3).

Maternal breastmilk feeding was less common in mothers with severe symptomatic COVID-19 at delivery (19 [6%] versus 73 [24%]; Table 4). The rate of SARS-CoV-2 positive neonates was similar in those who received maternal breastmilk and those who did not (13 [5%] and 13 [4%]). Premature neonates were less likely to receive maternal breastmilk (78 [22%] versus 119 [37%]), whereas asymptomatic neonates were more likely to receive maternal breastmilk (261 [74%] versus 205 [64%]). Feeding with maternal breastmilk was associated with rooming-in (risk difference 53%). Breastfeeding (exclusive or mixed) occurred in 250 (81%) of neonates rooming-in, compared to 18 (5%) separated. Maternal admission for reasons other than

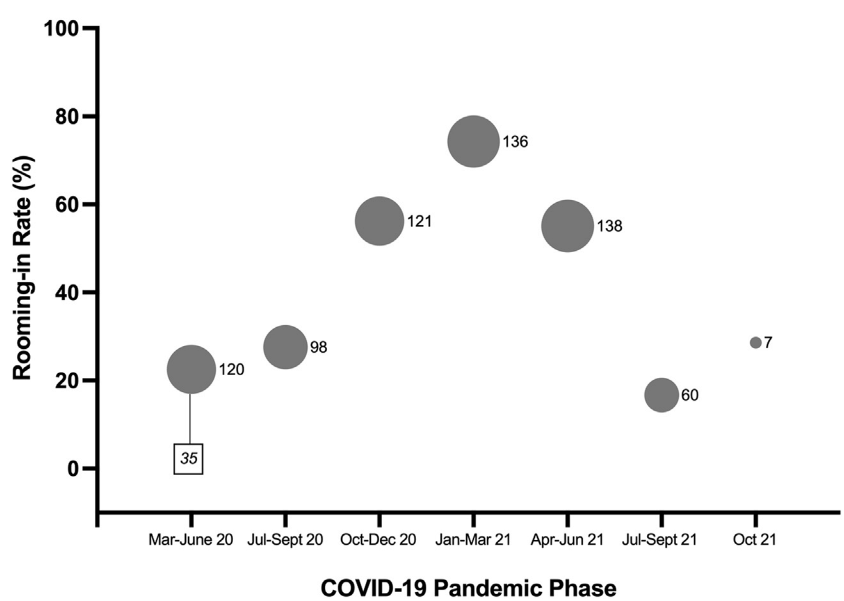

Fig. 2: Bubble plot representing the percentage of all mother-baby dyads rooming-in by number of enrolled neonates for each northern hemisphere season. Number indicates the total number of neonates for each season, and the bubble visualises the overall magnitude of each season to total sample population (n = 692). Separation was only mandated at 3 sites, and only during the first phase of the COVID-19 pandemic (March–June 2020). A total of 35 infants (highlighted with italicised box on graph) were born in these 3 sites and all were separated. By July–September 2020, all three sites had changed practice to allow rooming-in. The number of infants born to sites in which rooming-in practice was unknown are detailed in Online Supplementary Table S5.

