Effect of a Birthing on Country service redesign on maternal and neonatal health outcomes for First Nations Australians: a prospective, non-randomised, interventional trial

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Summary

Background There is an urgency to redress unacceptable maternal and infant health outcomes for First Nations families in Australia. A multi-agency partnership between two Aboriginal Community-controlled health services and a tertiary hospital in urban Australia designed, implemented, and evaluated the new Birthing in Our Community (BiOC) service. In this study, we aimed to assess and report the clinical effectiveness of the BiOC service on key maternal and infant health outcomes compared with that of standard care.

Methods Pregnant women attending the Mater Mothers Public Hospital (Brisbane, QLD, Australia) who were having a First Nations baby were invited to receive the BiOC service. In this prospective, non-randomised, interventional trial of the service, we specifically enrolled women who intended to birth at the study hospital, and had a referral from a family doctor or Aboriginal Medical Service. Participants were offered either standard care services or the BiOC service. Prespecified primary outcomes to test the effectiveness of the BiOC service versus standard care were the proportion of women attending five or more antenatal visits, smoking after 20 weeks of gestation, who had a preterm birth (<37 weeks), and who were exclusively breastfeeding at discharge from hospital. We used inverse probability of treatment weighting to balance confounders and calculate treatment effect. This trial is registered with the Australian New Zealand Clinical Trial Registry, ACTRN12618001365257.

Findings Between Jan 1, 2013, and June 30, 2019, 1867 First Nations babies were born at the Mater Mothers Public Hospital. After exclusions, 1422 women received either standard care (656 participants) or the BiOC service (766 participants) and were included in the analyses. Women receiving the BiOC service were more likely to attend five or more antenatal visits (adjusted odds ratio 1·54, 95% CI 1·13–2·09; p=0·0064), less likely to have an infant born preterm (0·62, 0·42–0·93; p=0·019), and more likely to exclusively breastfeed on discharge from hospital (1·34, 1·06–1·70; p=0·014). No difference was found between the two groups for smoking after 20 weeks of gestation, with both showing a reduction compared with smoking levels reported at their hospital booking visit.

Interpretation This study has shown the clinical effectiveness of the BiOC service, which was co-designed by stakeholders and underpinned by Birthing on Country principles. The widespread scale-up of this new service should be prioritised. Dedicated funding, knowledge translation, and implementation science are needed to ensure all First Nations families can access Birthing on Country services that are adapted for their specific contexts.

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Introduction

With little improvement in over a decade, innovative services are urgently needed to redress unacceptable maternal and infant health disparities for Aboriginal and Torres Strait Islander (hereafter called First Nations) families in Australia. Mortality of children younger than 5 years is not reducing in line with national targets set in 2008, when Australian governments pledged to close the gap in life expectancy, health, education, and employment outcomes between First Nations individuals and other Australians.[1] Most (85%) child deaths occur in the first year of life, about half (49%) of which are due to perinatal conditions such as preterm birth, which occurs in First Nations mothers at twice the rate of other Australians (14·2% *vs* 8·5%) and has remained static since targets addressing these issues were set in 2008 by the Closing the Gap framework.[1,2]

In 2019, the National Strategic Directions for Australian Maternity Services[3] recommended developing and implementing culturally safe, evidence-based models of care in partnership with First Nations communities underpinned by so-called Birthing on Country principles.[4] Culturally safe maternity care encompasses the entirety of a woman's needs (physical, psychosocial, spiritual, emotional, and cultural), with culturally safe practitioners treating women with respect

Research in context

Evidence before this study

Maternal and infant health outcomes for First Nations families in Australia are not improving in line with national targets and are significantly worse than those for non-Indigenous families. Evidence is needed on how to reduce preterm birth and infant mortality in socially disadvantaged and vulnerable women in high-income countries. Birthing on Country services are complex interventions designed to address these disparities, but there is a dearth of evidence on this topic. Early evaluation found a reduction in preterm birth. We actively monitor relevant publications and do literature reviews on a regular basis; therefore, no specific literature search was needed for this study.

Added value of this study

This study provides robust evidence that an urban Birthing on Country service can improve clinical outcomes for mothers and infants compared with standard care services, including a reduction of preterm birth. Established through a multi-agency partnership between two First Nations organisations and a tertiary hospital, key components of the Birthing in Our Community service include Indigenous governance, caseload midwifery, increased Indigenous workforce focused on family wellbeing and strength-based approaches to birthing and parenting, and improved cultural capability of the non-Indigenous workforce. This service has resulted in greater integration of care and support for families.

Implications of all the available evidence

Prevention of avoidable preterm birth in First Nations families is a major public health priority in Australia. Evidence about effective, scalable strategies to improve health outcomes among First Nations families is urgently needed to inform policy and practice. Replication of this Birthing on Country service should be tested in other settings as a key strategy to close the gap in maternal and infant health outcomes in Australia.

and dignity.[3,5] Culturally safe practitioners seek to reduce power dynamics between themselves and the women they care for.[5] Birthing on Country services are complex interventions that are philosophically aligned to the Aboriginal worldview,[6] with First Nations control, engagement, and governance as important inputs to their design.[7,8] These services are co-designed with the local community and include continuity of midwifery carer, a First Nations workforce, partnerships between primary and tertiary services, cultural strengthening programmes, and wrap-around services to support pregnant women and their families.[4] Increasing First Nations control of health services is recommended in national strategic documents.[6] However, the potential for Birthing on Country services to improve clinical outcomes in complex real-life settings is not yet known.

