BMJ Open

Addressing inequality at birth using caseload midwifery in a deprived diverse inner-city population: A cohort study

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2021-049991
Article Type:	Original research
Date Submitted by the Author:	09-Feb-2021
Complete List of Authors:	Hadebe, Ruth; Guy's and St Thomas' NHS Foundation Trust, Department of Women's Health Seed, Paul; King's College London, Department of Women and Children's Health Essien, Diana; Guy's and St Thomas' NHS Foundation Trust, Department of Women's Health Headen, Kyle; Guy's and St Thomas' NHS Foundation Trust, Deapartment of Women's Health Mahmud, Saheel; King's College London School of Medicine Owasil, Salwa; King's College London School of Medicine Fernandez Turienzo, Cristina; King's College London, Department of Women and Children's Health Stanke, Carla; National Childrens Bureau, Public Health; Lambeth Early Action Partnership Sandall, Jane; Kings College, London, Department of Women and Children's Health Bruno, Mara; Guy's and St Thomas' NHS Foundation Trust, Department of Women's Health Khazaezadeh, Nina; Guy's and St Thomas' NHS Foundation Trust, Department of Women's Health Oteng-Ntim, Eugene ; guys and st thomas nhs foundation trust, Department of Women's Health; King's College London, Department of Women and Children's Health
Keywords:	OBSTETRICS, ETHICS (see Medical Ethics), Health policy < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our licence.

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which Creative Commons licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

Addressing inequality at birth using caseload midwifery in a deprived diverse inner-city Population: A cohort study

Ruth Hadebe, ST6 obstetrics and gynaecology[1] (0000-0003-4020-8933), Paul Seed, reader in medical statistics[2] (0000-0001-7904-7933), Diana Essien, clinical fellow obstetrics and gynaecology[1], Kyle Headen ST2 obstetrics and gynaecology[1], Saheel Mahmud, medical student[3], Salwa Owasil, medical student[3], Cristina Fernandez Turienzo, midwife researcher[2] (0000-0002-7393-6593), Carla Stanke, public health specialist[4,5], Jane Sandall, professor of social science and women's health[5] (0000-0002-5384-3744), Mara Bruno, midwife[1], Nina Khazaezadeh, consultant midwife in public health[1], Eugene Oteng-Ntim, professor of obstetrics, [1,2](0000-0001-8867-2909).

Affiliations

1 Guy's and St Thomas' NHS Foundation Trust, Department of Women's Health London, UK,

2 Department of Women and Children's Health, Faculty of Life Science and Medicine, King's College London, London, United Kingdom.

3 King's College London School of Medicine, London, UK,

4 National Children's Bureau, Public Health, London, UK,

5 Lambeth Early Action Partnership

Corresponding Author: Ruth Hadebe, Dept Women's Health, 10th Floor, North Wing, St Thomas Hospital, Westminster Bridge Road, London. SE1 7EH. Email: ruth.hadebe@nhs.net

Article Summary:

Abstract

Objectives:

i. To report maternal and newborn outcomes of pregnant women in areas of social deprivation in inner-city London.
ii. To compare the effect of caseload midwifery with standard care on maternal and newborn outcomes in this cohort of women.

Design: Retrospective observational cohort study.

Setting: Four council wards in inner-city London, where over 90% of residents are in the two most deprived quintiles of the English Index of Multiple Deprivation (IMD 2015) and the population is ethnically diverse.

Participants: All women booked for antenatal care under Guys and St Thomas' NHS Foundation Trust after 11/7/2018 (when the Lambeth Early Action Partnership (LEAP) caseload midwifery team[a] was implemented) until data collection 18/6/2020. This included 523 pregnancies in the LEAP area, of which 293 were allocated to caseload midwifery, and 8430 pregnancies from other areas.

Main outcome measures: To explore if targeted caseload midwifery (known to reduce preterm birth) will improve important measurable outcomes (preterm birth, mode of delivery, and newborn outcomes).

Results: There was a significant reduction in preterm birth rate in women allocated to caseload midwifery, when compared to those who received traditional midwifery care (5.1% CL vs 11.2%; risk ratio: 0.45; P=0.04; confidence interval 0.21 to 0.96; number needed to treat: 14.9). Caesarean section births were significantly reduced in women allocated to caseload midwifery care, when compared to traditional midwifery care (24.3% vs 38.0%; risk ratio: 0.64: P=0.01; confidence interval: 0.46 to 0.89; number needed to treat: 7) including emergency caesarean deliveries (15.2% vs 22.5%; risk Ratio: 0.58; P=0.02; confidence interval: 0.36 to 0.92; number needed to treat: 9.5) without increase in neonatal unit admission or stillbirth.

Conclusion: This study shows that a model of caseload midwifery care implemented in an inner-city deprived community improves outcome by significantly reducing preterm birth and delivery by caesarean section when compared to traditional care. These data trend suggests that when applied to targeted groups (women in higher IMD quintile and women of diverse ethnicity) that the impact of intervention is greater.

Strengths and limitations of this study:

- This study leads the discussion of where we can best target a known effective intervention (midwifery continuity of care) in a resource limited health care system i.e. effect more marked in women of BAME ethnicity and women with complex social disadvantage, in order to reduce outcome inequality.
- This was a pragmatic study that included twin and triplet pregnancies, repeat pregnancies, and women with complex medical and obstetric histories, often excluded from other studies analysing a programme of care that has been shown to work in practice in a socially deprived area, rather than recruiting to a research study intervention.
- Intention to treat analysis was used where continuity was affected by provider circumstantial limitations, thus, results reflect the reality of intervention in a non-study clinical practice and logistical regression analysis was performed using an established statistical method (inverse probability weighting) to correct for bias in case selection.
- There may be confounders in caseload allocation and outcome which may bias our results. However, women allocated to the caseload midwifery care are anticipated to be at higher risk of adverse outcomes and hence allocated thus, making the improvements demonstrated in their outcomes potentially more significant.
- The small numbers in less common outcomes (e.g. Stillbirth and NND), allow trends to be only cautiously highlighted. Neonatal deaths outside the data collection period may have occurred in all groups, although numbers are likely to be small.

Introduction.

Fetal outcome is affected by social deprivation and parental ethnicity.[1] In 2016, 25.9% of all stillbirths in the UK occurred in the most deprived English Index of Multiple Deprivation (IMD) quintile compared with 14.9% in the least, with a similar distribution for neonatal death (25.7% and 15.9% respectively).[2] In 2017, the stillbirth rate for the UK was 3.74 per 1000, however in Black/Black British and Asian/Asian British women, rates were 7.46 and 5.70 per 1000 respectively, with an increase in neonatal mortality (despite a downward trend in the White patient population).[2] Preterm birth is more common in women affected by social deprivation[3], and the combination is associated with developmental problems in the early years.[4,5] Preterm birth negatively impacts maternal mental health, relationships between child and caregiver, and interaction with support services.[6]

Maternal mortality more than doubles from the least to the most deprived IMD quintiles (5 to 12 per 100,000).[7] Black women are 5 times more likely to die as a result of pregnancy than White women (38 compared with 7 per 100,000), women of mixed ethnicity 3 times, and women of Asian ethnicity 2 times.[7] Mortality is associated with suboptimal utilisation of antenatal services, including late/no booking and nonattendance, (most marked in Black African, Black Caribbean and Middle Eastern women).[8] For each step up in deprivation quintile, women are more likely to receive no antenatal care (25% increase per quintile), to have an unplanned caesarean section (15% per quintile) and any (elective and emergency) caesarean section(4% per quintile)[9]. Women with higher deprivation scores are less likely to be seen in the first trimester and more likely to report dissatisfaction with clarity of communication and respectful treatment by doctors and midwives.[9]

Considering that several causal determinants of adverse infant outcomes associated with low socioeconomic status are potentially avoidable, strategies that promise even modest improvements warrant serious consideration. Targeted interventions for vulnerable children in early childhood have been shown to work,[10, 11] to be economically effective,[12] and have been incorporated into standard public health practice.[13] Targeting early childhood alone misses the opportunity to address inequality in-utero and the disparity already present at birth.

Caseload midwifery describes continuity of midwifery care from booking, to the post-natal period, with longer and more frequent antenatal appointments including in the home setting. Continuity of midwifery care has been shown to reduce preterm birth.[14] If these findings are applicable in women whose infants are at greater risk of adverse outcomes, caseload midwifery as an intervention in a socially deprived and ethnically diverse inner-city population, may begin to address this disparity. We aim to investigate caseload midwifery antenatal intervention and its potential for improving pregnancy outcomes in areas of deprivation in inner-city London.

Objectives:

To report maternal and newborn outcomes of pregnant women in areas of social deprivation.

To compare maternal and newborn outcomes in this cohort of women when exposed to caseload midwifery intervention with standard care.

We hypothesise that in our deprived population, outcomes will be poorer than in the general population. We propose that caseload midwifery will improve important measurable outcomes (in relation to gestational age and mode of delivery) and bring them closer to the population mean.

Methods

Study design and data source

This was an observational, cohort study using retrospective data collected at Guys and St Thomas' NHS Foundation Trust, a tertiary level NHS facility in inner-city London. Pregnant women who booked at Guys and St Thomas NHS foundation trust, between 11/7/2018 and 18/6/2020, were allocated to 'traditional' care or 'caseload' care by a screening administration team (following submission of a self or GP referral form). In our main, caseload midwifery comparator population, to meet the referral criteria caseload care, women were required to live in a LEAP[a] area (defined by postcode, where more than 90% residents fall in the two most deprived IMD quintile,[15]) and meet the definition of "vulnerable" (table 1). It was possible for a woman to be transferred from traditional care to caseload care due to an evolving issue later in pregnancy. Twin and triplet pregnancies, repeat pregnancies and patients with complex medical and obstetric histories were included. Ongoing pregnancies on 18/6/2020, women marked "LEAP caseload" with non-LEAP post codes were excluded from the analysis and women with unknown midwifery care pathway.

In caseload care, teams of six midwives care for 18 pregnant women/month. Primigravid and parous women received ten 30-minute appointments in the woman's home or clinic setting as standard. Individualised care pathways allowed frequent and longer visits as required. Two midwives were involved from booking to post-natal care for each patient. Teams were on call for labour and provided extended post-natal care (up to 28 days). Early in antenatal care, a multiagency referral (for support services) form was completed entitled "Safeguarding risks to the unborn", as necessary. The midwifery team have access to social work, health visitors, substance use services and mental health services.

There were two routes for traditional care: 1) Traditional midwifery led care and 2) Consultant led/shared care. The traditional midwifery led care was for low-risk women, managed using the standard NICE guideline pathway (ten 15-minute appointments, mostly in a clinic setting for primiparous and seven for parous).[18] A variable number of midwives were involved antenatally, with a new midwife in labour and a new midwife postnatally. Consultant led/shared care was for women at high medical obstetric risk. The number of appointments was individualised, and appointments were usually 10 to 20 minutes in duration in an antenatal clinic setting. Antenatal midwifery involvement could vary significantly, with a new midwife in labour and a new midwife postnatally.

Non-LEAP area women received a mix of the above three models of care. Outcomes are reported as a guide for antenatal outcome standards in a less deprived, less diverse population.

Data collection

Anonymised data was extracted from maternity records (BadgerNet®) and collated on an Excel spreadsheet. Variables recorded were type of midwifery care provided, post code, age, marital status, BMI, ethnicity, and smoking status at booking and delivery. Data on newborn outcomes including stillbirths, neonatal death, neonatal admission, gestation of delivery, birthweight, breastfeeding at delivery, and skin to skin contact were recorded. Maternal morbidity including pregnancy induced hypertension (>140/90), pre-eclampsia (hypertension plus proteinuria[16]), gestational diabetes (GDM: GTT fasting BG of >5.6 and/or post prandial of

>7.8 at 120 mins) hospital admission, post-partum haemorrhage (PPH 500mls[17]) and mode of delivery were also recorded.

Data were gathered on variables utilised to allocate the women to caseload or traditional care from self and GP referral forms submitted. This included maternal history of need for interpreter services, learning disability, hearing or sight problems, IVF conception, birth location preference, history of previous live children, preterm births, miscarriages, ectopic pregnancies, stillbirths and neonatal deaths, previous caesarean or assisted delivery, thalassaemia or sickle disease, respiratory, diabetic, cardiac, hypertension, renal, liver, neurological or infectious diseases, history of substance abuse, domestic violence, safeguarding issues, and women with the status of refugee or asylum seeker. These questions were "yes/no" on the self-referral form with an opportunity for free text included. On the GP referral if any information was not included, it was assumed to be negative (as this was the information available to the triaging midwife).

Analysis:

Three separate groups were analysed:

1) LEAP area women allocated to caseload midwifery care
2) LEAP area women allocated to traditional care
3) Non-LEAP area women (mix of above care models)

Missing documentation was reported and included in statistical analysis. Neonatal outcomes outside the data collection period were not included.

IMD scores and quintiles were derived from patient postcodes using the National Perinatal Epidemiology Unit tool[18]. Data collection began in 2018, but 2019 IMD data was used in significance analysis[19] (rather than 2015), as likely to be most accurately representative of patient circumstance. They are reported in quintiles (rather than deciles) to simplify interpretation.

164 women who had no referral form, for the purpose of analysis, were assumed to be triaged at their booking visit and were included in absolute numbers but excluded from significance analysis. Information in the questionnaire relevant to the decision to allocate to caseload midwifery care was analysed by logistic regression. Adjustment was made for these differences by the inverse probability weighting method[20] to identify and correct the most important sources of bias (*see table 2).* Subgroup analysis was preformed according to ethnicity and IMD score. Significance analysis was performed by a statistician using Stata statistical package. Significance analysis performed adjusting for those whose continuity was interrupted due to service disruption e.g. staffing and COVID 19, did not affect our results, however we report the whole dataset as intention to treat analysis.