Maternal characteristics	Rooming-in Mothers (n = 303)	Separated Mothers (n = 356)	Difference	p value
Reason for admission	COVID-19 disease, 13 (4%) Delivery, 234 (78%) Perinatal complication, 3 (1%) Missing data, 3	COVID-19 disease, 147 (42%) Delivery, 182 (51%) Perinatal complication, 21 (6%) Missing data, 2	**−38%** 27% −5%	<0.0001[e]
Active COVID-19 at delivery	220 (73%) Missing data, 3	323 (91%) Missing data, 2	**−18%**	<0.0001[f]
Mode of delivery	Caesarean section, 91 (30%) Vaginal, 211 (70%) Missing data, 1	Caesarean section, 244 (69%) Vaginal, 112 (31%)	**−39%**	<0.0001[f]
Symptoms at delivery	None, 268 (89%) Mild[a], 24 (8%) Moderate[b], 3 (1%) Severe[c], 5 (2%) Missing data, 3	None, 165 (47%) Mild[a], 75 (21%) Moderate[b], 25 (7%) Severe[c], 88 (25%) Missing data, 3	**42%** −13% −6% **−23%**	<0.0001[e]
Symptoms during admission	None, 266 (88%) Mild[a], 22 (7%) Moderate[b], 6 (2%) Severe[c], 7 (2%) Missing data, 2	None, 160 (45%) Mild[a], 80 (23%) Moderate[b], 24 (7%) Severe[c], 89 (25%) Missing data, 3	**43%** −16% −5% **−23%**	<0.0001[e]
Neonatal characteristics	**Neonates (n = 311)**	**Neonates (n = 369)**		
Gestational age at birth (completed weeks)	39 (38, 40)[d] Missing data, 1	37 (33, 38)[d]	2 (2,3)[d]	<0.0001[c]
Gestational age <37 weeks	16 (5%)	182 (49%)	**−44%**	<0.0001[f]
Gestational age <30 weeks	1 (0.3%)	29 (8%)	−7.7%	<0.0001[f]
Clinical condition during hospitalisation until discharge or confirmed recovery	Asymptomatic, 298 (96%) Respiratory failure requiring respiratory support ± oxygen therapy, 2 (1%) Jaundice, 4 (1%) Feeding difficulties, 3 (1%) Apnoea, 2 (1%) Tachycardia, 2 (1%) Fever or temperature instability, 1 (0.3%) Gastrointestinal symptoms, 1 (0.3%) Lethargy, 1 (0.3%) Respiratory distress, 1 (0.3%) Sepsis, 3 (1%) Desaturation, 1 (0.3%) Hypoglycaemia, 1 (0.3%) Testicular torsion, 1 (0.3%)	Asymptomatic, 175 (47%) Respiratory failure requiring respiratory support ± oxygen therapy, 144 (39%) Jaundice, 15 (4%) Feeding difficulties, 14 (4%) Apnoea, 3 (1%) Tachycardia, 1 (0.3%) Fever or temperature instability, 3 (1%) Gastrointestinal symptoms, 3 (1%) Lethargy, 7 (2%) Respiratory distress, 11 (3%) Sepsis, 15 (4%) Myocarditis, 1 (0.3%) Other, 30 (8%)	**49%** **−38%** −3% −3% 0% 0.7% −0.7% −0.7% −1.7% −2.7% −3%	<0.0001[e]
Confirmed SARS-CoV-2 positive	12 (4%) Missing data, 88	14 (4%) Missing data, 17	**0%**	0.54[f]

Bold text highlight clinically important differences. [a]Mild maternal symptoms included fever, rhinitis, sore throat and/or cough. [b]Moderate symptoms included pneumonia and/or respiratory distress without ventilation or oxygen. [c]Severe symptoms were requiring non-invasive ventilation, invasive ventilation, acute respiratory distress syndrome, myocarditis, sepsis and/or shock. [d]Median (25th percentile, 75th percentile) and difference of medians (95% CI of difference); Mann–Whitney test. Symptom classification as per World Health Organisation classification of COVID-19 clinical severity.[9] [e]Chi-squared test. [f]Fisher exact test.

***Table 3*: Maternal and neonatal characteristics of those rooming-in versus separated.**

COVID-19 and maternal recovery from COVID-19 prior to birth were associated with increased breastmilk feeding on logistic regression (Online Supplementary Table S8).

Discussion

The COVID-19 pandemic has created unprecedented challenges for healthcare services, including the delivery of FCC. As part of a larger, multinational, prospective, observational cohort study on the epidemiology of COVID-19 in neonates and children managed by NICU and PICU services (EPICENTRE), we collected data on FCC practices for neonates born to mothers with COVID-19. At the start of the pandemic, rooming-in and maternal breastmilk feeding rates were low, but both increased over time. To our knowledge, this is the first study to assess temporal changes to FCC at a multinational scale. Our findings suggest that as the understanding of the risks of COVID-19 to neonates evolved, so did practice. Physical contact was highly restricted for neonates prior to separation from their mothers, irrespective of the reason for NICU or SCN admission. This highlights the ongoing challenges the pandemic poses for the delivery of FCC.