A 2012 evaluation of antenatal services for First Nations women birthing at the Mater Mothers Hospital (our study setting), done by our team, had identified a rising rate of preterm birth.[9] Women reported high satisfaction antenatally but felt abandoned and disappointed during birth and postnatally, at which point there was no assigned carer for labour and birth or postnatal follow-up; some reported not feeling culturally safe.[9] Stakeholders, including First Nations women, families and Elders, health professionals, and policy makers attended an engagement workshop to co-design a new service.[10] Key recommendations included strategies to increase cultural governance, the First Nations workforce, and cultural capability of hospital staff, and strategies for continuity of midwifery carer and for the establishment of a First Nations controlled community hub, including a birth centre.[10] A multi-agency partnership was formed between two First Nations Community-controlled health services and a tertiary hospital: the Institute for Urban Indigenous Health, the Aboriginal and Torres Strait Islander Community Health Service Brisbane, and the Mater Mothers' tertiary teaching hospital with a commitment to implement a new Birthing on Country service.

In this study, we aimed to assess and report the clinical effectiveness of the new service called Birthing in Our Community (BiOC) on key maternal and infant health outcomes compared with that of standard care.

Methods

Study design and participants

This prospective, non-randomised, interventional trial was done at the Mater Mothers Public Hospital (Brisbane), in South East Queensland, home to the second largest and fastest growing First Nations population in Australia (approximately 11% of Australia's Indigenous population), estimated to reach 130 000 by 2031.[11] The BiOC service is located on the lands of the Yuggera and Turrbul people, in Meanjin, the city now known as Brisbane. A community-based participatory action research approach[12] facilitated the implementation of the new co-designed service.[13] The BiOC service began operating in 2013 and is ongoing. It provided care for approximately 120–140 women per year in the first 3 years, and received more funding to double the annual caseload to approximately 240 women thereafter. The key components of the BiOC service and standard care are listed in table 1 and detailed in the study protocol.[13]

Steering Committee members (AC, JCu, CN, MR, KWi, SKi, and, later, YR) considered a randomised trial but chose a pragmatic, prospective, non-randomised, interventional trial to avoid delays in establishment. First Nations partners believed randomisation would be negatively perceived by the community as restricting

access to the new service. A longitudinal cohort enabled survey data to be collected at four timepoints up until 6 months postnatally (consent sought, data not shown). A previously published short-term evaluation (from January, 2013, to December, 2017) found a significant reduction in preterm birth among users of the BiOC service.[14]

This study includes among its authors members of the Birthing in Our Community Partnership Steering Committee and researchers and senior leaders of the partner organisations who are First Nations (AC, JCu, KWa, and YR) and non-Indigenous (CN, MR, KWi, SKi, SKr, YG, SH, JCo). Participants were eligible for study inclusion if they were carrying a First Nations baby, intended to birth at the study hospital, and had a referral from a family doctor or Aboriginal Medical Service. Participants were excluded if they had transferred in from other hospitals or had no antenatal care. Participants were also excluded if they had multiple births, fetal anomalies, fewer than two antenatal visits, and had their first contact with the health-care system after 36 weeks of gestation.

Ethical approval was granted by the Mater Health Services Human Research Ethics Committee (HREC/15/MHS/24), University of Queensland Human Research Ethics Committee (2015000624), and Charles Darwin University (H19057). This study was done in accordance with national Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research.

Procedures

At the study hospital, a midwife would refer women who were carrying First Nations babies to the BiOC service, and a midwife or family support worker would then call women and offer them a choice of services: standard care (at the hospital clinic or standard midwifery group practice) or the BiOC service (figure). Women were not referred to the BiOC service if the midwives were at capacity or if women had specific reasons for referral to a specialist service such as maternal fetal medicine or a clinic for pregnant women with substance addiction. Some women requested other services such as shared care with their family doctor or the First Nations (Murri) antenatal clinic, which had been in existence previously; these options were included in the standard care services. The Murri clinic was co-located with the hospital's First Nations liaison office.

Birth records of all First Nations babies born at the Mater Mothers Public Hospital were extracted from the hospital's routinely collected and prospectively entered obstetric database MatriX (which had a consent waiver).