Patient and Public Involvement statement (PPIE):

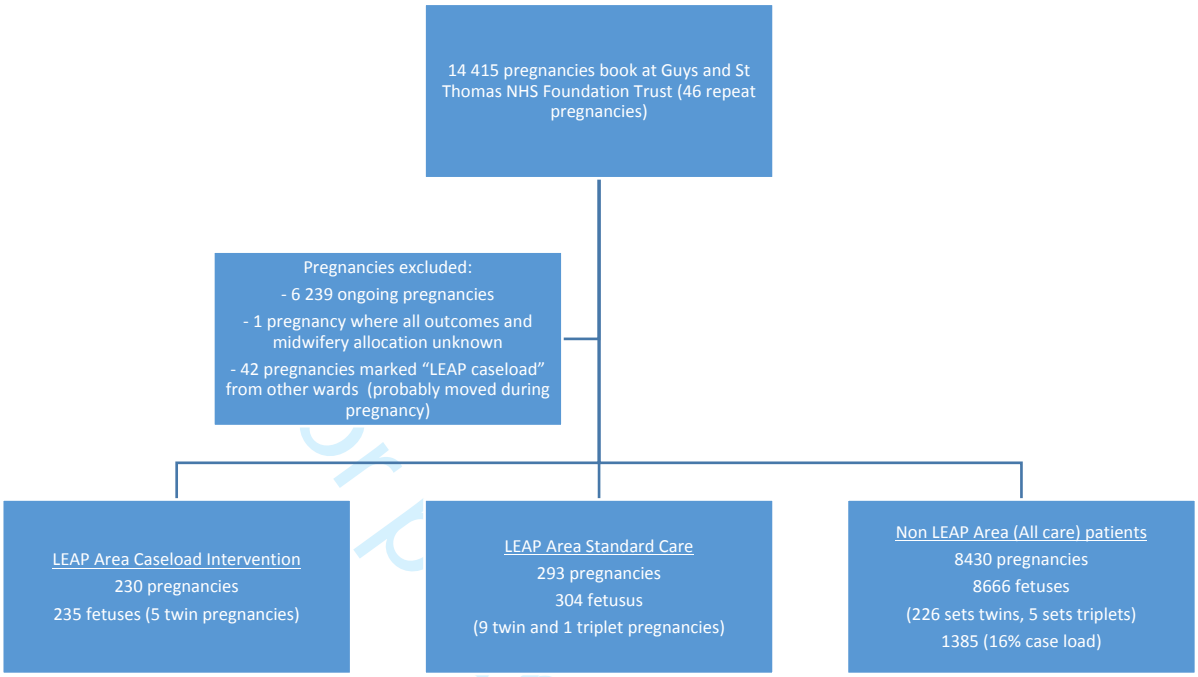
No women were directly involved in the design, conduct, reporting, or dissemination plans of this observational study. However the research question was stimulated by the leading request of women in the Better Births[21] report for continuity of care, and the increasing public consciousness and protest to inequality, including the Black Lives Matter movement. LEAP

Lambeth has parent representatives who feedback regarding early years services to local stakeholders.

Dissemination declaration:

The study findings will be disseminated to local women through the hospital and university websites, seminars and participant engagement events, NIHR ARC South London PPIE group, and conferences.

Results



A total of 14,415 pregnancies booked at Guys and St Thomas' foundation trust in the study period (11/7/2018 to 18/6/2020). We excluded 6239 ongoing pregnancies, 1 where no midwifery allocation or outcomes were known, and 42 pregnancies recorded as LEAP caseload midwifery care, but from other geographical areas (possibly explained by women moving home during pregnancy).

There were a total of 523 pregnancies in women in the LEAP area. Of these, 230 pregnancies (44%) were allocated to caseload midwifery and resulted in 235 fetuses (5 twin pregnancies). 293 pregnancies were allocated to traditional care and resulted in 304 fetuses (9 twin, 1 triplet pregnancy). There were a total of 8430 pregnancies from non-LEAP areas which resulted in 8666 fetuses (226 sets of twins, 5 sets of triplets). Of these, 1385 (16.4%) were allocated to caseload midwifery (non-LEAP team). 46 women had a second pregnancy during the study period, one of which was a twin pregnancy. All were included.

Statistical analysis into decision for caseload midwifery was performed on information available at allocation i.e. data from referral forms. Significant factors that were identified from referral forms in the LEAP area women were women, who needed an interpreter, of unknown ethnicity, with respiratory co-morbidity and previous instrumental delivery *(table 2)* and adjusted for in significance analysis. Multifetal pregnancy was not a statistically significant factor in decision making.

Demographics and modifiable lifestyle related risk factors

The LEAP area had a higher representation of BAME[b] women than in other post code areas (e.g. Black ethnicity: 27.8% vs 17.2%) and higher levels of deprivation (IMD quintile 5: 55.6% vs 28.0%) *(table 3).*

The LEAP area also had a higher proportion of single women (35.2% vs 27.0%), teenage women (3.6% vs 1.3%), women who were smokers at delivery (4.2% vs 2.8%) and obesity (19.5% vs 14.4%) than other areas *(table 4).*

Maternal outcomes:

Primary outcome (mode of delivery) in the LEAP area:

Both elective and emergency caesarean section (CS) rates were higher in the LEAP area (16.3% and 22.5% respectively) compared to other areas. In the LEAP area women allocated to caseload midwifery care, when compared to traditional care, had significantly reduced total CS (38.9 vs 24.3%; risk ratio: 0.64, P=0.01 confidence interval: 0.46 to 0.89, number needed to treat: 7) and emergency CS (22.5 vs 15.2%; Risk Ratio: 0.58, P=0.02; confidence interval: 0.36 to 0.92; number needed to treat: 9.5) *(table 5).*

Sub-analysis into vulnerability in the LEAP area

BAME population: There was a significant difference in the CS rate in those allocated to case load midwifery, compared to those allocated to traditional care. In BAME women the total rate of CS was significantly reduced in those allocated to caseload midwifery compared to those allocated to traditional care (27.8% vs 43.1%; risk ratio: 0.67; P=0.04; confidence interval: 0.40 to 0.99). The statistical significance was similar in White mothers (24.7% vs 39.8%; risk ratio: 0.63; P=0.04; confidence interval: 0.40 to 0.98), but the caesarean rate was higher overall in BAME women. The trend reduction in women allocated to caseload midwifery compared to those allocated to traditional care on emergency caesarean was more marked in BAME women (15.7% vs 26.2%) than White women (16% vs 20.4) but did not reach statistical significance in small numbers (P=0.10; confidence interval 0.38 to 1.08 in BAME women).

IMD quintile 5: The overall rate of CS was higher in women in IMD 5 compared to others (3rd and 4th quintiles combined) (30.3% vs 24.6%), and the rate of emergency CS was higher (21.2% vs 11.4%). The trend in emergency CS reduction in women allocated to caseload midwifery compared to traditional care in IMD 5 is more marked (24.1% vs 17.8%) than in IMD other (12.9% vs 9.8%) but did not reach statistical significance (risk ratio 0.75; P=0.47; confidence interval: 0.34 to 1.65). This trend was not observed for reduction in total CS rate.

Women who needed an interpreter: There was a statistically significant decrease in emergency CS in women allocated to caseload midwifery compared to traditional care (5.0% (1/20) vs 50.0% (4/8)); risk ratio 0.10; P=0.03; confidence interval: 0.01 to 0.75). There was a non-statistically significant reduction in total caesarean section (30% vs 50%; Risk ratio: 0.57; P=0.28; CI 0.21 to 1.59).

Teenage women: In the LEAP area, none of the 13 teenage women allocated to caseload midwifery had a CS (0/13). 33% (2/6) of teenage women allocated to traditional midwifery had an (emergency) CS.

Multifetal pregnancy: In women allocated to caseload midwifery 4/10 (40%) of twin babies were born by elective CS, 1/10 (10%) by emergency caesarean and 5/10 (50%) vaginally. In women allocated to traditional care 11/21 (52.4%) babies were born by elective caesarean, 4/21(19.0%) by emergency caesarean and 6/21 (28.6%) vaginally. Numbers of multifetal pregnancies were small and the impact of caseload midwifery in multifetal pregnancies was similar to singleton in total CS (multifetal risk ratio: 0.57 and singleton risk ratio: 0.65). This reduction remains significant when multifetal excluded P=0.01; confidence interval 0.47-0.91). Reduction in emergency caesarean sections in those allocated to caseload midwifery compared to traditional care was also comparable in multifetal and singleton pregnancies (multifetal risk ratio: 0.39 and singleton RR 0.62. Reduction in emergency caesarean remains significant when multifetal excluded P= 0.04; confidence interval: 0.39 to 0.98).

Secondary outcomes:

Numbers reported for gestational diabetes and hypertensive disease were small with no significant difference observed. *(Table 5)* Post-partum haemorrhage was lower by 8.7% in women allocated to caseload midwifery compared to traditional care, but this did not reach statistical significance (Risk ratio: 0.77; P=0.10; confidence interval: 0.57 to 1.04; number needed to treat: 11.6).

Newborn outcomes in LEAP area women:

Primary outcomes (preterm birth):

Preterm birth rate was reduced in women allocated to caseload midwifery before 37 weeks, before 34 weeks and before 24 weeks gestation relative to traditional care. This was statistically significant in births before 37 weeks (5.1% vs 11.2%; risk ratio: 0.45, P=0.04; confidence interval 0.21 to 0.96, number needed to treat: 14.9). There was a trend towards reduction in preterm birth before 34 weeks (1.7% vs 4.3%) which did not reach statistical significance in our small cohort (risk ratio 0.35; P= 0.11; confidence interval 0.10 to 1.27; number needed to treat: 27.7). There were no pre-viable preterm births in the caseload midwifery group *(table 6).*

Sub analysis into vulnerability

BAME population: Preterm births were reduced by approximately half in BAME women (14.4 to 7.3%) and White women (5.1% to 2.5%) who were allocated to caseload midwifery compared to traditional care. This highlights higher absolute numbers of preterm births in BAME women. There was a more marked trend in reduction in births under 34 weeks in BAME women (7.2% to 1.8%) compared to White women (2.0% to 1.2%) in those allocated to caseload midwifery compared to traditional care.

IMD quintile 5: When women in IMD quintile 5 were compared to other IMD quintiles (quintile 3+4) there were higher rates of premature births overall (7.0% vs 4.2%). In IMD 5 mothers, births before 37 weeks were reduced by almost half in women allocated to midwifery compared to traditional care (4.4% vs 9.1%; risk ratio 0.48; P 0.37; confidence interval: 0.10 to 2.39) compared to a smaller trend reduction in IMD 4 women (3.7% vs 4.7%).

Women who needed an interpreter: There was a statistically significant reduction in preterm birth rate (before 37 weeks) in those allocated to caseload midwifery compared to traditional care (5.3% vs 44.4%; risk ratio: 0.11; P=0.03; confidence interval: 0.01 to 0.83). The impact was more marked than in those not needing an interpreter (5.6% vs 9.2%). There was a statistically significant reduction in preterm birth before 34 weeks in those exposed to caseload midwifery compared to traditional care (0 vs 22.2%; risk ratio: 0.25; P=0.03; confidence interval 0.07 to 0.87), which was more marked compared to those not needing an interpreter (2.1% vs 4.1%)

Teenage women: There was only 1 case of preterm birth in teenage women.

Mutifetal pregnancy: In women allocated to caseload midwifery 20% (2/10) twins were born before 37 weeks and none (0/10) before 34 weeks. In women allocated to traditional care 52.4% (11/21) babies were born before 37 weeks and none before 34 weeks (0/21). There are more multifetal pregnancies in the traditional care group, however the trend reduction in those allocated to caseload midwifery was comparable in singleton (risk ratio 0.49) and multifetal pregnancies (risk ratio 0.21).

Secondary outcomes:

In non-LEAP areas, pregnancy resulted in still birth in 0.4% of pregnancies, neonatal death (NND) in 0.7%, and non-registerable death (pre-viable) in 1.2%. In the LEAP area there were no recorded stillbirths or NND in women allocated to caseload midwifery. There was 1 NND in women allocated to traditional care *(table 6).*

Low birthweight (<2.5kg): In LEAP area women allocated to caseload midwifery there was a trend reduction in low birthweight compared to those allocated to traditional care (7.3% vs 12.4%; risk ratio: 0.77; P=0.08; confidence interval: 0.24 to 1.08; number needed to treat: 15.2) *(table 6).*

Neonatal unit (NNU) admission: In LEAP area women allocated to caseload midwifery there was a trend reduction in NNU admission compared to those allocated to traditional care (8.1% vs 11.1%) *(table 6)*.

Breast feeding rates: In LEAP area women allocated to caseload midwifery there was a trend increase in breast feeding compared to those allocated to traditional care (94.0 vs 92.4%; risk ratio: 1.04; P= 0.29; confidence interval: 0.97 to 1.1) *(table 6)*.

Skin to skin: In LEAP area women allocated to caseload midwifery there was a trend increase in skin to skin contact within 1 hour compared to traditional care (66.8 vs 74.9%; P=0.09: confidence interval: 0.98 to 1.3; number needed to treat: 11.7) *(table 6).*

Discussion:

Principle findings: This study shows that caseload midwifery implemented in a deprived inner-city community improves outcomes by significantly reducing preterm delivery and delivery by caesarean section, without increasing neonatal unit admission or stillbirth. The data also suggest, that caseload midwifery had the greatest impact in the highest risk populations (mothers in higher IMD quintiles and from BAME backgrounds). In small numbers our data are suggestive of reduction in low birthweight infants, postpartum haemorrhage, pregnancy induced hypertension and pre-eclampsia, birth before 34 weeks, pre-viable birth, neonatal unit admission and neonatal death with improved breast feeding and skin-to-skin contact. No difference was observed in gestational diabetes mellitus (GDM) and macrosomia.

This study is important due to the potential impact of reducing preterm birth and caesarean rates in vulnerable women and addressing inequality and inequity at birth. Historically, attempts at reducing preterm labour and caesarean birth have been extensive but with limited impact,[22,23] and there are valid concerns regarding safety of reducing caesarean births[24]. Caseload midwifery, already shown to be acceptable [25] and beneficial [14] is not yet standard for all women in the UK (although targeted continuity of midwifery care to BAME and groups and women in living in deprived areas is an NHS Long Term Plan commitments).[26] This may be due to the incomplete understanding of the mechanism of improvement, and the enormity of the task of restructuring a care pathway. By reporting in a targeted group, we can suggest a hopeful starting point for change.

Strengths: This was a pragmatic study that included twin and triplet pregnancies, repeat pregnancies, and women with complex medical and obstetric histories, often excluded from other studies. It analysed a programme of care that has been shown to work in practice in a socially deprived area, rather than recruiting to a research study intervention. We used intention to treat analysis where continuity was affected by provider circumstantial limitations, thus, results reflect the reality of intervention in a non-study clinical practice.

Limitations: As a cohort study, and not a randomised controlled trial, it contains all the limitations of such a design. There may be potential confounders in caseload allocation and outcome which may bias our results. However, women allocated to the caseload midwifery care are anticipated to be at higher risk of adverse outcomes and hence allocated thus, making the improvements demonstrated in their outcomes potentially more significant. The small numbers in less common outcomes (e.g. Stillbirth and NND), allow trends to be only cautiously highlighted. Neonatal deaths outside the data collection period may have occurred in all groups, although numbers are likely to be small. We included multifetal pregnancies because we observed the same trend in main outcomes by caseload midwifery care as in singleton, but it must be considered as a potential confounder. Staffing and COVID 19 disrupted some aspects of continuity. We did not include economic analysis.