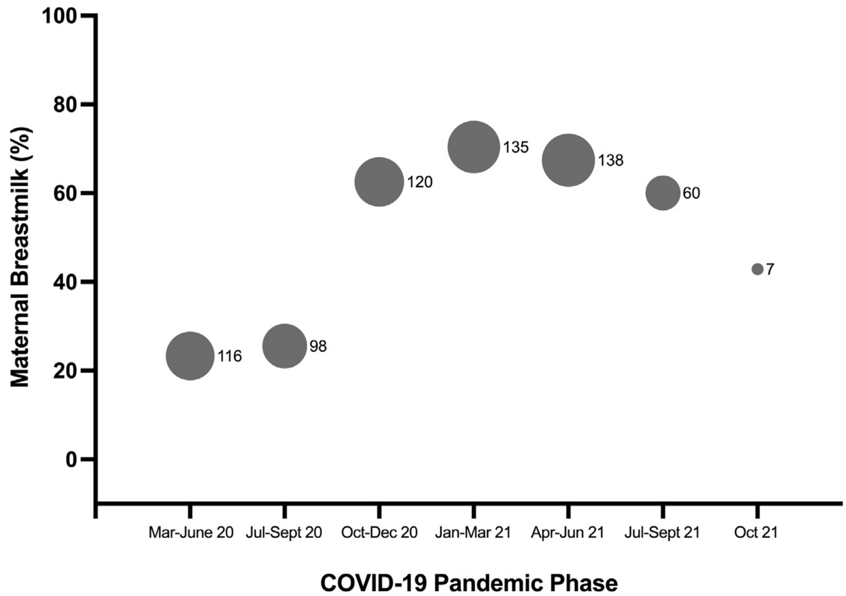

Fig. 3: Percentage of neonates who received maternal breastmilk from any method by northern hemisphere season. Number indicates the total number of neonates for each season, and the bubble is a representation of the overall magnitude of each season to total sample population (n = 692).

We found that of those neonates tested for SARS-CoV-2, 5% had a positive result. This incidence aligns with a living meta-analysis indicating that the SARS-CoV-2 positivity rate in neonates born to mothers with COVID-19 is as low as 1.8%.[12] Our incidence was higher than a UK population-based cohort of perinatally exposed neonates (17 neonates acquired SARS-CoV-2 infection)[13] and the 0.9% of infants born to SARS-CoV-2 positive mothers in a nationwide cohort study in Sweden.[14] This likely reflects our NICU-focused design, which was limited to high-risk perinatal hospitals within a research network and the lack of testing in 116 neonates. Early in the pandemic, case reports of symptomatic cases in neonates born to mothers with COVID-19 emerged.[15,16] Fortunately, as the pandemic progressed, it became clear that the severity of neonatal disease is usually mild.[13] This is a finding we also identified with 52% of our SARS-CoV-2 positive neonates being asymptomatic, consistent with a meta-analysis of neonatal SARS-CoV-2 infections reporting clinical features of COVID-19 in half of patients.[17] Many symptomatic positive neonates were also born preterm, making it difficult to differentiate the cause of respiratory failure and other symptoms. Although perinatal transmission is rare, and generally asymptomatic when it occurs, our study has shown that the provision of FCC may be impacted for any neonate born to a SARS-CoV-2 positive mother, independent of neonatal infection. We therefore promote the implementation of FCC practices into infection control measures during the future stages of this pandemic to provide neonates and mothers with the best health benefits.

Our study identified that only 46% of mother-baby dyads roomed-in together. Local reports of rooming-in practices at the start of the pandemic were varied, ranging from 13% to 83%.[18–23] In our cohort, rooming-in was unlikely to have influenced rates of neonatal infection. In contrast, a meta-analysis found that rooming-in was associated with a risk of delayed neonatal SARS-CoV-2 infection.[17] Neonates can be separated from their mothers for other reasons, principally the need for NICU care. This was present in our cohort, with more separated neonates being born preterm or to mothers with perinatal complications. The unnecessary separation of the mother-baby dyad is associated with negative outcomes for both neonates and mothers.[24] Thus, it is concerning that in our cohort of neonates, in whom only a small number were infected with SARS-CoV-2, 73% of those separated from their mother were admitted into a NICU or SCN without any symptoms or co-morbidities to account for admission. This may impact NICU access for other neonatal conditions.[25] It has been suggested that high NICU admission rates may be secondary to the logistical challenges of isolating neonates in a postnatal ward setting.[5] Our data, however, showed that it was rare for an asymptomatic neonate to be managed in a NICU due to lack of postnatal ward capacity.