	BiOC service (intervention cohort)	Standard care (reference cohort)
Partnerships and governance	Multi-agency partnership: First Nations leadership and governance formalised through a Steering Committee underpinned by a joint Statement of Commitment and Memorandum of Understanding.	No overarching First Nations governance of maternity services.
Continuity of midwifery carer across the maternity journey	A community-based MGP, providing continuity of care for 24 h a day and 7 days a week by a known (caseload) midwife to enrolled women throughout pregnancy, birth, and up to 6 weeks postnatally; care is provided in a community-based hub, the home, and the hospital according to hospital guidelines; and birthing services are in the hospital (no home or birth centre service). The caseload midwife works in a small group of midwives who provide backup in designated circumstances such as annual leave, sick leave, having more than one woman in labour, or not being scheduled on call. Midwives are employed on an annualised salary and women are allocated a primary midwife and have telephone access to their MGP midwife or backup midwife for 24 h a day and 7 days a week.	Antenatal care can be received from a community-based Aboriginal Medical Service, family doctor, hospital-based midwives or doctors who rotate throughout the service on rosters, or the Murri Antenatal Clinic based at the hospital (provides antenatal continuity, but no intrapartum or postnatal care). Care is done according to primary carer or hospital guidelines and birthing services are in the hospital (no home or birth centre service). Birthing support is likely to be by a midwife whom the woman has never met. Women can call the hospital birthing suite in an emergency. Women receive postnatal visits or telephone calls from a rostered community midwife available for women who discharge before 48 h for vaginal birth and 72 h for caesarean section, usually for less than 2 weeks.
First Nations workforce	Investment from partner organisations in strengthening the First Nations workforce: resourcing and actively creating opportunities to access professional pathways in education and training (cadetships for midwifery and human services students) and vocationally prepared roles (such as family support workers and administration and transport workers). As per standard care, Aboriginal Liaison Officers are available in the hospital.	Hospital care is supported by Aboriginal Liaison Officers who provide cultural and social support during business hours across all hospital services, including maternity. If accessing care in an Aboriginal Medical Service, women can see Aboriginal Health Practitioners or other First Nations staff.
Cultural safety framework	Front-line staff are provided with regular clinical and cultural supervision, orientation, and cultural training through the partner organisations.	Front-line staff can seek out their own cultural training or clinical supervision, but it is not routinely provided.
Holistic wrap-around services	The community-based hub includes transport and activities to connect, interact, share, and learn from each other and Elders, with community drop-in days, cook-ups, and cultural activities. A strong focus is placed on social and emotional health and wellbeing, ready access to social work, perinatal psychology, parenting support, and education at the hub. Access to hospital medical staff, a social worker, child safety officers, and other professionals (eg, diabetic educator) is available as required.	Women may be referred to allied health services (eg, psychologist, social worker) via the hospital or their primary health service (family doctor or Aboriginal Medical Service). Access to hospital medical staff, a social worker, child safety officers, and other professionals (eg, diabetic educator) is granted as required.
Coordinated care integrating primary health network with tertiary services	A dedicated BiOC service manager is employed by the Community-controlled partner to provide overarching service coordination and day-to-day management of the BiOC team and be a single point of reference for communication with external stakeholders. Middle managers from all organisations meet monthly. Troubleshooting is often managed between the BiOC service manager and the MGP manager at the hospital. Referrals to community support agencies are done as required.	Electronic or postal referrals and discharge summaries are the main source of communication between agencies. Referrals to community support agencies are done as required.

BiOC=Birthing in Our Community. MGP=midwifery group practice.