Comparison to other studies: This study is the first study to our knowledge focused on targeting vulnerable women based on IMD score and ethnicity, and so is not directly comparable to other studies on caseload midwifery. Unlike some studies, we did not exclude women with medical/obstetric complications. A Cochrane review of available evidence prior to 2016[14] showed continuity (including caseload midwifery), when compared to standard care, reduced preterm birth (aRR 0.7), but did not reduce caesarean birth, despite a higher vaginal delivery rate (aRR 1.05).[14] Our study showed significant reduction in birth before 37 weeks (risk ratio: 0.45) and all caesarean and emergency caesarean birth rate (risk ratio 0.64

and 0.58 respectively). The POPPIE pilot RCT (2020) of women at high risk for preterm birth, found midwifery continuity of care did not significantly impact gestation, or mode of delivery.[27] A prospective cohort study comparing caseload midwifery to standard care in an Aboriginal population in Australia however, found OR of preterm birth to be 0.57.[28] A retrospective cohort study of caseload midwifery in vulnerable women with complex social factors in London found a similar reduction in caesarean section (relative risk total caesarean: 0.51 and emergency caesarean: 0.42) and enhanced multidisciplinary support.[29] Descriptive analysis of caseload midwifery in a London population of ethnically diversity and socio-economic disadvantage, also found low caesarean rates 16%[30].

Meaning of the study: Due to these varied outcomes, these studies suggest a need to consider appropriate targeting and the mechanism of action of caseload care. We need to consider why our study found a reduction in caesarean birth (and so markedly so), why the impact in preterm birth before 37 weeks appears bigger (aRR 0.45) and why our high-risk group responded so differently from those in the POPPIE trial?

The intervention at the crux of caseload midwifery care is providing time, continuity, and communication.[31, 32,33] Time with a women, to build trust and rapport,[34] to observe a woman's surroundings and assess what risks have not been verbalised, to establish solutions that tailor into a woman's framework and community.[35,36]

In the POPPIE pilot trial high risk was identified by history, but also by structural abnormalities and smoking.[27] This is testament to the heterogenicity of preterm labour aetiology[22], and so must the solution be. There was minimal change in smoking behaviour in our caseload group. A link between a continuity-based intervention and structural adaptation (i.e. cervix and uterine abnormalities) is not known. Furthermore, continuity was often in a hospital, rather than a community-based setting (like in this study), the importance of which is currently under research.

Mechanisms of spontaneous preterm labour include the premature triggering of the hypothalamic-pituitary axis of the fetus, inflammation, matrix remodelling, abruption of the placenta and mechanical stretch.[37,38] Stress response is incompletely realised, but can physiologically manifest as an endocrine and/or a pro-inflammatory response[39,40]. Pregnancy is a state of relatively reduced systemic cortisol and inflammatory cytokines, however acute and less acute psychosocial stressors in pregnancy can counteract this, and even modulate the development of the fetus' hypothalamic-pituitary-adrenal axis.[39] Stress affects maternal health behaviours such as diet, sleep and exercise, it reduces the effectiveness of the maternal immune response, and it exacerbates mental illness such as anxiety and depression.[39] These stimuli have been shown to have impact early in pregnancy[40] and so must be tackled early.

If we have evidence that psychosocial stress and its associated effects, are linked to pre-term labour and low birthweight[40], it is intuitive to imagine that early impact on these stressors (when the physiological adaptation to pregnancy is so marked and rapid structural and functional development of the fetus is taking place) could be integral to improving outcome. One aspect of caseload midwifery care, is time to identify need for, and access social support services relative to other traditional care[29]. If a multi-agency referral is done early, from the first trimester, the potential burden of anxiety around visa status, housing, finances etc (that may be heightened by the impending addition of a new child) may be lightened. Intimate

partner violence support, and potential freedom from financial abuse can impact both the stress response and the physical abruption risk associated with pre-term labour. This information may come to light in person, rather than with questionnaire screening, which is why early identification of risk and flexible allocation to caseload midwifery may be important.

From a longer-term perspective, maternal stressors on the fetus in-utero have been linked to neurodevelopmental disorders in children[41]. Preterm birth is associated with anxiety and depression long beyond the perinatal period in caregivers and bonding difficulties in those admitted to NNU (greater at earlier gestations).[42 43 44] A later gestation of birth may avoid a financial implication to the parents and the health care system in early years[45] and in adult hood with reduced disability, chronic illness and increased educational attainment in children born closer to term[46].

CS is a life-saving intervention, but rates above 9-16%[47] have minimal proven benefit, with negative maternal and neonatal consequences[48]. A systematic review has not reported caesarean rate reduction by caseload midwifery[14]. However deprivation is associated with unplanned CS, and our target population are vulnerable to lack of clear communication and failed engagement with services[49]. The impact of communication is clearly illustrated by the risk ratio of 0.10 of caesarean section in mothers who need an interpreter.

It could be anticipated that more and longer appointments, with continuity of the health care professional may have more impact. Opportunities to address fears regarding labour may reduce antenatal motivation for caesarean delivery. Identification of a healthy support structure in labour, may be aided by enhanced knowledge of the family dynamics, through appointments in the family home and prolonged rapport with women. Discussion around women's expectations of what is a normal labour, may impower women in their birth support and analgesia options. A known carer may enhance support to execute birth plans, thereby improving motivation in labour to pursue vaginal birth. Benefits of a vaginal birth extend from the women to health economics, reducing need for additional antenatal appointments, a lower-cost labour location and reduced CS in the next pregnancy[50].

Future research: Further research is needed to determine whether the significant improvement seen, will translate to other inner-city populations with similar demographics. Long term follow-up of these women would determine whether there are long-term clinical and economic benefits of caseload midwifery in this population. Further research is needed into the effectiveness of continuity of care in a hospital-based setting for those with high medical obstetric risk.

Conclusion

Before the umbilical cord is cut, paths for inequality in health out-comes have begun and are marked in communities of high socioeconomic deprivation and ethnic diversity.

Justice and equality should be a priority in any health-care setting, and caseload midwifery, may be a part of the solution. Recognising resource limitations, this study demonstrates for the first time how targeting disadvantaged inner city communities may have the most marked

effect in reduction of pre-term labour before 37 weeks, all caesarean delivery (and emergency caesarean delivery) and their subsequent impact.

Further research is needed into the generalisability of this approach in other populations and into its impact on health economics is required. Long term follow-up of these patients is planned.

Footnote:

a: The Lambeth Early Action Partnership (LEAP) programme is a 10-year programme that works with pregnant women and children aged 0-3 years and their families and aims to give them a better start. Part of this programme includes caseload midwifery care. The majority, of women allocated to caseload midwifery in this study were cared for by this team, and the postcode areas/wards are identified as areas of deprivation by the LEAP programme. However, some women received the same package of care under the umbrella of other caseload teams in Guys and St Thomas NHS Foundation trust.

b: In this paper a large group of people are grouped under the umbrella term “Black, Asian and Minority Ethnic (BAME)”, to enable us to quantify and target outcome inequality, rather than ignorance of the diversity within that label. It should not imply uniformity of experience within these communities and does not include White minority communities that may also experience inequality in this instance.

Acknowledgement: We thank Clare White, Anne Kerrigan, Rachel Erskine and Emily Miller for their thoughtful comments on improving how we communicate to the reader and editing previous drafts. We thank the caseload midwives, in particular the LEAP team, for their ongoing care of women, and the women whose experience we have been able to learn from.

Contributor statement:

Eugene Oteng-Ntim conceived the presented study, organised outcome data extraction, methodology and verified the data analysis. He co-wrote the manuscript, approved the final draft and is responsible for the overall content and guarantor for the study.

Ruth Hadebe was lead in curation and analysis of the main data and was lead author of the original draft manuscript. Responsible for incorporating content from co-authors, and for the overall content of the manuscript.

Paul Seed performed statistical analysis of main results. He guided methodology and performed statistical adjustment for data confounders. He supported review and editing of the manuscript.

Dianna Essien, Kyle Headen, Saheel Mahmood and Salwa Owasil curated data regarding women’s allocation to caseload midwifery. They reviewed and edited the manuscript.

Christina Fernandez Turienzo, Carla Stankes, Mara Bruno and Jane Sandall, reviewed and edited the manuscript, providing expertise on interpretation of the data set, and clinical application to bettering women’s health.

Nina Khadzaezadeh, provided expertise in the study conception.

Transparency declaration : Ruth Hadebe and Eugene Oteng-Ntim affirm that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

Competing interests: All authors have completed the ICMJE uniform disclosure form and declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

Funding: The Lambeth Early Action Partnership (LEAP) programme is a 10-year programme that works with pregnant women and children aged 0-3 years and their families and aims to give them a better start. LEAP received £36 million from the National Lottery Community Fund as part of the national 'A Better Start programme.' Part of this programme includes caseload midwifery. The majority, but not all women allocated to caseload midwifery were cared for by this team. No funding was received specifically for this study. The funders had no role in the study design, data collection, analysis and interpretation of data, writing of the report, or the decision to submit the paper for publication.

Jane Sandall at King's College is an NIHR Senior Investigator and with Cristina Fernandez Turienzo are supported by the National Institute for Health Research (NIHR) Applied Research Collaboration South London (NIHR ARC South London) at King's College Hospital NHS Foundation Trust. The views expressed are those of the author[s] and not necessarily those of the NIHR or the Department of Health and Social Care

Data sharing statement: The complete de-identified patient data set and analytical/Statistical code will be available on request form the corresponding author ruth.hadebe@nhs.net from date of publication.

Ethical approval was granted by the London School of Hygiene and Tropical Medicine Ethics committee. The study was based on routinely collected hospital data. Individual patient consent was not obtained; all patient records were anonymised and de-identified prior to analysis.

Tables:

Table 1. Agreed definition of vulnerability from LEAP service plan.

Women who find services hard to access	**Women needing multi-agency services**
Socially isolated women Those living in poverty / deprivation / who are homeless Refugees / asylum seekers Non-native language speakers Victims of abuse Sex workers Young mothers Unsupported mothers Women within travelling communities	Women who are subject of safeguarding concerns Women with substance and/or alcohol abuse issues Women with physical / emotional and/or learning disabilities Women who have been victims of female genital mutilation Women who are HIV positive

Table 2. Decision to caseload from booking survey. Summary of significant and important factors that were corrected for by inverse probability weighting in statistical analysis. (Women who did not complete a booking survey excluded as interview allocation subject to bias).

Variable reported	Caseload midwifery	Traditional care	Unadjusted Risk Ratio (95% CI)	P
Interpreter needed	20/165 (12.1%)	9/210 (4.3%)	2.83 (1.32 to 6.05)	0.005
Unknown ethnicity	29/165 (17.6%)	57/210 (27.1%)	0.65 (0.43 to 0.96)	0.029
Respiratory co-morbidity	10/165 (6.1%)	26/210 (12.4%)	0.49 (0.24 to 0.99)	0.039
Previous instrumental delivery	13/165 (7.9%)	8/210 (3.8%)	2.07 (0.88 to 4.87)	0.089

Table 3 Comparison of ethnic diversity and IMD scores in LEAP area women allocated to caseload midwifery and traditional care, and women in other post code areas (all care models).

	Other areas		LEAP area caseload midwifery		LEAP area traditional care	
Ethnicity	N 8430	(%)	N (230)	(%)	N (293)	(%)
White (British, Irish, Other)	4030	47.8	81	35.2	98	33.4
Black (African, Caribbean, other)	1452	17.2	66	28.7	79	27.0
Asian (including Bangladeshi, Indian, Pakistani, Asian other)	638	7.6	6	2.6	11	3.8
Chinese	200	2.4	3	1.3	2	0.7
Mixed (including White-Black, white-Asian, mixed other)	357	4.2	14	6.1	16	5.5
Other ethnic group	536	6.4	21	9.1	17	5.8
Not recorded	1253	14.9	39	17.0	70	23.9
IMD quintile						
1 (least deprived)	241	2.9	0	0	0	0
2	528	6.3	0	0	0	0
3	1151	13.7	3	1.3	4	1.4
4	3288	39.0	89	38.7	105	35.8
5 (most deprived)	2361	28.0	121	52.6	170	58.0
unknown	861	10.2	17	7.4	14	4.8

Table 4. Risk factors relating to pregnancy in women in the LEAP area allocated to case load midwifery and traditional care, and women in other post code areas.

	Other areas		LEAP area caseload midwifery		LEAP area traditional care	
	N 8430	%	N 230	%	N 293	%
Smoker at booking	324	3.8	14	6.0	10	3.4
Non-smoker at booking	7767	92.1	207	90.0	274	93.5
Status not recorded at booking	339	4.0	9	3.9	9	3.1
Smoker at delivery	233	2.8	14	6.0	8	2.7
Non smoker at delivery	7899	93.7	206	89.6	267	91.1
Status not recorded at delivery	298	3.6	10	4.3	18	6.1
Age </+19	112	1.3	13	5.7	6	2.0
Age >/=40	738	8.8	14	6.1	19	6.5
Age not recorded	0	0	0	0	0	0
Single/separated/divorced/widowed	2276	27.0	87	37.8	97	33.1
Married/co-habiting/partner	4863	57.7	114	49.6	146	49.8
Relationship status not recorded	1291	15.3	29	12.6	50	17.1
BMI 30-39 (all ethnicities)	1213	14.4	47	20.4	55	18.8
BMI>40 (all ethnicities)	145	1.7	1	0.4	10	3.4
BMI not recorded	624	7.4	30	13.0	22	7.5
BMI 23-27.49 and BAME population	985	11.6	29	12.6	33	11.3
BMI >27.5 and BAME population	1054	12.5	37	16.1	50	17.1

Table 5 *Maternal outcomes in LEAP area women allocated to caseload midwifery and traditional care and women in other post code.*

	Other areas	LEAP area Caseload midwifery	LEAP area traditional care	Comparison of caseload midwifery and traditional care in LEAP area[a]		
	N 8430 (%)	N 230 (%)	N 293 (%)	Risk Ratio (95% CI)	Interaction test P value	NNT[b]
Mode of delivery						
Any Caesarean delivery	3061 (36.3)	56 (24.3)	114 (38.9)	0.65 (0.47-0.90)	0.01	7.4
Elective Caesarean delivery	1317 (15.6)	21 (9.1)	48 (16.3)			
Emergency Caesarean delivery	1744 20.7)	35 (15.2)	66 (22.5)	0.59 (0.38-0.94)	0.03	10
Assisted vaginal delivery (forceps/ventouse)	1205 (14.3)	34 (14.8)	31 (10.6)			
Normal vaginal delivery	4035 (47.9)	138 (60)	143 (48.8)			
Breech vaginal	43 (0.5)	2 (0.9)	2 (0.7)			
Unknown	86 (1.0)	0 (0)	3 (1.0)			
GDM	960 (11.4)	22 (9.6)	29 (9.9)			
PIH	141 (1.7)	3 (1.3)	8 (2.7)			
PET	205 (2.4)	5 (2.2)	7 (2.4)			
PPH (>501mls)	3289 (39.0)	67 (29.1)	111 (37.8)	0..77 (0.57-1.04)	0.10	11.6
Inpatient admission						
<24 hours	1148 (13.6)	27 (11.1)	38 (13.0)			
>5 days (121 hours)	1387 (16.5)	32 (13.9)	41 (14.0)			
Admission not documented	120 (1.4)	5 (2.2)	5 (1.7)			

a Comparisons carried out using inverse probability weighting to minimise potential bias

b NNT: Number of women who need to be treated to prevent one bad outcome

Table 6 Newborn outcomes in LEAP and non-LEAP areas following the introduction of LEAP case-loading intervention.