The onset of the pandemic varied across regions, but FCC guidelines appeared consistent within participating sites, with most recommending rooming-in for all the

Maternal characteristics	Received maternal breastmilk Mothers (n = 340)	No maternal breastmilk Mothers (n = 313)	Difference	p value
Reason for admission	COVID-19 disease, 33 (10%) Delivery, 244 (72%) Perinatal complication, 11 (3%) Missing data, 2	COVID-19 disease, 126 (41%) Delivery, 169 (55%) Perinatal complication, 12 (4%) Missing data, 3	**−31%** 17% −1%	<0.0001[f]
Active COVID-19 at delivery	251 (74%) Missing data, 2	287 (93%) Missing data, 3	**−19%**	<0.0001[e]
Mode of delivery	Caesarean section, 141 (41%) Vaginal, 199 (59%)	Caesarean section, 191 (61%) Vaginal, 122 (39%)	**−20%**	<0.0001[e]
Symptoms at delivery	None, 273 (81%) Mild[a], 38 (11%) Moderate[b], 8 (2%) Severe[c], 19 (6%) Missing data, 2	None, 156 (50%) Mild[a], 60 (19%) Moderate[b], 20 (6%) Severe[c], 73 (24%) Missing data, 4	**31%** −8% −4% **−18%**	<0.0001[f]
Symptoms during admission	None, 271 (80%) Mild[a], 36 (11%) Moderate[b], 9 (3%) Severe[c], 23 (7%) Missing data, 1	None, 151 (49%) Mild[a], 64 (21%) Moderate[b], 21 (7%) Severe[c], 73 (24%) Missing data, 4	**31%** −10% −4% **−17%**	<0.0001[f]
Neonatal characteristics	**Neonates (n = 354)**	**Neonates (n = 320)**		
Gestational age at birth (completed weeks)	38 (37, 40)[d]	37 (35, 39)[d]	1 (0.7, 1)[d]	<0.0001[d]
Gestational age <37 weeks	78 (22%)	119 (37%)	**−15%**	<0.0001[e]
Gestational age <30 weeks	13 (4%)	17 (5%)	−1%	0.35[e]
Clinical condition during hospitalisation until discharge or confirmed recovery	Asymptomatic, 261 (74%) Respiratory failure requiring respiratory support ± oxygen therapy, 64 (18%) Jaundice, 10 (3%) Sepsis, 8 (2%) Feeding difficulties, 4 (1%) Lethargy, 4 (1%) Respiratory distress, 4 (1%) Fever or temperature instability, 3 (1%) Apnoea, 2 (1%) Gastrointestinal symptoms, 1 (0.3%) Tachycardia, 1 (0.3%) Other, 12 (3%)	Asymptomatic, 205 (64%) Respiratory failure requiring respiratory support ± oxygen therapy, 83 (26%) Jaundice, 10 (3%) Sepsis, 10 (3%) Feeding difficulties, 13 (4%) Lethargy, 4 (1%) Respiratory distress, 7 (2%) Fever or temperature instability, 1 (0.3%) Apnoea, 2 (0.6%) Gastrointestinal symptoms, 3 (1%) Tachycardia, 2 (0.6%) Other, 22 (7%)	**10%** −8% 0% −1% 0% 0% −1% 0.7% 0.4% −0.7% −0.3% 4%	0.059[f]
Confirmed SARS-CoV-2 positive	13 (5%) Missing data, 74	13 (4%) Missing data, 30	**1%**	0.84[e]
Rooming-in with mother during hospital admission	251 (71%)	58 (18%)	**53%**	<0.0001[e]

Bold text highlight clinically important differences. [a]Mild maternal symptoms included fever, rhinitis, sore throat and/or cough. [b]Moderate symptoms included pneumonia and/or respiratory distress without ventilation or oxygen. [c]Severe symptoms were requiring non-invasive ventilation, invasive ventilation, acute respiratory distress syndrome, myocarditis, sepsis and/or shock. [d]Median (25th percentile, 75th percentile) and difference of medians (95% CI of difference); Mann–Whitney test. Symptom classification as per World Health Organisation classification of COVID-19 clinical severity.[9] [e]Fisher exact test. [f]Chi-squared test.