Table 1: **Key components of standard care and BiOC sevices**

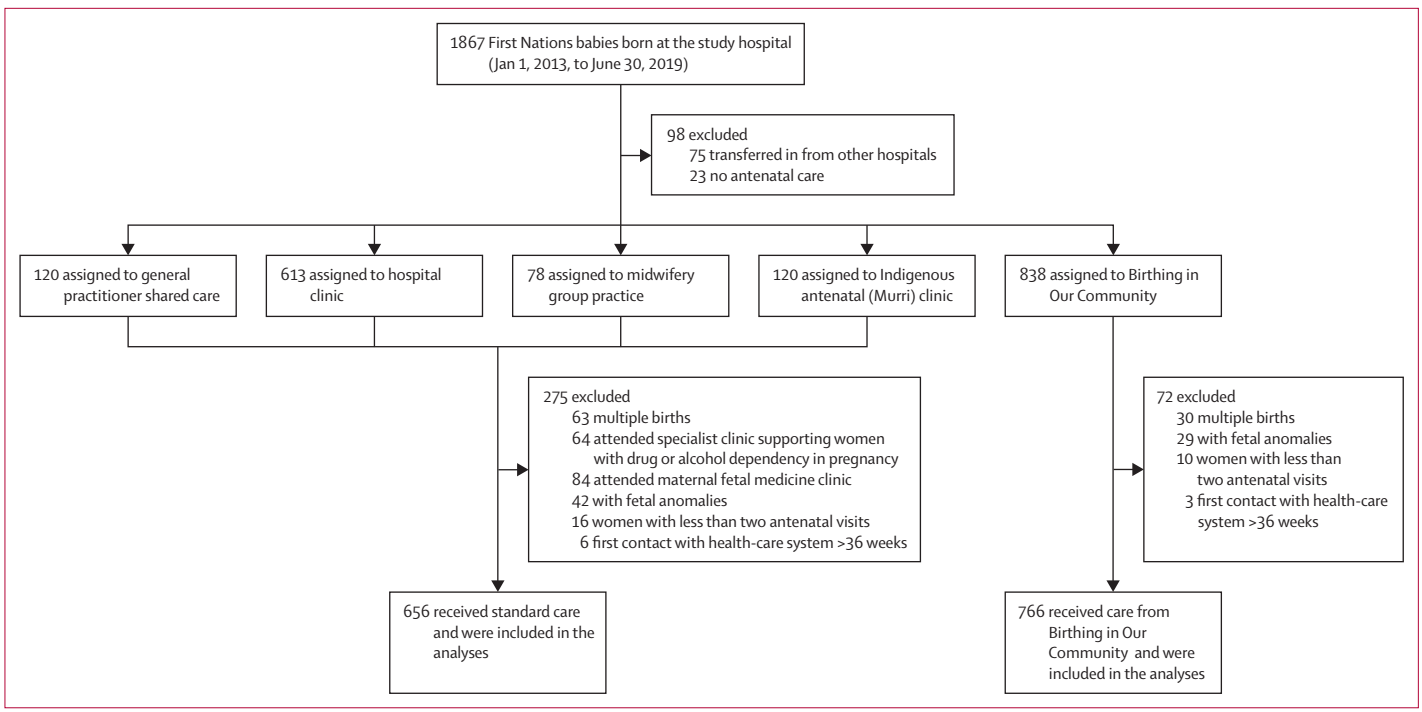

Figure: **Trial profile**

Outcomes

Predefined primary outcomes were antenatal care attendance (five or more visits), smoking after 20 weeks of gestation, preterm birth (at least 20 weeks of gestation or birthweight 400 g and fewer than 37 weeks of gestation), and exclusive breastfeeding (breastmilk at the breast, expressed breastmilk, or both) at discharge from hospital.

Secondary outcomes were also predefined[13] and included first antenatal contact within first trimester (<14 weeks), spontaneous onset of labour, analgesia in first stage of labour (epidural, narcotics, or nitrous oxide), method of birth, post-partum haemorrhage (≥500 mL), physiological management of third stage, perineal trauma (third-degree or fourth-degree tear, episiotomy), exclusive breastfeeding intention at birth (breastmilk at the breast, expressed breastmilk, or both), low birthweight (<2500 g), stillbirth, Apgar score lower than 7 at 5 min, neonatal nursery admission (special care nursery and neonatal intensive care unit), and neonatal deaths before hospital discharge (≤28 days).

Statistical analysis

The study was powered for all primary outcomes.[13] The calculation of sample size for the study was based on preterm birth. To detect a preterm rate change from 16% to 9% with 80% power and a type 1 error of 5%, 350 women for whom data could be analysed in each group were needed. We anticipated a 20% attrition rate, and the final sample size needed was 420 women in each group. We did two-sample Student's *t* test for baseline continuous variable with normal distribution, Wilcoxon rank-sum for non-normally distributed continuous variables, and Pearson's χ^2 test for categorical variables to explore any differences between the two cohorts. Analyses were done on a per-protocol basis.

To quantify the association between the study outcomes and the BiOC service, we did bivariate logistic regressions with a robust error variance to calculate crude odds ratios (ORs) and 95% CIs. We used inverse probability of treatment weighting to control confounding, by constructing a weighted cohort of women who only differed in the model of care they received but were similar in other measured characteristics. A propensity score of the participant was defined as the conditional probability of her receiving the BiOC service given the values of observed baseline confounders. We adjusted all baseline variables including demographic variables (maternal age, body-mass index, First Nations mother, education, and relationship status), socioeconomic variables (Socio-Economic Indexes for Areas quintiles), obstetric history (parity, smoking status at booking, previous caesarean section, previous stillbirth, and previous preterm birth), and maternal pre-existing comorbidities (autoimmune disease, thyroid disease, haematological disease [anaemia, bleeding, clotting disorder, and leukaemia], heart disease, renal disease, liver disease, mental health illness, essential hypertension, and diabetes). Standardised differences and summary measures Rubin's B and Rubin's R were

calculated to assess the balance of measured baseline variables.[15,16]

To ensure that the treatment effect was not biased by missing data, we did a multiple imputation analysis by chained equations (n=10), and treatment effect analyses were done for both complete case sample and imputed sample for the primary outcomes. We assumed that our missing data were at least missing at random.

The secondary outcomes analysis was based on the imputed sample alone. The robustness of our findings for the primary outcomes was assessed through several sensitivity analyses. We used different propensity score matching strategies such as nearest neighbour matching (1:1) within specified calliper with replacement and without replacement. All analyses were done in Stata, version 16.0. This trial is registered with the Australian New Zealand Clinical Trial Registry, ACTRN12618001365257.

Role of the funding source

The funder of the study had no role in study design, data analysis, data interpretation, or writing of this paper.

Results

Between Jan 1, 2013, and June 30, 2019, 1867 First Nations babies were born at the Mater Mothers Public Hospital. After exclusions, 1422 women received either standard care (656 participants) or the BiOC service (766 participants) and were included in the analyses (figure). The BiOC service and standard care cohorts had significant differences in several maternal and obstetric characteristics, with some risk factors for the primary outcomes higher in one group than in the other (table 2). Compared with women receiving standard care, those who received care through the BiOC service were more likely to be a First Nations mother, younger, single, socioeconomically disadvantaged, or primiparous; and to have lower education levels, mental health illness, or renal disease. Participants in the BiOC service were also less likely to have haematological disease, thyroid disease, essential hypertension, or a previous caesarean section than those receiving standard care (table 2). We were missing data on nine variables, which accounted for 164 (12%) of 1422 records: 134 (9%) had one variable missing and 30 (2%) had between two and six variables missing.