Outcome	Other areas	LEAP area Caseload midwifery	LEAP area traditional care	Comparison of caseload midwifery and traditional care in LEAP area[a]		
	N 8666 (%)	N 235 (%)	N 304 (%)	Risk Ratio (95% CI)	Interaction test P value	NNT[b]
Stillbirth	37 (0.4)	0 (0)	0 (0)			
Neonatal death	59 (0.7)	0 (0)	1 (0.3)			
Non-registerable birth	106 (1.2)	0 (0)	3 (1.0)			
Not recorded	1 (0.01)	0 (0)	0 (0)			
Neonatal unit admission	889 (10.3)	19 (8.1)	34 (11.1)			
Not documented if NNU admission	1 (0.01)	0 (0)	0 (0)			
All births <37 weeks	912 (10.5%)	12 (5.1%)	34 (11.2)	0.41 (0.18-0.86)	0.02	11.9
All births <34 weeks	417 (4.8)	4 (1.7)	13 (4.3)	0.35 (0.97-1.28)	0.11	27.7
Birth 12-23+6 weeks	134 (1.5)	0 (0)	4 (1.3)			
Birth 24- 33+6 weeks	283 (3.3)	4 (1.7)	9 (3.0)			
Birth 34-36+6 weeks	495 (5.7)	8 (3.4)	21 (6.9)			
Gestation of birth not recorded	0 (0)	0 (0)	0 (0)			
Birth weight <2.5kg	967 (11.1)	17 (7.2)	37 (12.2)	0.77 (0.24-1.08)	0.08	15.2
Birthweight >4.5kgs	60 (0.7)	1 (0.4)	1 (0.3)			
Birth weight not recorded	2 (0.02)	0 (0)	0 (0)			
Breast fed (at all)	7832 (90.4)	221 (94.0)	281 (92.4)	1.04 (0.97-1.11)	0.29	30.9
Not recorded if breastfed	214 (2.5)	0 (0)	4 (1.3)			
Skin to skin within 1 hour	5827 (67.2)	176 (74.9)	203 (66.8)	1.12 (0.98-1.30)	0.09	11.7

a Comparisons carried out using inverse probability weighting to minimise potential bias

b NNT: Number of women who need to be treated to prevent one bad outcome

References

1. National Institute for Health and Clinical Excellence. *Pregnant Women With Complex Social Factors: a model for service provision*. www.nice.org.uk.

2. *MBRRACE-UK Perinatal Mortality Surveillance report. UK Perinatal Deaths for Births from January to December 2016*. https://www.npeu.ox.ac.uk/downloads/files/mbrrace-uk/reports/MBRRACE-UK Perinatal Surveillance Full Report for 2016 - June 2018.pdf (2018).

3. Taylor-Robinson, D. *et al.* Quantifying the Impact of Deprivation on Preterm Births: A Retrospective Cohort Study. *PLoS One* **6**, e23163 (2011).

4. Ene, D. *et al.* Associations of Socioeconomic Deprivation and Preterm Birth With Speech, Language, and Communication Concerns Among Children Aged 27 to 30 Months. *JAMA Netw. Open* **2**, e1911027 (2019).

5. Beauregard, J. L., Drews-Botsch, C., Sales, J. M., Flanders, W. D. & Kramer, M. R. Preterm Birth, Poverty, and Cognitive Development. *Pediatrics* **141**, e20170509 (2018).

6. Henderson, J., Carson, C. & Redshaw, M. Impact of preterm birth on maternal well-being and women's perceptions of their baby: a population-based survey. *BMJ Open* **6**, e012676 (2016).

7. MBRRACE-UK. *Saving Lives, Improving Mothers' Care*. (2019).

8. Health, C. E. into M. and C. *Saving Mothers Lives: Reviewing maternal deaths to make motherhood safer*. (2007).

9. Lindquist, A., Kurinczuk, J., Redshaw, M. & Knight, M. Experiences, utilisation and outcomes of maternity care in England among women from different socio-economic groups: findings from the 2010 National Maternity Survey. *BJOG An Int. J. Obstet. Gynaecol.* **122**, 1610–1617 (2015).

10. Conti, G., Heckman, J. J. & Pinto, R. The Effects of Two Influential Early Childhood Interventions on Health and Healthy Behaviour. *Econ. J.* **126**, F28–F65 (2016).

11. Frank Porter Graham Child Development Institute. The Abecedarian Project. *https://abc.fpg.unc.edu/abecedarian-project*.

12. Barnett, W. S. & Masse, L. N. Comparative benefit–cost analysis of the Abecedarian program and its policy implications. *Econ. Educ. Rev.* **26**, 113–125 (2007).

13. *Health Matters:giving every child the best start in life*. https://www.gov.uk/government/publications/health-matters-giving-every-child-the-best-start-in-life/health-matters-giving-every-child-the-best-start-in-life (2016).

14. Sandall, J., Soltani, H., Gates, S., Shennan, A. & Devane, D. Midwife-led continuity models versus other models of care for childbearing women. *Cochrane Database Syst. Rev.* (2016) doi:10.1002/14651858.CD004667.pub5.

15. *Demography Factsheet: Lambeth:- 'a diverse and changing population'*. https://www.lambeth.gov.uk/sites/default/files/ssh-demography-factsheet-2017.pdf

(2017).

16. National Institute for Health and Clinical Excellence. *NICE Guideline 133: Hypertension in pregnancy: diagnosis and management*. https://www.nice.org.uk/guidance/ng133/chapter/Recommendations#management-of-pre-eclampsia.

17. Royal College of Obstericians and Gynaecologists. *Green Top Guideline 52: Postpartum Haemorhage, Prevention and Management*. (2016).

18. NPEU. IMD tool | NPEU Tools. http://tools.npeu.ox.ac.uk/imd/.

19. No Title. http://imd-by-postcode.opendatacommunities.org/imd/2019.

20. Cattaneo, M. D. Efficient semiparametric estimation of multi-valued treatment effects under ignorability. *J. Econom.* **155**, 138–154 (2010).

21. Professor Sir Cyril Chantler *et al.* Better births Improving outcomes of maternity services in England. A five year View for maternity care . *Natl. Matern. Rev. found https//www.england.nhs.uk/wp-content/uploads/2016/02/national-maternity-review-report.pdf* (2015).

22. Medley, N., Vogel, J. P., Care, A. & Alfirevic, Z. Interventions during pregnancy to prevent preterm birth: an overview of Cochrane systematic reviews. *Cochrane Database Syst. Rev.* (2018) doi:10.1002/14651858.CD012505.pub2.

23. World Health Organisation. *Non-Clinical Interventions to Reduce Unnecessary Caesarean Sections*. (2018).

24. Ockenden, D. *Ockenden Report: Emerging Findings and Reccommendations form the Independent Review of Maternity Services at the Shrewsbury and Telford Hospital NHS Trust*. https://www.donnaockenden.com/downloads/news/2020/12/ockenden-report.pdf (2020).

25. Tracy, S. K. *et al.* Caseload midwifery care versus standard maternity care for women of any risk: M@NGO, a randomised controlled trial. *Lancet* **382**, 1723–1732 (2013).

26. *The NHS Long Term Plan*. https://www.longtermplan.nhs.uk/wp-content/uploads/2019/01/nhs-long-term-plan-june-2019.pdf (2019).

27. Fernandez Turienzo, C. *et al.* Midwifery continuity of care versus standard maternity care for women at increased risk of preterm birth: A hybrid implementation–effectiveness, randomised controlled pilot trial in the UK. *PLOS Med.* **17**, e1003350 (2020).

28. Kildea, S. *et al.* Reducing preterm birth amongst Aboriginal and Torres Strait Islander babies: A prospective cohort study, Brisbane, Australia. *EClinicalMedicine* **12**, 43–51 (2019).

29. Rayment-Jones, H., Murrells, T. & Sandall, J. An investigation of the relationship between the caseload model of midwifery for socially disadvantaged women and childbirth outcomes using routine data – A retrospective, observational study. *Midwifery* **31**, 409–417 (2015).

30. Homer, C. S., Leap, N., Edwards, N. & Sandall, J. Midwifery continuity of carer in an area of high socio-economic disadvantage in London: A retrospective analysis of Albany Midwifery Practice outcomes using routine data (1997–2009). *Midwifery* **48**, 1–10 (2017).

31. Kennedy, H. P. A Model Of Exemplary Midwifery Practice: Results Of A Delphi Study. *J. Midwifery Womens. Health* **45**, 4–19 (2000).

32. Davis, J. A. P. Midwives and Normalcy in Childbirth: A Phenomenologic Concept Development Study. *J. Midwifery Womens. Health* **55**, 206–215 (2010).

33. Phillippi, J. C. & Avery, M. D. The 2012 American College of Nurse-Midwives Core Competencies for Basic Midwifery Practice: History and Revision. *J. Midwifery Womens. Health* **59**, 82–90 (2014).

34. Rayment-Jones, H., Silverio, S. A., Harris, J., Harden, A. & Sandall, J. Project 20: Midwives' insight into continuity of care models for women with social risk factors: what works, for whom, in what circumstances, and how. *Midwifery* **84**, 102654 (2020).

35. ten Hoope-Bender, P. *et al.* Improvement of maternal and newborn health through midwifery. *Lancet* **384**, 1226–1235 (2014).

36. McRae, D. N. *et al.* Is model of care associated with infant birth outcomes among vulnerable women? A scoping review of midwifery-led versus physician-led care. *SSM - Popul. Heal.* **2**, 182–193 (2016).

37. Robinson, J. N., Regan, J. A. & Norwitz, E. R. The epidemiology of preterm labor. *Semin. Perinatol.* **25**, 204–214 (2001).

38. Georgiou, H. M., Di Quinzio, M. K. W., Permezel, M. & Brennecke, S. P. Predicting Preterm Labour: Current Status and Future Prospects. *Dis. Markers* **2015**, 1–9 (2015).

39. Coussons-Read, M. E. Effects of prenatal stress on pregnancy and human development: mechanisms and pathways. *Obstet. Med.* **6**, 52–57 (2013).

40. Shapiro, G. D., Fraser, W. D., Frasch, M. G. & Séguin, J. R. Psychosocial stress in pregnancy and preterm birth: associations and mechanisms. *J. Perinat. Med.* **41**, (2013).

41. KINSELLA, M. T. & MONK, C. Impact of Maternal Stress, Depression and Anxiety on Fetal Neurobehavioral Development. *Clin. Obstet. Gynecol.* **52**, 425–440 (2009).

42. Trumello, C. *et al.* Mothers' Depression, Anxiety, and Mental Representations After Preterm Birth: A Study During the Infant's Hospitalization in a Neonatal Intensive Care Unit. *Front. Public Heal.* **6**, (2018).

43. Ionio, C. *et al.* Mothers and fathers in NICU: The impact of preterm birth on parental distress. *Eur. J. Psychol.* **12**, 604–621 (2016).

44. Pace, C. C. *et al.* Evolution of Depression and Anxiety Symptoms in Parents of Very Preterm Infants During the Newborn Period. *JAMA Pediatr.* **170**, 863 (2016).

45. Jacob, J. *et al.* Cost effects of preterm birth: a comparison of health care costs

associated with early preterm, late preterm, and full-term birth in the first 3 years after birth. *Eur. J. Heal. Econ.* **18**, 1041–1046 (2017).

46. Lindstrom, K., Winbladh, B., Haglund, B. & Hjern, A. Preterm Infants as Young Adults: A Swedish National Cohort Study. *Pediatrics* **120**, 70–77 (2007).

47. Betran, A. P. *et al.* What is the optimal rate of caesarean section at population level? A systematic review of ecologic studies. *Reprod. Health* **12**, 57 (2015).

48. Sandall, J. *et al.* Short-term and long-term effects of caesarean section on the health of women and children. *Lancet* **392**, 1349–1357 (2018).

49. Modder, J. *et al. CEMACH: Perinatal Mortality 2007*.

50. Royal College of Obstericians and Gynaecologists. *Green Top Guideline No 45. Birth After Previous Caesarean Section*. (2015).

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 (*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	1-2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up (*b*) For matched studies, give matching criteria and number of exposed and unexposed	5-6
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5-6
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	5-6
Bias	9	Describe any efforts to address potential sources of bias	6
Study size	10	Explain how the study size was arrived at	
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	5-6
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding (*b*) Describe any methods used to examine subgroups and interactions (*c*) Explain how missing data were addressed (*d*) If applicable, explain how loss to follow-up was addressed (*e*) Describe any sensitivity analyses	6
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 (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram	8
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest (c) Summarise follow-up time (eg, average and total amount)	9
Outcome data	15*	Report numbers of outcome events or summary measures over time	9-11

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	9-11
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	9-11
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
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	12-13
Generalisability	21	Discuss the generalisability (external validity) of the study results	13
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	17

*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.