Table 4: **Maternal and neonatal characteristics of those who received maternal breastmilk and those who did not.**

study period. Whilst our data does not allow evaluation for the cause of separation, the increase in rate of rooming-in within sites that had an active policy to do so likely indicates that COVID-19 status did influence separation practices early in the pandemic. With time, clinicians became more familiar with managing COVID-19 in a perinatal population. FCC rates were highest when there were the lowest rates of moderate to severe symptomatic COVID-19 in mothers and symptomatic disease of any cause in neonates. It is therefore also possible that FCC increased due to maternal and neonatal clinical manifestations, not due to changes in practice. We observed a decrease in rates of rooming-in and maternal breastmilk feeding from April–June 2021 after a clear trend of improved FCC practices. This epoch coincided with the emergence of the Delta wave over the northern hemisphere, which is known to cause more severe disease in mothers. Although a smaller sample than the preceding epochs, our data support this and suggest potential additional neonatal implications. Rates of moderate to severe symptomatic COVID-19 in mothers, caesarean sections, prematurity, and neonatal ventilation increased in the epochs following April–June 2021. There were no changes to guidelines, which all recommended vaginal birth where possible for pregnant women with COVID-19 in 2021. Unfortunately, we did not document the strain of SARS-CoV-2 or have access to mother-baby dyads without perinatal SARS-CoV-2 infection. The latter limits our ability to determine whether the changes in FCC were specific to maternal infection status or due restrictions applied to all mothers. We also do not know how the impact of new viral strains after October 2021, such as Omicron, in a population that is mostly no longer immunologically virgin impacts perinatal transmission and eventually FCC practices.

Another striking finding was the lack of mother-baby physical contact prior to separation in almost all neonates who were separated. This translated to almost half of all neonates being denied early and close contact with their mother, even though most sites had a general approach to allow it. This may be confounded by the fact that separated mothers and neonates were more unwell than those who roomed-in so may have been unfit for SSC. This may also, however, represent infection control measures overriding FCC recommendations. In an online survey of mother-baby physical contact in the NICU during the COVID-19 pandemic, only 20% of parents had some contact with their newborn.[7] As the risk of perinatal transmission is low and neonatal COVID-19 is generally mild, it is imperative that health services prioritise early and close SSC with appropriate hygiene precautions, as per current recommendations.[26] A limitation of this study was that we did not collect data on physical contact after initial separation and the use of hygiene precautions during contact, like masks and hand sanitiser.

The benefits of infant feeding with maternal breastmilk are well-understood. It was concerning that only 52% of neonates in our cohort received breastmilk from their mother. This rate is lower than previously reported in localised studies during the pandemic[19,21,27,28] and the generally accepted rates in large NICU populations (75% in United States pre-pandemic).[29] Rates of maternal breastmilk feeding in our international cohort are unlikely to be uniform before the pandemic and may have been influenced by maternal, neonatal, and cultural factors, as well as limitations on NICU visiting after maternal discharge from birthing hospital. We contend however, that it is likely due to study design. EPICENTRE was designed to capture populations managed by neonatal clinicians, which will be skewed towards sicker neonatal and obstetric populations, in which maternal breastmilk exposure will be less. Previous reports of feeding practices were derived from obstetric cohorts or population-wide data. Despite this, it was reassuring that maternal breastmilk feeding increased over the pandemic from 23% to 70% by January–March 2021. This temporal change in maternal breastmilk exposure rates is likely due to health services adapting their policies and increased clinician comfort in response to data showing no association between breastmilk and positive neonatal infections.[17,30] Although our study was not designed to address infectivity, we also found no difference in neonatal infections between the neonates who received maternal breastmilk and those who did not.