The univariate analysis from the imputed unweighted sample showed that infants of women accessing care through the BiOC service were significantly less likely to be born preterm (OR 0·53, 95% CI 0·37–0·76). In the same analysis, we found no significant differences between groups for the outcomes of five or more antenatal visits, smoking after 20 weeks of gestation, and exclusively breastfeeding at discharge from hospital (table 3).

Next, we analysed the inverse probability weighted cohort, which balanced all the measured baseline covariates between the groups (all had standardised difference <10%; appendix pp 1–11). Results from the imputed weighted sample showed that women attending the BiOC service were significantly less likely to have

	Standard care (n=656)	Birthing in Our Community (n=766)	p value
Maternal age, years	27·4 (6·3)	26·5 (6·2)	0·0076
Body-mass index	24·5 (20·8–30·7; n=654)	24·6 (20·9–30·1; n=765)	0·94
First Nations mother	398 (61%)	673 (88%)	<0·0001
First Nations father	403 (61%)	370 (48%)	<0·0001
Socioeconomic status			0·042
Quintile 1 (most disadvantaged)	129 (20%)	190 (25%)	..
Quintile 2	100 (15%)	101 (13%)	..
Quintile 3	93 (14%)	126 (16%)	..
Quintile 4	193 (29%)	217 (28%)	..
Quintile 5 (most advantaged)	140 (21%)	131 (17%)	..
Not recorded	1 (<1%)	1 (<1%)	..
Education			0·011
Grade <10	55 (8%)	58 (8%)	..
Grade 10–12	412 (63%)	534 (70%)	..
Tertiary	151 (23%)	131 (17%)	..
Not recorded	38 (6%)	43 (6%)	..
Marital status			0·022
Married or cohabiting	347 (53%)	352 (46%)	..
Not married nor cohabiting	299 (46%)	388 (51%)	..
Not recorded	10 (2%)	26 (3%)	..
Parity			0·078
Primiparous	255 (39%)	289 (38%)	..
1–3 births	312 (48%)	400 (52%)	..
4–12 births	88 (13%)	77 (10%)	..
Not recorded	1 (<1%)	0	..
Previous stillbirth	17 (3%)	20 (3%)	0·98
Previous neonatal deaths	4 (1%)	2 (<1%)	0·31
Previous preterm	67 (10%)	61 (8%)	0·14
Previous caesarean section	115 (18%)	121 (16%)	0·38
Reported smoking status at booking			0·15
Non-smoker	439 (67%)	493 (64%)	..
Smoker	205 (31%)	271 (35%)	..
Not recorded	12 (2%)	2 (<1%)	..
Pre-existing comorbidities			
Autoimmune disease	13 (2%)	13 (2%)	0·69
Thyroid disease	28 (4%)	22 (3%)	0·15
Liver disease	14 (2%)	23 (3%)	0·31
Haematological disease	24 (4%)	11 (1%)	0·0070
Heart disease	45 (7%)	48 (6%)	0·65
Kidney renal disease	70 (11%)	88 (11%)	0·62
Mental health illness	231 (36%; n=645)	310 (41%; n=763)	0·064
Hypertension (including previous gestational hypertension)	43 (7%)	29 (4%)	0·018
Diabetes (including previous gestational diabetes)	83 (13%)	94 (12%)	0·83

Data are mean (SD), median (IQR), or n (%).

Table 2: **Demographic and clinical characteristics of participants**

See Online for appendix

	Crude OR (95% CI)	p value	Adjusted OR* (95% CI)	p value
Complete case sample† (n=1258)				
Preterm birth	0·42 (0·26–0·66)	<0·0001	0·53 (0·32–0·88)	0·015
≥5 antenatal visits	1·49 (1·06–2·09)	0·021	1·82 (1·29–2·58)	0·0007
Smoking after 20 weeks of gestation	1·13 (0·85–1·49)	0·40	0·98 (0·79–1·22)	0·88
Exclusive breastfeeding at discharge from hospital	1·23 (0·96–1·58)	0·097	1·38 (1·06–1·79)	0·016
Imputed sample† (n=1422)				
Preterm birth	0·53 (0·37–0·76)	0·0007	0·62 (0·42–0·93)	0·019
≥5 antenatal visits	1·35 (0·99–1·83)	0·053	1·54 (1·13–2·09)	0·0064
Smoking after 20 weeks of gestation	1·18 (0·92–1·52)	0·20	1·03 (0·84–1·26)	0·79
Exclusive breastfeeding at discharge from hospital	1·22 (0·97–1·53)	0·096	1·34 (1·06–1·70)	0·014

OR=odds ratio. *Variables used in the propensity score model are demographic (maternal age, body-mass index, First Nations mother, education, and relationship status), socioeconomic (Socio-Economic Indexes for Areas quintiles), obstetric history (parity, smoking status at booking, previous caesarean section, previous stillbirth, and previous preterm birth), and maternal pre-existing comorbidities (autoimmune disease, thyroid disease, haematological disease, heart disease, renal disease, liver disease, mental health illness, essential hypertension, and diabetes). †Balanced all the measured baseline covariates between the groups.