BMJ Open

Can birth outcome inequality be reduced using targeted caseload midwifery in a deprived diverse inner-city population? A retrospective cohort study, London UK

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2021-049991.R1
Article Type:	Original research
Date Submitted by the Author:	29-Jun-2021
Complete List of Authors:	Hadebe, Ruth; Guy's and St Thomas' NHS Foundation Trust, Department of Women's Health Seed, Paul; King's College London, Department of Women and Children's Health Essien, Diana; Guy's and St Thomas' NHS Foundation Trust, Department of Women's Health Headen, Kyle; Guy's and St Thomas' NHS Foundation Trust, Deapartment of Women's Health Mahmud, Saheel; King's College London School of Medicine Owasil, Salwa; King's College London School of Medicine Fernandez Turienzo, Cristina; King's College London, Department of Women and Children's Health Stanke, Carla; National Childrens Bureau, Public Health; Lambeth Early Action Partnership Sandall, Jane; Kings College, London, Department of Women and Children's Health Bruno, Mara; Guy's and St Thomas' NHS Foundation Trust, Department of Women's Health Khazaezadeh, Nina; Guy's and St Thomas' NHS Foundation Trust, Department of Women's Health Oteng-Ntim, Eugene ; guys and st thomas nhs foundation trust, Department of Women's Health; King's College London, Department of Women and Children's Health
Primary Subject Heading:	Obstetrics and gynaecology
Secondary Subject Heading:	Health policy, Obstetrics and gynaecology, Public health
Keywords:	OBSTETRICS, Health policy < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, PUBLIC HEALTH

I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our licence.

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which Creative Commons licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

Can birth outcome inequality be reduced using targeted caseload midwifery in a deprived diverse inner-city population? A retrospective cohort study, London UK

Ruth Hadebe, ST6 obstetrics and gynaecology[1] (0000-0003-4020-8933), Paul Seed, reader in medical statistics[2] (0000-0001-7904-7933), Diana Essien, clinical fellow obstetrics and gynaecology[1], Kyle Headen ST2 obstetrics and gynaecology[1], Saheel Mahmud, medical student[3], Salwa Owasil, medical student[3], Cristina Fernandez Turienzo, midwife researcher[2] (0000-0002-7393-6593), Carla Stanke, public health specialist[4,5], Jane Sandall, professor of social science and women's health[5] (0000-0002-5384-3744), Mara Bruno, midwife[1], Nina Khazaezadeh, consultant midwife in public health[1], Eugene Oteng-Ntim, professor of obstetrics, [1,2](0000-0001-8867-2909).

Affiliations

1 Guy's and St Thomas' NHS Foundation Trust, Department of Women's Health London, UK,

2 Department of Women and Children's Health, Faculty of Life Science and Medicine, King's College London, London, United Kingdom.

3 King's College London School of Medicine, London, UK,

4 National Children's Bureau, Public Health, London, UK,

5 Lambeth Early Action Partnership

Corresponding Author: Ruth Hadebe, Dept Women's Health, 10th Floor, North Wing, St Thomas Hospital, Westminster Bridge Road, London. SE1 7EH. Email: ruth.hadebe@nhs.net

Abstract

Objectives:

i. To report maternal and newborn outcomes of pregnant women in areas of social deprivation in inner-city London.
ii. To compare the effect of caseload midwifery with standard care on maternal and newborn outcomes in this cohort of women.

Design: Retrospective observational cohort study.

Setting: Four council wards (electoral districts) in inner-city London, where over 90% of residents are in the two most deprived quintiles of the English Index of Multiple Deprivation (2015) and the population is ethnically diverse.

Participants: All women booked for antenatal care under Guys and St Thomas' NHS Foundation Trust after 11/7/2018 (when the Lambeth Early Action Partnership (LEAP) caseload midwifery team[a] was implemented) until data collection 18/6/2020. This included 523 pregnancies in the LEAP area, of which 293 were allocated to caseload midwifery, and 8430 pregnancies from other areas.

Main outcome measures: To explore if targeted caseload midwifery (known to reduce preterm birth) will improve important measurable outcomes (preterm birth, mode of birth, and newborn outcomes).

Results: There was a significant reduction in preterm birth rate in women allocated to caseload midwifery, when compared to those who received traditional midwifery care (5.1% vs 11.2%; risk ratio: 0.41; P=0.02; confidence interval 0.18 to 0.86; number needed to treat: 11.9). Caesarean section births were significantly reduced in women allocated to caseload midwifery care, when compared to traditional midwifery care (24.3% vs 38.0%; risk ratio: 0.64: P=0.01; confidence interval: 0.47 to 0.90; number needed to treat: 7.4) including emergency caesarean deliveries (15.2% vs 22.5%; risk Ratio: 0.59; P=0.03; confidence interval: 0.38 to 0.94; number needed to treat: 10) without increase in neonatal unit admission or stillbirth.

Conclusion: This study shows that a model of caseload midwifery care implemented in an inner-city deprived community improves outcome by significantly reducing preterm birth and birth by caesarean section when compared to traditional care. These data trend suggests that when applied to targeted groups (women in higher IMD quintile and women of diverse ethnicity) that the impact of intervention is greater.

Strengths and limitations of this study:

- This study question addresses a clinically and economically important problem (preterm birth and mode of delivery) and first reports caseload midwifery effects in women disadvantaged due to social complexity.
- This study pragmatically represents a clinical setting, including women of all medical risk, with intention to treat analysis, and thus results reflect the reality of intervention in a non-study clinical practice.
- Logistical regression analysis was performed using an established statistical method (inverse probability weighting) to correct for bias in case selection.
- Confounders in caseload allocation and outcome may bias our results.
- Numbers in less common outcomes are small (e.g., Stillbirth and NND), and neonatal deaths may be underreported if they occurred outside the data collection period.

Introduction.

Fetal outcome is affected by social deprivation and parental ethnicity.[1] The English Index of Multiple Deprivation (IMD) comparatively ranks areas according to markers of socioeconomic deprivation using domains of income, employment, education, skills and training, health and disability, crime, barriers to housing services, and living environment. In 2016, 25.9% of all stillbirths in the UK occurred in the most deprived IMD quintile compared with 14.9% in the least, with a similar distribution for neonatal death (25.7% and 15.9% respectively).[2] In 2017, the stillbirth rate for the UK was 3.74 per 1000, however in Black/Black British and Asian/Asian British women, rates were 7.46 and 5.70 per 1000 respectively, with an increase in neonatal mortality (despite a downward trend in the White patient population).[2] Preterm birth is more common in women affected by social deprivation[3], and the combination is associated with developmental problems in the early years.[4,5] Preterm birth negatively impacts maternal mental health, relationships between child and caregiver, and interaction with support services.[6]

Maternal mortality doubles when comparing women in the least deprived IMD quintiles to women in the most deprived (5 to 12 per 100,000).[7] Black women are 5 times more likely to die as a result of pregnancy than White women (38 compared with 7 per 100,000), women of mixed ethnicity 3 times, and women of Asian ethnicity 2 times more likely to die.[7] Mortality is associated with suboptimal utilisation of antenatal services, including late/no booking and nonattendance, (most marked in Black African, Black Caribbean and Middle Eastern women).[8] For each step up in deprivation quintile, women are more likely to receive no antenatal care (25% increase per quintile), to have an unplanned caesarean section (15% per quintile) and any (elective and emergency) caesarean section(4% per quintile)[9]. Women with higher deprivation scores are less likely to be seen in the first trimester and more likely to report dissatisfaction with clarity of communication and respectful treatment by doctors and midwives.[9]

Considering that several causal determinants of adverse infant outcomes that are associated with low socioeconomic status are potentially avoidable, strategies that promise even modest improvements warrant serious consideration. Targeted interventions for vulnerable children in early childhood have been shown to work,[10, 11] to be economically effective,[12] and have been incorporated into standard public health practice.[13] Targeting early childhood alone misses the opportunity to address inequality in-utero and the disparity already present at birth.

Caseload midwifery describes continuity of midwifery care from booking, to the post-natal period, with longer and more frequent antenatal appointments including in the home setting. Continuity of midwifery care has been shown to reduce preterm birth.[14] If these findings are applicable in women whose infants are at greater risk of adverse outcomes, caseload midwifery as an intervention in a socially deprived and ethnically diverse inner-city population, may begin to address this disparity. We aim to investigate caseload midwifery antenatal intervention and its potential for improving pregnancy outcomes in areas of social deprivation in inner-city London.

Objectives:

To report maternal and newborn outcomes of pregnant women in areas of social deprivation.

To compare maternal and newborn outcomes in this cohort of women when exposed to caseload midwifery intervention with standard care.

We hypothesise that in a deprived population cohort, outcomes will be poorer than in the general population. We propose that caseload midwifery will improve important measurable outcomes (in relation to gestational age and mode of birth) and bring them closer to the population mean.

Methods

Study design and data source

This was an observational, cohort study using retrospective data collected at Guys and St Thomas' NHS Foundation Trust, a tertiary level NHS facility in inner-city London. Pregnant women who booked at Guys and St Thomas NHS foundation trust, between 11/7/2018 and 18/6/2020, were allocated to 'traditional' care or 'caseload' care by a screening administration team (following submission of a self or GP referral form). In our main, caseload midwifery comparator population, to meet the referral criteria caseload care, women were required to live in a LEAP[a] area (defined by postcode, where more than 90% residents fall in the two most deprived IMD quintile,[15]) and meet the definition of "vulnerable" (*table 1*). Other information on the referral form (see below), was not included in the defined allocation criteria. It was possible for a woman to be transferred from traditional care to caseload care due to an evolving issue later in pregnancy. Twin and triplet pregnancies, repeat pregnancies and patients with complex medical and obstetric histories were included. Ongoing pregnancies on 18/6/2020, women marked "LEAP caseload" with non-LEAP post codes were excluded from the analysis and women with unknown midwifery care pathway.

In caseload care, teams of six midwives care for 18 pregnant women/month. Primigravid and parous women received ten 30-minute appointments in the woman's home or clinic setting as standard. Individualised care pathways allowed frequent and longer visits as required. Two midwives were involved from booking to post-natal care for each patient. Teams were on call for labour and provided extended post-natal care (up to 28 days). Early in antenatal care, a multiagency referral (for support services) form was completed entitled "Safeguarding risks to the unborn", as necessary. The midwifery team have access to social work, health visitors, substance use services and mental health services.

There were two routes for traditional care: 1) Traditional midwifery led care and 2) Consultant led/shared care. The traditional midwifery led care was for low-risk women, managed using the standard NICE guideline pathway (ten 15-minute appointments, mostly in a clinic setting for primiparous and seven for parous).[16] A variable number of midwives were involved antenatally, with a new midwife in labour and a new midwife postnatally. Consultant led/shared care was for women at high medical obstetric risk. The number of appointments was individualised, and appointments were usually 10 to 20 minutes in duration in an antenatal clinic setting. Antenatal midwifery involvement could vary significantly, with a new midwife in labour and a new midwife postnatally.

Non-LEAP area women received a mix of the above three models of care. Outcomes are reported as a guide for antenatal outcome standards in a less deprived, less diverse population.

Data collection

Anonymised data was extracted from maternity records (BadgerNet®) and collated on an Excel spreadsheet. Variables recorded were type of midwifery care provided, post code, age, marital status, BMI, ethnicity, and smoking status at booking and time of birth. Data on newborn outcomes including stillbirths, neonatal death, neonatal admission, gestation of birth, birthweight, breastfeeding at time of birth, and skin to skin contact were recorded. Maternal morbidity including pregnancy induced hypertension (>140/90), pre-eclampsia

(hypertension plus proteinuria[17]), gestational diabetes (GDM: GTT fasting BG of >5.6 and/or post prandial of >7.8 at 120 mins) hospital admission, post-partum haemorrhage (PPH 500mls[18]) and mode of birth were also recorded.

Data were gathered on variables utilised to allocate the women to caseload or traditional care from self and GP referral forms submitted. This included maternal history of need for interpreter services, learning disability, hearing or sight problems, IVF conception, birth location preference, history of previous live children, preterm births, miscarriages, ectopic pregnancies, stillbirths and neonatal deaths, previous caesarean or assisted birth, thalassaemia or sickle disease, respiratory, diabetic, cardiac, hypertension, renal, liver, neurological or infectious diseases, history of substance abuse, domestic violence, safeguarding issues, and women with the status of refugee or asylum seeker. These questions were "yes/no" on the self-referral form with an opportunity for free text included. On the GP referral if any information was not included, it was assumed to be negative (as this was the information available to the triaging midwife).

Analysis:

Three separate groups were analysed:

1) LEAP area women allocated to caseload midwifery care
2) LEAP area women allocated to traditional care
3) Non-LEAP area women (mix of above care models)

Missing documentation was reported and included in statistical analysis. Neonatal outcomes outside the data collection period were not included.

IMD scores and quintiles were derived from patient postcodes using the National Perinatal Epidemiology Unit tool[19]. Data collection began in 2018, but 2019 IMD data was used in significance analysis[20] (rather than 2015), as likely to be most accurately representative of patient circumstance. They are reported in quintiles (rather than deciles) to simplify interpretation.

164 women who had no referral form, for the purpose of analysis, were assumed to be triaged at their booking visit and were included in absolute numbers but excluded from significance analysis. Information in the questionnaire relevant to the decision to allocate to caseload midwifery care was analysed by logistic regression. Adjustment was made for these differences by the inverse probability weighting method[21] to identify and correct the most important sources of bias (*see table 2).* The inverse probability weightings were based on the four strongest predictors in the questionnaire of a decision to caseload: unknown ethnicity, breathing problems, need for an interpreter, and previous delivery by Ventouse. Probabilities were first calculated using logistic regression, and the weighting calculated for each woman as 1/(probability of caseload care) in those allocated to caseload care; and 1/(probability of not caseload care) in the other participants. Subgroup analysis was preformed according to ethnicity and IMD score. Significance analysis was performed by a statistician using Stata statistical package. Significance analysis performed adjusting for those whose continuity was interrupted due to service disruption e.g. staffing and COVID 19, did not affect our results, however we report the whole dataset as intention to treat analysis.

Patient and Public Involvement statement (PPIE):

No women were directly involved in the design, conduct, reporting, or dissemination plans of this observational study. However the research question was stimulated by the leading request of women in the Better Births[22] report for continuity of care, and the increasing public consciousness and protest to inequality, including the Black Lives Matter movement. LEAP Lambeth has parent representatives who feedback regarding early years services to local stakeholders.

Dissemination declaration:

The study findings will be disseminated to local women through the hospital and university websites, seminars and participant engagement events, NIHR ARC South London PPIE group, and conferences.