Only 22.4% of neonates born to mothers with moderate-severe COVID-19 disease at birth received any breastmilk, despite breastmilk being broadly promoted. Promoting breastmilk feeding is not the same as achieving it when there are maternal co-morbidities. Our study demonstrates that it is possible to maintain lactation even in mothers with severe COVID-19. This provides invaluable insights into breastmilk exposure more broadly for neonates born to moderate-severely unwell mothers of any cause. Reports of lactation support, and conversely suppression, during postnatal maternal illness are sparse. We would suggest that neonatal, obstetric, midwifery, and if appropriate, infection control clinicians, collaborate to advocate for stimulation of lactation when caring for neonates, irrespective of severity of maternal illness.

There are several other limitations to this study. This is an observational study limited to participating NICUs across different regions with different healthcare models and cultural influences. This may cause differences to the approaches to FCC. The similarities in available guidelines during the pandemic and the increases in FCC as the pandemic progressed suggest that maternal COVID-19 status had a major impact on FCC. Whilst all hospitals embraced the same core principles of FCC before the pandemic, we do not have data on pre-pandemic implementation rates. This is a limitation broadly applicable to the field of FCC as high quality data on implementation of FCC is rare. Our study demonstrates the importance of collecting these data and feasibility of doing so. Compared to population-wide registries, our results may not reflect practice or populations in other NICUs within each region, lacking external validity and selection bias due to voluntary site participation and differing stages of the pandemic on societal and healthcare restrictions between sites. In contrast, population-wide registries of perinatal COVID-19 have generally lacked the ability to document mother-baby care at a detailed level. Data-entry expertise was at the discretion of each site and independent verification of all source data was not always possible. The quality of data entry may have been compromised by increasing clinical and research demands placed upon sites at times during the pandemic. To mitigate this, we employed established common NICU data fields used for quality and outcome reporting, such as the Vermont–Oxford Network. Our study period encompassed the Alpha to Delta waves of SARS-CoV-2 mutations, and not the more virulent Omicron variant. Vaccination against SARS-CoV-2 became available during the latter half of the study period, and at a variable rate across participating countries. It is possible that FCC practices may differ in regions with high vaccination rates. The EPICENTRE registry now requires all sites to document maternal vaccination status.

In conclusion, our study suggests that the COVID-19 pandemic has impacted FCC practices for neonates born to SARS-CoV-2 positive mothers, but health services adapted over time. We demonstrated that perinatal transmission is rare and usually mild when it occurs. Therefore, we strongly encourage health services to continue implementing FCC practices during the future stages of this pandemic to ensure neonates and mothers receive the well-established benefits.

Contributors

DD-L, GC, OD, YNE, HMS, AM, MK and DGT developed the concept of the EPICENTRE Registry. DGT, EJP and GD developed the concept of this report. GD, EJP and DGT were responsible for data extraction, cleaning, and analysis. All authors and Site Collaborators entered data. GD, EJP, HMS, GC, OD, YNE, WB, NA-N, SR, MC, SV-L, FJP-O, PT, WAGF, DB, BR, AM, AP, CNMB, MK, DD-L, DGT participated in data verification and interpretation. DGT supervised all aspects of the study and subsequent data analysis. GD wrote the first draft and all authors contributed to redrafting the manuscript.

Data sharing statement

All data, including raw data used for all figures and analysis, is available upon request to the corresponding author from three months following article publication to researchers who provide a methodologically sound proposal, with approval by an independent review committee ("learned intermediary"). Proposals should be directed to david.tingay@mcri.edu.au to gain access. Data requestors will need to sign a data access or material transfer agreement approved by the MCRI. EPICENTRE REDCap Data Dictionary, latest approved version on Protocol (Version 2.0a dated 17 August 2020) and Data Sharing Agreement (V1.0a dated 8 October 2020) and Data Transfer Agreement (dated 27 August 2020) available on request from A/Prof David Tingay (david.tingay@mcri.edu.au).

Declaration of interests

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Appendix A. Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.eclinm.2022.101822.

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