Table 3: **Treatment effect of Birthing in Our Community service on primary outcomes among unweighted cohort and inverse probability weighted cohort**

	Crude OR (95% CI)	p value	Adjusted OR* (95% CI)	p value
First contact within first trimester	1·35 (1·05–1·73)	0·021	1·50 (1·15–1·96)	0·0027
Spontaneous onset of labour	1·18 (0·96–1·46)	0·12	1·08 (0·88–1·33)	0·45
Epidural in first stage of labour	0·68 (0·54–0·85)	0·0009	0·76 (0·61–0·96)	0·022
Narcotics in first stage of labour	1·04 (0·76–1·41)	0·82	1·08 (0·78–1·49)	0·66
Nitrous oxide gas in first stage of labour	0·96 (0·78–1·18)	0·69	0·96 (0·78–1·19)	0·72
Spontaneous vaginal birth	1·23 (0·98–1·54)	0·070	1·09 (0·89–1·34)	0·41
Instrumental vaginal birth	0·84 (0·58–1·23)	0·38	0·93 (0·62–1·39)	0·72
Planned caesarean section	0·72 (0·50–1·02)	0·064	0·68 (0·50–0·92)	0·013
Emergency caesarean section	0·97 (0·72–1·32)	0·86	1·17 (0·85–1·60)	0·34
Post-partum haemorrhage	0·84 (0·65–1·09)	0·20	0·83 (0·63–1·09)	0·18
Physiological management of third stage	3·91 (2·07–7·39)	<0·0001	3·85 (1·94–7·66)	0·0001
Third-degree or fourth-degree tear	1·07 (0·42–2·73)	0·89	1·27 (0·46–3·53)	0·65
Episiotomy	0·75 (0·50–1·11)	0·15	0·84 (0·55–1·27)	0·40
Exclusive breastfeeding intention at birth	0·87 (0·63–1·20)	0·38	1·03 (0·74–1·43)	0·87
Low birthweight	0·60 (0·41–0·89)	0·012	0·69 (0·46–1·04)	0·074
Stillbirth	0·86 (0·21–3·43)	0·83	0·98 (0·24–3·91)	0·98
Apgar score <7 at 5 min	1·53 (0·75–3·13)	0·25	1·50 (0·72–3·14)	0·28
Admission to neonatal nursery	0·69 (0·51–0·92)	0·013	0·69 (0·51–0·94)	0·019
Neonatal death before discharge	0·86 (0·05–13·72)	0·91	0·55 (0·03–8·73)	0·67

Data are for the imputed sample (n=1422). OR=odds ratio. *Variables used in the propensity score model are demographic (maternal age, body-mass index, First Nations mother, education, and relationship status), socioeconomic (Socio-Economic Indexes for Areas quintiles), obstetric history (parity, smoking status at booking, previous caesarean section, previous stillbirth, and previous preterm birth), and maternal pre-existing comorbidities (autoimmune disease, thyroid disease, haematological disease, heart disease, renal disease, liver disease, mental health illness, essential hypertension, and diabetes).

Table 4: **Treatment effect of Birthing in Our Community service on secondary outcomes among unweighted cohort and inverse probability weighted cohort**

infants born preterm (adjusted OR 0·62, 95% CI 0·42–0·93), more likely to have received five or more antenatal visits (1·54, 1·13–2·09), and more likely to exclusively breastfeed at discharge from hospital (1·34, 1·06–1·70; table 3). We found no significant difference between the two cohorts for odds of smoking after 20 weeks of gestation in the weighted or unweighted sample. The findings from the complete case analysis were consistent with those of the imputed sample.

The inverse probability of treatment weighting analysis found that, compared with women receiving standard care, women in the BiOC service had significantly earlier engagement with the health service, used less epidural pain relief in the first stage of labour, and had fewer planned caesarean sections. Babies in the care of the BiOC service were significantly less likely to be admitted to a special neonatal care nursery or neonatal intensive care unit (table 4). Additionally, women in the BiOC service were more likely to have their third stage of labour managed without intervention than those receiving standard care (table 4). More details of the univariate analysis of primary and secondary outcomes between the two cohorts, such as frequency and proportion, are presented in the appendix (p 12).

Of the two alternative propensity score matching strategies, the results are consistent with the main findings. The nearest 1:1 propensity score matching without replacement model successfully balanced the measured covariates (appendix p 13), with similar findings to the main analysis: preterm birth (adjusted OR 0·52, 95% CI 0·28–0·94), having five or more antenatal visits (1·73, 1·13–2·65), smoking after 20 weeks of gestation (1·14, 0·80–1·61), and exclusively breastfeeding at discharge (1·39, 1·00–1·92; appendix p 14). However, the 1:1 nearest matching without replacement model resulted in a smaller number of matched pairs (379 pairs), which might limit the generalisability of the estimated effect because of some treated women being excluded. The 1:1 matching with replacement did not balance all the covariates (appendix p 15).