Results

A total of 14,415 pregnancies booked at Guys and St Thomas' foundation trust in the study period (11/7/2018 to 18/6/2020). We excluded 6239 ongoing pregnancies, 1 where no midwifery allocation or outcomes were known, and 42 pregnancies recorded as LEAP caseload midwifery care, but from other geographical areas (possibly explained by women moving home during pregnancy). (*fig 1*)

There were a total of 523 pregnancies in women in the LEAP area. Of these, 230 pregnancies (44%) were allocated to caseload midwifery and resulted in 235 fetuses (5 twin pregnancies). 293 pregnancies were allocated to traditional care and resulted in 304 fetuses (9 twin, 1 triplet pregnancy). There were a total of 8430 pregnancies from non-LEAP areas which resulted in 8666 fetuses (226 sets of twins, 5 sets of triplets). Of these, 1385 (16.4%) were allocated to caseload midwifery (non-LEAP team). 46 women had a second pregnancy during the study period, one of which was a twin pregnancy. All were included. (*Fig 1*)

Statistical analysis into decision for caseload midwifery was performed on information available at allocation i.e. data from referral forms. Significant factors that were identified from referral forms in the LEAP area women were women, who needed an interpreter, of unknown ethnicity, with respiratory co-morbidity and previous instrumental birth *(table 2)* and adjusted for in significance analysis. Multifetal pregnancy was not a statistically significant factor in decision making.

Demographics and modifiable lifestyle related risk factors

The LEAP area had a higher representation of BAME[b] women than in other post code areas (e.g. Black ethnicity: 27.8% vs 17.2%) and higher levels of deprivation (IMD quintile 5: 55.6% vs 28.0%) *(table 3).*

The LEAP area also had a higher proportion of single women (35.2% vs 27.0%), teenage women (3.6% vs 1.3%), women who were smokers at time of birth (4.2% vs 2.8%) and obesity (19.5% vs 14.4%) than other areas *(table 4).*

Maternal outcomes:

Primary outcome (mode of birth) in the LEAP area:

Both elective and emergency caesarean section (CS) rates were higher in the LEAP area (16.3% and 22.5% respectively) compared to other areas. In the LEAP area women allocated to caseload midwifery care, when compared to traditional care, had significantly reduced total CS (38.9 vs 24.3%; risk ratio: 0.65, P=0.01 confidence interval: 0.47 to 0.90, number needed to treat: 7.4) and emergency CS (22.5 vs 15.2%; Risk Ratio: 0.59, P=0.03; confidence interval: 0.38 to 0.94; number needed to treat: 10) *(table 5).*

Sub-analysis into vulnerability in the LEAP area

BAME population: There was a significant difference in the CS rate in those allocated to case load midwifery, compared to those allocated to traditional care. In BAME women the total

rate of CS was significantly reduced in those allocated to caseload midwifery compared to those allocated to traditional care (27.8% vs 43.1%; risk ratio: 0.68; P=0.04; confidence interval: 0.47 to 0.99). The statistical significance was similar in White mothers (24.7% vs 39.8%; risk ratio: 0.63; P=0.04; confidence interval: 0.40 to 0.99), but the caesarean rate was higher overall in BAME women. The trend reduction in women allocated to caseload midwifery compared to those allocated to traditional care on emergency caesarean was more marked in BAME women (15.7% vs 26.2%) than White women (16% vs 20.4%) but did not reach statistical significance in small numbers. (P=0.10; confidence interval 0.38 to 1.08 in BAME women). (*Table 6*)

IMD quintile 5: The overall rate of CS was higher in women in IMD 5 compared to others (3rd and 4th quintiles combined) (30.3% vs 24.6%), and the rate of emergency CS was higher (21.2% vs 11.4%). The trend in emergency CS reduction in women allocated to caseload midwifery compared to traditional care in IMD 5 is more marked (24.1% vs 17.8%) than in IMD other (12.9% vs 9.8%) but did not reach statistical significance (risk ratio 0.75; P=0.47; confidence interval: 0.34 to 1.65). This trend was not observed for reduction in total CS rate.

Women who needed an interpreter: There was a statistically significant decrease in emergency CS in women allocated to caseload midwifery compared to traditional care (5.0% (1/20) vs 50.0% (4/8)); risk ratio 0.10; P=0.03; confidence interval: 0.01 to 0.75). There was a non-statistically significant reduction in total caesarean section (30% vs 50%; Risk ratio: 0.57; P=0.28; confidence interval: 0.21 to 1.59).

Teenage women: In the LEAP area, none of the 13 teenage women allocated to caseload midwifery had a CS (0/13). 33% (2/6) of teenage women allocated to traditional midwifery had an emergency CS.

Multifetal pregnancy: In women allocated to caseload midwifery 4/10 (40%) of twin babies were born by elective CS, 1/10 (10%) by emergency caesarean and 5/10 (50%) vaginally. In women allocated to traditional care 11/21 (52.4%) babies were born by elective caesarean, 4/21(19.0%) by emergency caesarean and 6/21 (28.6%) vaginally. Numbers of multifetal pregnancies were small and the impact of caseload midwifery in multifetal pregnancies was similar to singleton in total CS (multifetal risk ratio: 0.57 and singleton risk ratio: 0.65). This reduction remains significant when multifetal excluded (P=0.01; confidence interval: 0.47 to 0.91). Reduction in emergency caesarean sections in those allocated to caseload midwifery compared to traditional care was also comparable in multifetal and singleton pregnancies (multifetal risk ratio: 0.39 and singleton RR 0.62. Reduction in emergency caesarean remains significant when multifetal excluded P= 0.04; confidence interval: 0.39 to 0.98).

Previous caesarean birth: In women allocated to traditional midwifery care, more had a history of previous caesarean birth than in women allocated caseload midwifery (20.1% vs 14.0%). When mode of delivery was analysed separately in women who had had a CS in a previous pregnancy, the rate of any caesarean birth in women receiving caseload midwifery compared to traditional care (66.7 vs 72.5%; risk ratio: 0.96; P=0.8; confidence interval: 0.60 to 1.5; risk difference: -0.03; number needed to treat: 35.9), did not reach significant difference. Furthermore, the rate of emergency cs was higher in the caseload group (27.3% vs 25.0%).

However, analysis of mode of delivery in women with no history of previous cs, found the rate of any cs birth was significantly less in the women allocated to caseload midwifery compared to traditional care (17.9% vs 32.1%; risk ratio: 0.54; P=0.004; confidence interval: 0.35 to 0.82; Risk difference: 0.16; number needed to treat: 6.2), as was the rate of emergency cs (12.9% vs 21.8%; risk ratio: 0.58; P= 0.04; confidence interval: 0.36 to 0.96; risk difference: 0.10; number needed to treat: 9.6), Interaction test suggests that while the effect of caseload midwifery on mode of delivery is strong in women without previous CS, there is no clear evidence for women with previous CS.

Secondary outcomes:

Numbers reported for gestational diabetes and hypertensive disease were small, with no significant difference observed. *(Table 5)* Post-partum haemorrhage was lower by 8.7% in women allocated to caseload midwifery compared to traditional care, but this did not reach statistical significance (Risk ratio: 0.77; P=0.10; confidence interval: 0.57 to 1.04; number needed to treat: 11.6).

Newborn outcomes in LEAP area women:

Primary outcomes (preterm birth):

Preterm birth rate was reduced in women allocated to caseload midwifery before 37 weeks, before 34 weeks and before 24 weeks gestation relative to traditional care. This was statistically significant in births before 37 weeks (5.1% vs 11.2%; risk ratio: 0.41, P=0.02; confidence interval 0.18 to 0.86, number needed to treat: 11.9). There was a trend towards reduction in preterm birth before 34 weeks (1.7% vs 4.3%) which did not reach statistical significance in our small cohort (risk ratio 0.35; P= 0.11; confidence interval 0.97 to 1.28; number needed to treat: 27.7). There were no pre-viable preterm births in the caseload midwifery group *(table 7).*

Sub analysis into vulnerability in the LEAP area

BAME population: Preterm births were reduced by approximately half in BAME women (14.4 to 7.3%) and White women (5.1% to 2.5%) who were allocated to caseload midwifery compared to traditional care. This highlights higher absolute numbers of preterm births in BAME women. There was a more marked trend in reduction in births under 34 weeks in BAME women (7.2% to 1.8%) compared to White women (2.0% to 1.2%) in those allocated to caseload midwifery compared to traditional care. (*Table 6*)

IMD quintile 5: When women in IMD quintile 5 were compared to other IMD quintiles (quintile 3 and 4) there were higher rates of premature births overall (7.0% vs 4.2%). In IMD 5 mothers, births before 37 weeks were reduced by almost half in women allocated to midwifery compared to traditional care (4.4% vs 9.1%; risk ratio 0.48; P 0.37; confidence interval: 0.10 to 2.39) compared to a smaller trend reduction in IMD 4 women (3.7% vs 4.7%).

Women who needed an interpreter: There was a statistically significant reduction in preterm birth rate (before 37 weeks) in those allocated to caseload midwifery compared to traditional

care (5.3% vs 44.4%; risk ratio: 0.11; P=0.03; confidence interval: 0.01 to 0.83). The impact was more marked than in those not needing an interpreter (5.6% vs 9.2%). There was a statistically significant reduction in preterm birth before 34 weeks in those exposed to caseload midwifery compared to traditional care (0 vs 22.2%; risk ratio: 0.25; P=0.03; confidence interval 0.07 to 0.87), which was more marked compared to those not needing an interpreter (2.1% vs 4.1%)

Teenage women: There was only 1 case of preterm birth in teenage women.

Mutifetal pregnancy: In women allocated to caseload midwifery 20% (2/10) twins were born before 37 weeks and none (0/10) before 34 weeks. In women allocated to traditional care 52.4% (11/21) babies were born before 37 weeks and none before 34 weeks (0/21). There were more multifetal pregnancies in the traditional care group, however the trend reduction in those allocated to caseload midwifery was comparable in singleton (risk ratio 0.49) and multifetal pregnancies (risk ratio 0.21).

Secondary outcomes:

In non-LEAP areas, pregnancy resulted in still birth in 0.4% of pregnancies, neonatal death (NND) in 0.7%, and non-registerable death (pre-viable) in 1.2%. In the LEAP area there were no recorded stillbirths or NND in women allocated to caseload midwifery. There was 1 NND in women allocated to traditional care *(table 7).*

Low birthweight (<2.5kg): In LEAP area women allocated to caseload midwifery there was a trend reduction in low birthweight compared to those allocated to traditional care (7.2% vs 12.2%; risk ratio: 0.77; P=0.08; confidence interval: 0.24 to 1.08; number needed to treat: 15.2) *(table 7).*

Neonatal unit (NNU) admission: In LEAP area women allocated to caseload midwifery there was a trend reduction in NNU admission compared to those allocated to traditional care (8.1% vs 11.1%) *(table 7)*.

APGAR scores: There was no significant difference APGAR scores at 1 minute less than 7 or APGAR scores at 5 minutes less than 7 *(table 7).*

Breast feeding rates: In LEAP area women allocated to caseload midwifery there was a trend increase in breast feeding compared to those allocated to traditional care (94.0 vs 92.4%; risk ratio: 1.04; P= 0.29; confidence interval: 0.97 to 1.1) *(table 7)*.

Skin to skin: In LEAP area women allocated to caseload midwifery there was a trend increase in skin to skin contact within 1 hour compared to traditional care (66.8 vs 74.9%; P=0.09: confidence interval: 0.98 to 1.3; number needed to treat: 11.7) *(table 7).*

Discussion:

Principle findings: This study shows that caseload midwifery implemented in a deprived inner-city community improves outcomes by significantly reducing preterm births and birth by caesarean section, without increasing neonatal unit admission or stillbirth. The data also suggest, that caseload midwifery had the greatest impact in the highest risk populations (mothers in higher IMD quintiles and from BAME backgrounds). In small numbers our data are suggestive of reduction in low birthweight infants, postpartum haemorrhage, pregnancy induced hypertension and pre-eclampsia, birth before 34 weeks, pre-viable birth, neonatal unit admission and neonatal death with improved breast feeding and skin-to-skin contact. No difference was observed in gestational diabetes mellitus (GDM) and macrosomia.

This study is important due to the potential impact of reducing preterm birth and caesarean rates in vulnerable women and addressing inequality and inequity at birth. Historically, attempts at reducing preterm labour and caesarean birth have been extensive but with limited impact,[23,24] and there are valid concerns regarding safety of reducing caesarean births[25]. Caseload midwifery, already shown to be acceptable [26] and beneficial [14] is not yet standard for all women in the UK (although targeted continuity of midwifery care to BAME and groups and women in living in deprived areas is an NHS Long Term Plan commitments).[27] This may be due to the incomplete understanding of the mechanism of improvement, and the enormity of the task of restructuring a care pathway. By reporting in a targeted group, we can suggest a hopeful starting point for change.

Strengths: This was a pragmatic study that included twin and triplet pregnancies, repeat pregnancies, and women with complex medical and obstetric histories, often excluded from other studies. It analysed a programme of care that has been shown to work in practice in a socially deprived area, rather than recruiting to a research study intervention. We used intention to treat analysis where continuity was affected by provider circumstantial limitations, thus, results reflect the reality of intervention in a non-study clinical practice.

Limitations: As a cohort study, and not a randomised controlled trial, it contains all the limitations of such a design. There may be potential confounders in caseload allocation and outcome which may bias our results. However, women allocated to the caseload midwifery care are anticipated to be at higher risk of adverse outcomes and hence allocated thus, making the improvements demonstrated in their outcomes potentially more significant. The small numbers in less common outcomes (e.g. Stillbirth and NND), allow trends to be only cautiously highlighted. Neonatal deaths outside the data collection period may have occurred in all groups, although numbers are likely to be small. We included multifetal pregnancies because we observed the same trend in main outcomes by caseload midwifery care as in singleton, but it must be considered as a potential confounder. Staffing and COVID 19 disrupted some aspects of continuity. We did not include economic analysis.

Comparison to other studies: This study is the first study to our knowledge focused on targeting vulnerable women based on IMD score and ethnicity, and so is not directly comparable to other studies reporting outcomes of caseload midwifery. Unlike some studies, we did not exclude women with medical/obstetric complications. A Cochrane review of available evidence prior to 2016[14] showed continuity (including caseload midwifery), when compared to standard care, reduced preterm birth (aRR 0.7), but did not reduce caesarean birth, despite a higher vaginal birth rate (aRR 1.05).[14] Our study showed significant reduction in birth before 37 weeks (risk ratio: 0.41) and all caesarean and emergency caesarean birth

rate (risk ratio 0.65 and 0.59 respectively). The POPPIE pilot RCT (2020) of women at high risk for preterm birth, found midwifery continuity of care did not significantly impact gestation, or mode of birth.[28] A prospective cohort study comparing caseload midwifery to standard care in an Aboriginal population in Australia however, found the odds ratio (OR) of preterm birth to be 0.57.[29] A retrospective cohort study of caseload midwifery in vulnerable women with complex social factors in London found a similar reduction in caesarean section (relative risk total caesarean: 0.51 and emergency caesarean: 0.42) and enhanced multidisciplinary support.[30] A previous descriptive analysis of caseload midwifery care in a London population (who were ethnically diversity with high levels of social deprivation), also found low caesarean birth rates of 16%[31].