Discussion

The results from this study provide much needed evidence of the clinical effectiveness of a service designed to implement national Birthing on Country policy for the best start in life for First Nations babies in an urban setting. We found three of the four primary outcomes significantly improved within our BiOC service: antenatal care attendance, preterm birth, and breastfeeding at discharge. Our early reduction in preterm birth (2013–17)[14] has been sustained. This is particularly noteworthy given the international concern for rising preterm birth rates, and the evidence gap on how best to reduce preterm birth and infant mortality internationally[17] and in socially disadvantaged and vulnerable women in high-income countries.[18] In the Australian First Nations context, our results highlight the successes of co-designed community-led approaches to improve outcomes. These improvements were achieved in spite of the failures of successive governments to implement

the Closing the Gap Strategy,[19] few improvements in health outcomes including child mortality and life expectancy,[1] and no change in the national preterm birth gap in many years.[2]

First Nations leaders and organisations are calling for structural changes that enable greater self-determination, leadership, and control of health services, both nationally[20] and internationally through the UN Declaration on the Rights of Indigenous Peoples. Our BiOC multi-agency partnership increased First Nations governance and control, an approach recommended when reconfiguring services in the Australian First Nations context.[21] Key enablers were having a shared vision, committed leadership, and strategies to support the development of trusting relationships between partners and staff.[22,23]

The continuity of midwifery carer is well established in reducing preterm birth in the general population and, as such, it was deemed an essential component. Midwifery continuity within the BiOC service differs from that of standard care in that the relationship-based service addresses not only the physical, but the social, cultural, spiritual, and psychological wellbeing of the woman and her family, while also promoting normal physiological birth.[24] This philosophy aligns well with the National Aboriginal and Torres Strait Islander Health Plan and First Nations holistic understanding of health that recommends a strengths-based approach to ensure programmes improve health, social and emotional wellbeing, and resilience.[6]

Universal coverage of midwifery services, operating within an enabling environment in low-income and middle-income countries, is projected to avert 67% of maternal deaths, 64% of neonatal deaths, and 65% of stillbirths.[25] How this translates to the First Nations environment is unclear, but serious structural barriers currently prevent the Aboriginal Community-controlled sector from increasing midwifery service coverage. No appropriate insurance product is available for Aboriginal Community-controlled health services to use their own midwives to provide intrapartum care, and thus partnerships with other services are a necessary work-around to enable the provision of midwifery continuity of carer. Funding to provide this gold-standard midwifery care through the universal primary health care funding scheme (Medicare) is also inadequate, with 92% of funding for maternity services attributed to hospital expenditure rather than primary care.[26] A national taskforce review of Medicare, completed in 2018, recommended substantial changes to increase universal access to midwifery care, noting the potential impact on Birthing on Country services; their recommendations are yet to be implemented.[26] Both the insurance and funding barriers have been highlighted as substantial problems in multiple national reviews and are hampering the roll-out of Birthing on Country services, and midwifery care, to the First Nations population. Addressing these barriers to maximise the enabling environment for the greatest impact can only be done by the Commonwealth Government and requires urgent action.

The National Aboriginal and Torres Strait Islander Health Plan emphasises the centrality of culture in the health of First Nations Australians and the importance of reducing systematic, institutionalised racism.[6] The First Nations workforce strategy of the BiOC service not only addresses the social determinants of health inequality by increasing employment and education, but also addresses racism and provides social support. Within the BiOC service, family support workers work side by side with midwives, increasing the cultural safety of the BiOC service, hosting regular community days, and providing practical, cultural, social, and emotional support for families.[23] The support workers link women to housing, financial, and legal support when required and are based at a welcoming community hub, operated by one of the Community-controlled partners. Services include transport and onsite access to social work, perinatal psychology, and both paediatric and women's health outreach. If a specialist referral is required, the family support worker can accompany women to the hospital or primary health-care clinics to ensure women are well supported with integrated care.

Antenatal smoking is an important modifiable cause of adverse pregnancy outcomes, including preterm birth and perinatal death.[17] Rates are high among pregnant First Nations women in Australia (43%) compared with those of non-Indigenous mothers (11%).[2] Although we found no difference in smoking after 20 weeks of gestation, both cohorts reported rates lower than the national rate (appendix p 2), potentially reflecting broader public health messaging and a range of smoking cessation support being offered to pregnant women in this urban setting.

Almost 90% of women in both groups intended to breastfeed at birth, but exclusive breastfeeding on discharge was significantly higher in the intervention cohort. Breastfeeding at birth is a key predictor of longer-term breastfeeding, which has significant health benefits for mothers and infants.[27] Breastfeeding is correlated with reductions in health conditions for which First Nations people are over-represented, such as childhood mortality and morbidity, hypertension, obesity, some types of cancer, diarrhoea, respiratory infections, and diabetes.[27] Possible long-term maternal benefits include a reduced risk of type 2 diabetes and breast and ovarian cancer.[27] The continued support for women in the BiOC service until 6 weeks after birth and a strong integration with the primary health-care network services are likely to further sustain breastfeeding rates.