Meaning of the study: Due to these varied outcomes, these studies suggest a need to consider appropriate targeting and the mechanism of action of caseload care. We need to consider why our study found a reduction in caesarean birth (and so markedly so), why the impact in preterm birth before 37 weeks appears bigger (aRR 0.45) and why our high-risk group responded so differently from those in the POPPIE trial?

The intervention at the crux of caseload midwifery care is providing time, continuity, and communication.[32, 33,34] Time with a women, to build trust and rapport,[35] to observe a woman's surroundings and assess what risks have not been verbalised, to establish solutions that tailor into a woman's framework and community.[36,37]

In the POPPIE pilot trial high risk was identified by history, but also by structural abnormalities and smoking.[28] This is testament to the heterogenicity of preterm labour aetiology[23], and so the solution must also be multifaceted and patient centred. There was minimal change in smoking behaviour in our caseload group. A link between a continuity-based intervention and structural adaptation (i.e. cervix and uterine abnormalities) is not known. Furthermore, continuity was often in a hospital, rather than a community-based setting (like in this study), the importance of which is currently under research.

Mechanisms of spontaneous preterm labour include the premature triggering of the hypothalamic-pituitary axis of the fetus, inflammation, matrix remodelling, abruption of the placenta and mechanical stretch.[38,39] Stress response is incompletely realised, but can physiologically manifest as an endocrine and/or a pro-inflammatory response[40,41]. Pregnancy is a state of relatively reduced systemic cortisol and inflammatory cytokines, however acute and less acute psychosocial stressors in pregnancy can counteract this, and even modulate the development of the fetus' hypothalamic-pituitary-adrenal axis.[40] Stress affects maternal health behaviours such as diet, sleep and exercise, it reduces the effectiveness of the maternal immune response, and it exacerbates mental illness such as anxiety and depression.[40] These stimuli have been shown to have impact early in pregnancy[41] and so must be tackled early.

If we have evidence that psychosocial stress and its associated effects, are linked to pre-term labour and low birthweight[41], it is intuitive to imagine that early impact on these stressors (when the physiological adaptation to pregnancy is so marked and rapid structural and functional development of the fetus is taking place) could be integral to improving outcome. One aspect of caseload midwifery care, is time to identify need for, and access social support services relative to other traditional care[30]. If a multi-agency referral is completed early, from the first trimester, the potential burden of anxiety around visa status, housing, finances etc

(that may be heightened by the impending addition of a new child) may be lightened. Intimate partner violence support, and potential freedom from financial abuse can impact both the stress response and the physical abruption risk associated with pre-term labour. This information may come to light in person, rather than with questionnaire screening, which is why early identification of risk and flexible allocation to caseload midwifery may be important.

From a longer-term perspective, maternal stressors on the fetus in-utero have been linked to neurodevelopmental disorders in children[42]. Preterm birth is associated with anxiety and depression long beyond the perinatal period in caregivers and bonding difficulties in those admitted to NNU (greater at earlier gestations).[43 44 45] A later gestation of birth may avoid a financial implication to the parents and the health care system in early years[46] and in adult hood with reduced disability, chronic illness and increased educational attainment in children born closer to term[47].

CS is a life-saving intervention, but rates above 9-16%[48] have minimal proven benefit, with negative maternal and neonatal consequences[49]. A systematic review has not reported lower caesarean rate to be associated with caseload midwifery[14]. However, deprivation is associated with unplanned CS. Our cohort population, diverse and socioeconomically deprived, are vulnerable to lack of clear communication and failed engagement with services[50]. The impact of communication is clearly illustrated by the risk ratio of 0.10 of caesarean section in mothers who need an interpreter.

It could be anticipated that more and longer antenatal appointments, with continuity of the health care professional may have more impact. Opportunities to address fears regarding labour may reduce antenatal motivation for caesarean birth. Identification of a healthy support structure in labour, may be aided by enhanced knowledge of the family dynamics, through appointments in the family home and prolonged rapport with women. Discussion around women's expectations of what is a normal labour, may impower women in their birth support and analgesia options. A known carer may enhance support to execute birth plans, thereby improving motivation in labour to pursue vaginal birth. Benefits of a vaginal birth extend from the women to health economics, reducing need for additional antenatal appointments, a lower-cost labour location and reduced CS in the next pregnancy[51]. Our results may differ from the POPPIE trial, due to a higher representation of BAME women (in POPPIE trial 58.6% were White vs 34% in LEAP area women) and women affected by deprivation (over 93% of LEAP area women in the 2 most deprived IMD quintiles vs 70% in the POPPIE trial).

Future research: Further research is needed to determine whether the significant improvement seen, will translate to other inner-city populations with similar demographics. Long term follow-up of these women would determine whether there are long-term clinical and economic benefits of caseload midwifery in this population. Further research is needed into the effectiveness of continuity of care in a hospital-based setting for those with high medical obstetric risk.

Conclusion

Before the umbilical cord is cut, paths for inequality in health out-comes have begun and are marked in communities of high socioeconomic deprivation and ethnic diversity.

Justice and equality should be a priority in any health-care setting, and caseload midwifery, may be a part of the solution. Recognising resource limitations, this study demonstrates for the first time how targeting disadvantaged inner city communities may have the most marked effect in reduction of pre-term labour before 37 weeks, all caesarean birth (and emergency caesarean birth) and their subsequent impact.

Further research is needed into the generalisability of this approach in other populations and into its impact on health economics is required. Long term follow-up of these patients is planned.

Footnote:

a: The Lambeth Early Action Partnership (LEAP) programme is a 10-year programme that works with pregnant women and children aged 0-3 years and their families and aims to give them a better start. Part of this programme includes caseload midwifery care. The majority, of women allocated to caseload midwifery in this study were cared for by this team, and the postcode areas/wards are identified as areas of deprivation by the LEAP programme. However, some women received the same package of care under the umbrella of other caseload teams in Guys and St Thomas NHS Foundation trust.

b: In this paper a large group of people are grouped under the umbrella term “Black, Asian and Minority Ethnic (BAME)”, to enable us to quantify and target outcome inequality, rather than ignorance of the diversity within that label. It should not imply uniformity of experience within these communities and does not include White minority communities that may also experience inequality in this instance.

Figure Legend:

Figure 1. Allocation of women booking at Guys and St Thomas’ foundation trust to antenatal care groups for purposes of data analysis.

Acknowledgement: We thank Clare White, Anne Kerrigan, Rachel Erskine and Emily Miller for their thoughtful comments on improving how we communicate to the reader and editing previous drafts. We thank the caseload midwives, in particular the LEAP team, for their ongoing care of women. Most importantly, we thank the women whose experience we have been able to learn from.

Contributor statement:

Eugene Oteng-Ntim conceived the presented study, organised outcome data extraction, methodology and verified the data analysis. He co-wrote the manuscript, approved the final draft and is responsible for the overall content and guarantor for the study.

Ruth Hadebe was lead in curation and analysis of the main data and was lead author of the original draft manuscript. Responsible for incorporating content from co-authors, and for the overall content of the manuscript.

Paul Seed performed statistical analysis of main results. He guided methodology and performed statistical adjustment for data confounders. He supported review and editing of the manuscript.

Dianna Essien, Kyle Headen, Saheel Mahmood and Salwa Owasil curated data regarding women's allocation to caseload midwifery. They reviewed and edited the manuscript.

Christina Fernandez Turienzo, Carla Stankes, Mara Bruno and Jane Sandall, reviewed and edited the manuscript, providing expertise on interpretation of the data set, and clinical application to bettering women's health.

Nina Khadzaezadeh, provided expertise in the study conception.

Transparency declaration : Ruth Hadebe and Eugene Oteng-Ntim affirm that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

Competing interests: All authors have completed the ICMJE uniform disclosure form and declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

Funding: The Lambeth Early Action Partnership (LEAP) programme is a 10-year programme that works with pregnant women and children aged 0-3 years and their families and aims to give them a better start. LEAP received £36 million from the National Lottery Community Fund as part of the national 'A Better Start programme.' Part of this programme includes caseload midwifery. The majority, but not all women allocated to caseload midwifery were cared for by this team. No funding was received specifically for this study. The funders had no role in the study design, data collection, analysis and interpretation of data, writing of the report, or the decision to submit the paper for publication.

Jane Sandall at King's College is an NIHR Senior Investigator and with Cristina Fernandez Turienzo are supported by the National Institute for Health Research (NIHR) Applied Research

Collaboration South London (NIHR ARC South London) at King's College Hospital NHS Foundation Trust. The views expressed are those of the author[s] and not necessarily those of the NIHR or the Department of Health and Social Care

Data sharing statement: The complete de-identified patient data set and analytical/Statistical code will be available on request form the corresponding author ruth.hadebe@nhs.net from date of publication.

Ethics statement: Ethical approval was granted by the London School of Hygiene and Tropical Medicine Ethics committee. The study was based on routinely collected hospital data. Individual patient consent was not obtained; all patient records were anonymised and de-identified prior to analysis.

Tables:

Table 1. Agreed definition of vulnerability from LEAP service plan.

Women who find services hard to access	**Women needing multi-agency services**
Socially isolated women Those living in poverty / deprivation / who are homeless Refugees / asylum seekers Non-native language speakers Victims of abuse Sex workers Young mothers Unsupported mothers Women within travelling communities	Women who are subject of safeguarding concerns Women with substance and/or alcohol abuse issues Women with physical / emotional and/or learning disabilities Women who have been victims of female genital mutilation Women who are HIV positive

Table 2. Decision to caseload from booking survey. Summary of significant and important factors that were corrected for by inverse probability weighting in statistical analysis. (Women who did not complete a booking survey excluded as interview allocation subject to bias).

Variable reported	Caseload midwifery	Traditional care	Unadjusted Risk Ratio (95% CI)	P
Interpreter needed	20/165 (12.1%)	9/210 (4.3%)	2.83 (1.32 to 6.05)	0.005
Unknown ethnicity	29/165 (17.6%)	57/210 (27.1%)	0.65 (0.43 to 0.96)	0.029
Respiratory co-morbidity	10/165 (6.1%)	26/210 (12.4%)	0.49 (0.24 to 0.99)	0.039
Previous instrumental birth	13/165 (7.9%)	8/210 (3.8%)	2.07 (0.88 to 4.87)	0.089

Table 3 Comparison of ethnic diversity and IMD scores in LEAP area women allocated to caseload midwifery and traditional care, and women in other post code areas (all care models).

	Other areas		LEAP area caseload midwifery		LEAP area traditional care	
Ethnicity	N 8430	(%)	N (230)	(%)	N (293)	(%)
White (British, Irish, Other)	4030	47.8	81	35.2	98	33.4
Black (African, Caribbean, other)	1452	17.2	66	28.7	79	27.0
Asian (including Bangladeshi, Indian, Pakistani, Asian other)	638	7.6	6	2.6	11	3.8
Chinese	200	2.4	3	1.3	2	0.7
Mixed (including White-Black, white-Asian, mixed other)	357	4.2	14	6.1	16	5.5
Other ethnic group	536	6.4	21	9.1	17	5.8
Not recorded	1253	14.9	39	17.0	70	23.9
IMD quintile						
1 (least deprived)	241	2.9	0	0	0	0
2	528	6.3	0	0	0	0
3	1151	13.7	3	1.3	4	1.4
4	3288	39.0	89	38.7	105	35.8
5 (most deprived)	2361	28.0	121	52.6	170	58.0
unknown	861	10.2	17	7.4	14	4.8

Table 4. Risk factors relating to pregnancy in women in the LEAP area allocated to case load midwifery and traditional care, and women in other post code areas.

	Other areas		LEAP area caseload midwifery		LEAP area traditional care	
	N 8430	%	N 230	%	N 293	%
Smoker at booking	324	3.8	14	6.0	10	3.4
Non-smoker at booking	7767	92.1	207	90.0	274	93.5
Status not recorded at booking	339	4.0	9	3.9	9	3.1
Smoker at time of birth	233	2.8	14	6.0	8	2.7
Non smoker at time of birth	7899	93.7	206	89.6	267	91.1
Status not recorded at time of birth	298	3.6	10	4.3	18	6.1
Age </+19	112	1.3	13	5.7	6	2.0
Age >/=40	738	8.8	14	6.1	19	6.5
Age not recorded	0	0	0	0	0	0
Single/separated/divorced/widowed	2276	27.0	87	37.8	97	33.1
Married/co-habiting/partner	4863	57.7	114	49.6	146	49.8
Relationship status not recorded	1291	15.3	29	12.6	50	17.1
BMI 30-39 (all ethnicities)	1213	14.4	47	20.4	55	18.8
BMI>40 (all ethnicities)	145	1.7	1	0.4	10	3.4
BMI not recorded	624	7.4	30	13.0	22	7.5
BMI 23-27.49 and BAME population	985	11.6	29	12.6	33	11.3
BMI >27.5 and BAME population	1054	12.5	37	16.1	50	17.1

Table 5 *Maternal outcomes in LEAP area women allocated to caseload midwifery and traditional care and women in other post code.*

	Other areas	LEAP area Caseload midwifery	LEAP area traditional care	Comparison of caseload midwifery and traditional care in LEAP area[a]			
	N 8430 (%)	N 230 (%)	N 293 (%)	Risk Ratio (95% CI)	Interaction test P value	Risk difference	Number needed to treat[b]
Mode of Birth							
Any Caesarean section	3061 (36.3)	56 (24.3)	114 (38.9)	0.65 (0.47-0.90)	0.01	-0.14	7.4
Elective Caesarean	1317 (15.6)	21 (9.1)	48 (16.3)				
Emergency Caesarean	1744 20.7)	35 (15.2)	66 (22.5)	0.59 (0.38-0.94)	0.03	-0.11	10
Assisted vaginal birth (forceps/ventouse)	1205 (14.3)	34 (14.8)	31 (10.6)				
Normal vaginal birth	4035 (47.9)	138 (60)	143 (48.8)				
Breech vaginal	43 (0.5)	2 (0.9)	2 (0.7)				
Unknown	86 (1.0)	0 (0)	3 (1.0)				
Gestational diabetes	960 (11.4)	22 (9.6)	29 (9.9)				
Pregnancy induced hypertension	141 (1.7)	3 (1.3)	8 (2.7)				
Pre-eclampsia	205 (2.4)	5 (2.2)	7 (2.4)				
Postpartum Haemorrhage (>501mls)	3289 (39.0)	67 (29.1)	111 (37.8)	0..77 (0.57-1.04)	0.10	-0.09	11.6
Inpatient admission							
<24 hours	1148 (13.6)	27 (11.1)	38 (13.0)				
>5 days (121 hours)	1387 (16.5)	32 (13.9)	41 (14.0)				
Admission not documented	120 (1.4)	5 (2.2)	5 (1.7)				

a Comparisons carried out using inverse probability weighting to minimise potential bias

b NNT: Number of women who need to be treated to prevent one bad outcome

Table 6. Comparison of primary maternal and newborn outcomes in the LEAP area following introduction of caseload midwifery in women of White and women of BAME ethnicity.