Our secondary outcomes highlighted that more women accessed antenatal care through the BiOC service in the first trimester than those receiving standard care. We chose this as an outcome rather than a potential confounder because we believed that the community engagement approach to the service

redesign led by the First Nations primary health-care network would drive early presentations. Anecdotally, the BiOC service's popularity with the community was evident: many inquiries were made directly by women early in the first trimester on how they could book into the service, after hearing positive experiences from friends and family. Our secondary outcomes also highlighted fewer epidurals and planned caesarean sections in the intervention cohort, with more women having physiological management of third stage. These are also features often associated with midwifery continuity models that encourage physiological birth.[24] Additionally, fewer babies born with BiOC services were admitted to a neonatal nursery.

Despite not randomly assigning participants, we have used best statistical practice to identify, separate, and subsequently control for baseline imbalances and effects that might confound our estimate of the BiOC service on the outcomes reported. Although propensity score weighting modelling might be superior to standard regression modelling for observational studies facing violations of the unfoundedness assumptions and selection bias, it cannot control for hidden bias between cohorts or provide definitive answers to questions of treatment effect. Despite this, in the absence of randomised studies, these results provide much needed evidence for redesigning services to improve health outcomes for First Nations people.

At this stage, it is difficult to say which elements of this complex intervention are essential and which could be done without. Synergistically, this combination of elements are driving improved outcomes, most likely by increasing cultural safety and driving early and frequent health engagement. This facilitates the development of trusting relationships, disclosure of issues to allow early intervention (eg, homelessness or family violence), and opportunities to modify predictors of preterm birth. Although we do not know how the components should be modified for rural and remote settings, especially when women are relocated from their home communities for birth, it is likely that a scale-up would see similar results for First Nations women and babies across similar urban and regional settings. Our team have developed a framework[28] to guide implementation that allows for customisation of the service to the local community context through a participatory action process, enabled by strong partnerships and leadership from First Nations people and Community-controlled organisations.

In conclusion, our study found that the urban multi-agency BiOC service redesign resulted in significantly improved maternal and infant outcomes, which were sustainable over time and are likely to affect individuals across the lifecourse and intergenerationally. These results strengthen the evidence regarding the effectiveness of such services for women at risk of preterm birth[29] and support policy recommendations for national implementation[3] of Birthing on Country services[30] for First Nations Australians. Real-life implementation of complex interventions such as Birthing on Country services can be challenging;[28] however, testing on a national scale will be important given the contribution of preterm birth to child mortality.[1] A realist review of the BiOC service will help strengthen our understanding of the causal mechanisms and key features thought to be essential for improved outcomes, while further research will need to focus on testing replication, adaption, and fine tuning of the intervention.

Contributors

SKi was involved in developing the intervention; led the literature search, protocol development, successful funding applications, study design, ethical approvals, data interpretation, and writing of the manuscript; oversaw data collection; and contributed to key decisions in analysis. YG was involved in protocol and study design, writing the successful funding proposal, interpretation of results, and writing of the manuscript; and did the data analysis, leading key decisions in analysis, and completed the tables and figures. SH contributed to the conduct and monitoring of the study, collection of data, ethical approvals, interpretation of results, and writing of the manuscript. CN was involved in developing the intervention, protocol and study design, writing the successful funding proposals, interpretation of results, and writing of the manuscript. SKr contributed to the protocol and study design, writing the successful funding proposal, interpretation of results, and writing of the manuscript. AC, JCu, MR, KWa, KWi, and JCo contributed to the delivery of the intervention, interpretation of results, and writing of the manuscript. SKi, SKr, CN, KWi, and SH were involved in monitoring intervention fidelity. YR provided Indigenous oversight of the study; was involved in protocol development, study design, and writing the successful funding proposal and Indigenous methods; and contributed to key decisions in analysis, interpretation of results, and writing of the manuscript. SKi and YG accessed and verified all the data in the study. All authors had full access to study data and the corresponding author had final responsibility for the decision to submit for publication.

Declaration of interests

The research team received an Australian National Health and Medical Research Council partnership grant, with the partner organisations funding delivery of the new health service, with additional funding from the Queensland Government to the Institute for Urban Indigenous Health (to AC, CN, and KWa) to expand health service delivery. SKi and YG were employed by Mater Research Institute and University Queensland, then Charles Darwin University during the course of the study. SH was employed by Mater Research Institute then Charles Darwin University. YR was employed by the Institute of Urban Indigenous Health, then Mater Research Institute, then Charles Darwin University, during the course of the study. CN, AC, JCu, KWa, and SKr were employed by Institute of Urban Indigenous Health, with JCu then employed by Aboriginal and Torres Strait Islander Community Health Service Brisbane, and SKr then employed by Charles Darwin University. MR, KWi and JCo were employed by Mater Hospital. Some of the National Health and Medical Research Council funding that supported the research contributed to salaries of YR, SH and YG. We declare no other competing interests.

Data sharing

The study protocol is published and available in an open-access article. The statistical analysis plan will be made available for research purposes upon request to the corresponding author. The deidentified data supporting the conclusion of this article will be available for researchers after approval by the Birthing in Our Community Steering Committee (Brisbane, Australia).

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