	White Ethnicity Caseload midwifery	White Ethnicity Traditional care	Comparison of caseload midwifery and traditional care in LEAP area[a]		BAME ethnicity Caseload midwifery	BAME ethnicity Traditional care	Comparison of caseload midwifery and traditional care in LEAP area[a]	
			Risk ratio (95% CI)	P value			Risk ratio (95% CI)	P value
Maternal outcomes								
Any caesarean section	24.7%	39.8%	0.63 (0.40-0.99)	0.04	27.8%	43.1%	0.68 (0.47-0.99)	0.04
Emergency caesarean section	16.0%	20.4%	0.76(0.42-1.44))	0.42	15.7%	26.2%	0.64 (0.38-1.08)	0.10
Neonatal outcomes								
Birth Before 37 weeks	2.5%	5.1%	0.45 (0.08-2.31)	0.23	7.3%	14.4%	0.49 (0.21-1.09)	0.08
Birth before 34 weeks	1.2%	2.0%	0.66 (0.07-7.2)	0.7	1.8%	7.2%	0.24 (0.05-1.12)	0.07

a Comparisons carried out using inverse probability weighting to minimise potential bias

Table 7 Newborn outcomes in LEAP and non-LEAP areas following the introduction of LEAP case-loading intervention.

Outcome	Other areas	LEAP area Caseload midwifery	LEAP area Traditional care	Comparison of caseload midwifery and traditional care in LEAP area[a]			
	N 8666 (%)	N 235 (%)	N 304 (%)	Risk Ratio (95% CI)	Interaction test P value	Risk Difference	NNT[b]
Stillbirth	37 (0.4)	0 (0)	0 (0)				
Neonatal death	59 (0.7)	0 (0)	1 (0.3)				
Non-registerable birth	106 (1.2)	0 (0)	3 (1.0)				
Not recorded	1 (0.01)	0 (0)	0 (0)				
Neonatal unit admission	889 (10.3)	19 (8.1)	34 (11.1)				
Not documented if NNU admission	1 (0.01)	0 (0)	0 (0)				
Apgar score <7 (1 min)		15 (6.4%)	27 (8.9%)	0.68 (0.35-1.33)	0.26	-0.04	
Apgar <7 (5 min)		6 (2.6%)	3 (1.0%)	3.9 (0.79-19.3)	0.10	0.03	
Apgar not fully recorded		5 (2.1%)	8 (2.6%)				
All births <37 weeks	912 (10.5)	12 (5.1)	34 (11.2)	0.41 (0.18-0.86)	0.02	-0.07	11.9
All births <34 weeks	417 (4.8)	4 (1.7)	13 (4.3)	0.35 (0.97-1.28)	0.11	-0.04	27.7
Birth 12-23+6 weeks	134 (1.5)	0 (0)	4 (1.3)				
Birth 24- 33+6 weeks	283 (3.3)	4 (1.7)	9 (3.0)				
Birth 34-36+6 weeks	495 (5.7)	8 (3.4)	21 (6.9)				
Gestation of birth not recorded	0 (0)	0 (0)	0 (0)				
Birth weight <2.5kg	967 (11.1)	17 (7.2)	37 (12.2)	0.77 (0.24-1.08)	0.08	-0.07	15.2
Birthweight >4.5kgs	60 (0.7)	1 (0.4)	1 (0.3)				
Birth weight not recorded	2 (0.02)	0 (0)	0 (0)				
Breast fed (at all)	7832 (90.4)	221 (94.0)	281 (92.4)	1.04 (0.97-1.11)	0.29	0.03	30.9
Not recorded if breastfed	214 (2.5)	0 (0)	4 (1.3)				
Skin to skin within 1 hour	5827 (67.2)	176 (74.9)	203 (66.8)	1.12 (0.98-1.30)	0.09	0.09	11.7

a Comparisons carried out using inverse probability weighting to minimise potential bias

b NNT: Number of women who need to be treated to prevent one bad outcome

References

1. National Institute for Health and Clinical Excellence. *Pregnant Women With Complex Social Factors: a model for service provision*. www.nice.org.uk.
2. *MBRRACE-UK Perinatal Mortality Surveillance report. UK Perinatal Deaths for Births from January to December 2016*. https://www.npeu.ox.ac.uk/downloads/files/mbrrace-uk/reports/MBRRACE-UK Perinatal Surveillance Full Report for 2016 - June 2018.pdf (2018).
3. Taylor-Robinson, D. *et al.* Quantifying the Impact of Deprivation on Preterm Births: A Retrospective Cohort Study. *PLoS One* **6**, e23163 (2011).
4. Ene, D. *et al.* Associations of Socioeconomic Deprivation and Preterm Birth With Speech, Language, and Communication Concerns Among Children Aged 27 to 30 Months. *JAMA Netw. Open* **2**, e1911027 (2019).
5. Beauregard, J. L., Drews-Botsch, C., Sales, J. M., Flanders, W. D. & Kramer, M. R. Preterm Birth, Poverty, and Cognitive Development. *Pediatrics* **141**, e20170509 (2018).
6. Henderson, J., Carson, C. & Redshaw, M. Impact of preterm birth on maternal well-being and women's perceptions of their baby: a population-based survey. *BMJ Open* **6**, e012676 (2016).
7. MBRRACE-UK. *Saving Lives, Improving Mothers' Care*. (2019).
8. Health, C. E. into M. and C. *Saving Mothers Lives: Reviewing maternal deaths to make motherhood safer*. (2007).
9. Lindquist, A., Kurinczuk, J., Redshaw, M. & Knight, M. Experiences, utilisation and outcomes of maternity care in England among women from different socio-economic groups: findings from the 2010 National Maternity Survey. *BJOG An Int. J. Obstet. Gynaecol.* **122**, 1610–1617 (2015).
10. Conti, G., Heckman, J. J. & Pinto, R. The Effects of Two Influential Early Childhood Interventions on Health and Healthy Behaviour. *Econ. J.* **126**, F28–F65 (2016).
11. Frank Porter Graham Child Development Institute. The Abecedarian Project. *https://abc.fpg.unc.edu/abecedarian-project*.
12. Barnett, W. S. & Masse, L. N. Comparative benefit–cost analysis of the Abecedarian program and its policy implications. *Econ. Educ. Rev.* **26**, 113–125 (2007).
13. *Health Matters:giving every child the best start in life*. https://www.gov.uk/government/publications/health-matters-giving-every-child-the-best-start-in-life/health-matters-giving-every-child-the-best-start-in-life (2016).
14. Sandall, J., Soltani, H., Gates, S., Shennan, A. & Devane, D. Midwife-led continuity models versus other models of care for childbearing women. *Cochrane Database Syst. Rev.* (2016) doi:10.1002/14651858.CD004667.pub5.
15. *Demography Factsheet: Lambeth:- 'a diverse and changing population'*. https://www.lambeth.gov.uk/sites/default/files/ssh-demography-factsheet-2017.pdf

(2017).

16. Excellence, N. I. or H. C. *Clinical Guideline 62: Antenatal Care for uncomplicated pregnancies*. https://www.nice.org.uk/guidance/cg62.

17. National Institute for Health and Clinical Excellence. *NICE Guideline 133: Hypertension in pregnancy: diagnosis and management*. https://www.nice.org.uk/guidance/ng133/chapter/Recommendations#management-of-pre-eclampsia.

18. Royal College of Obstericians and Gynaecologists. *Green Top Guideline 52: Postpartum Haemorhage, Prevention and Management*. (2016).

19. NPEU. IMD tool | NPEU Tools. http://tools.npeu.ox.ac.uk/imd/.

20. No Title. http://imd-by-postcode.opendatacommunities.org/imd/2019.

21. Cattaneo, M. D. Efficient semiparametric estimation of multi-valued treatment effects under ignorability. *J. Econom.* **155**, 138–154 (2010).

22. Professor Sir Cyril Chantler *et al.* Better births Improving outcomes of maternity services in England. A five year View for maternity care . *Natl. Matern. Rev. found https//www.england.nhs.uk/wp-content/uploads/2016/02/national-maternity-review-report.pdf* (2015).

23. Medley, N., Vogel, J. P., Care, A. & Alfirevic, Z. Interventions during pregnancy to prevent preterm birth: an overview of Cochrane systematic reviews. *Cochrane Database Syst. Rev.* (2018) doi:10.1002/14651858.CD012505.pub2.

24. World Health Organisation. *Non-Clinical Interventions to Reduce Unnecessary Caesarean Sections*. (2018).

25. Ockenden, D. *Ockenden Report: Emerging Findings and Reccommendations form the Independent Review of Maternity Services at the Shrewsbury and Telford Hospital NHS Trust*. https://www.donnaockenden.com/downloads/news/2020/12/ockenden-report.pdf (2020).

26. Tracy, S. K. *et al.* Caseload midwifery care versus standard maternity care for women of any risk: M@NGO, a randomised controlled trial. *Lancet* **382**, 1723–1732 (2013).

27. *The NHS Long Term Plan*. https://www.longtermplan.nhs.uk/wp-content/uploads/2019/01/nhs-long-term-plan-june-2019.pdf (2019).

28. Fernandez Turienzo, C. *et al.* Midwifery continuity of care versus standard maternity care for women at increased risk of preterm birth: A hybrid implementation–effectiveness, randomised controlled pilot trial in the UK. *PLOS Med.* **17**, e1003350 (2020).

29. Kildea, S. *et al.* Reducing preterm birth amongst Aboriginal and Torres Strait Islander babies: A prospective cohort study, Brisbane, Australia. *EClinicalMedicine* **12**, 43–51 (2019).

30. Rayment-Jones, H., Murrells, T. & Sandall, J. An investigation of the relationship between the caseload model of midwifery for socially disadvantaged women and

childbirth outcomes using routine data – A retrospective, observational study. *Midwifery* **31**, 409–417 (2015).

31. Homer, C. S., Leap, N., Edwards, N. & Sandall, J. Midwifery continuity of carer in an area of high socio-economic disadvantage in London: A retrospective analysis of Albany Midwifery Practice outcomes using routine data (1997–2009). *Midwifery* **48**, 1–10 (2017).

32. Kennedy, H. P. A Model Of Exemplary Midwifery Practice: Results Of A Delphi Study. *J. Midwifery Womens. Health* **45**, 4–19 (2000).

33. Davis, J. A. P. Midwives and Normalcy in Childbirth: A Phenomenologic Concept Development Study. *J. Midwifery Womens. Health* **55**, 206–215 (2010).

34. Phillippi, J. C. & Avery, M. D. The 2012 American College of Nurse-Midwives Core Competencies for Basic Midwifery Practice: History and Revision. *J. Midwifery Womens. Health* **59**, 82–90 (2014).

35. Rayment-Jones, H., Silverio, S. A., Harris, J., Harden, A. & Sandall, J. Project 20: Midwives' insight into continuity of care models for women with social risk factors: what works, for whom, in what circumstances, and how. *Midwifery* **84**, 102654 (2020).

36. ten Hoope-Bender, P. *et al.* Improvement of maternal and newborn health through midwifery. *Lancet* **384**, 1226–1235 (2014).

37. McRae, D. N. *et al.* Is model of care associated with infant birth outcomes among vulnerable women? A scoping review of midwifery-led versus physician-led care. *SSM - Popul. Heal.* **2**, 182–193 (2016).

38. Robinson, J. N., Regan, J. A. & Norwitz, E. R. The epidemiology of preterm labor. *Semin. Perinatol.* **25**, 204–214 (2001).

39. Georgiou, H. M., Di Quinzio, M. K. W., Permezel, M. & Brennecke, S. P. Predicting Preterm Labour: Current Status and Future Prospects. *Dis. Markers* **2015**, 1–9 (2015).

40. Coussons-Read, M. E. Effects of prenatal stress on pregnancy and human development: mechanisms and pathways. *Obstet. Med.* **6**, 52–57 (2013).

41. Shapiro, G. D., Fraser, W. D., Frasch, M. G. & Séguin, J. R. Psychosocial stress in pregnancy and preterm birth: associations and mechanisms. *J. Perinat. Med.* **41**, (2013).

42. KINSELLA, M. T. & MONK, C. Impact of Maternal Stress, Depression and Anxiety on Fetal Neurobehavioral Development. *Clin. Obstet. Gynecol.* **52**, 425–440 (2009).

43. Trumello, C. *et al.* Mothers' Depression, Anxiety, and Mental Representations After Preterm Birth: A Study During the Infant's Hospitalization in a Neonatal Intensive Care Unit. *Front. Public Heal.* **6**, (2018).

44. Ionio, C. *et al.* Mothers and fathers in NICU: The impact of preterm birth on parental distress. *Eur. J. Psychol.* **12**, 604–621 (2016).

45. Pace, C. C. *et al.* Evolution of Depression and Anxiety Symptoms in Parents of Very

Preterm Infants During the Newborn Period. *JAMA Pediatr.* **170**, 863 (2016).

46. Jacob, J. *et al.* Cost effects of preterm birth: a comparison of health care costs associated with early preterm, late preterm, and full-term birth in the first 3 years after birth. *Eur. J. Heal. Econ.* **18**, 1041–1046 (2017).

47. Lindstrom, K., Winbladh, B., Haglund, B. & Hjern, A. Preterm Infants as Young Adults: A Swedish National Cohort Study. *Pediatrics* **120**, 70–77 (2007).

48. Betran, A. P. *et al.* What is the optimal rate of caesarean section at population level? A systematic review of ecologic studies. *Reprod. Health* **12**, 57 (2015).

49. Sandall, J. *et al.* Short-term and long-term effects of caesarean section on the health of women and children. *Lancet* **392**, 1349–1357 (2018).

50. Modder, J. *et al. CEMACH: Perinatal Mortality 2007*.

51. Royal College of Obstericians and Gynaecologists. *Green Top Guideline No 45. Birth After Previous Caesarean Section*. (2015).

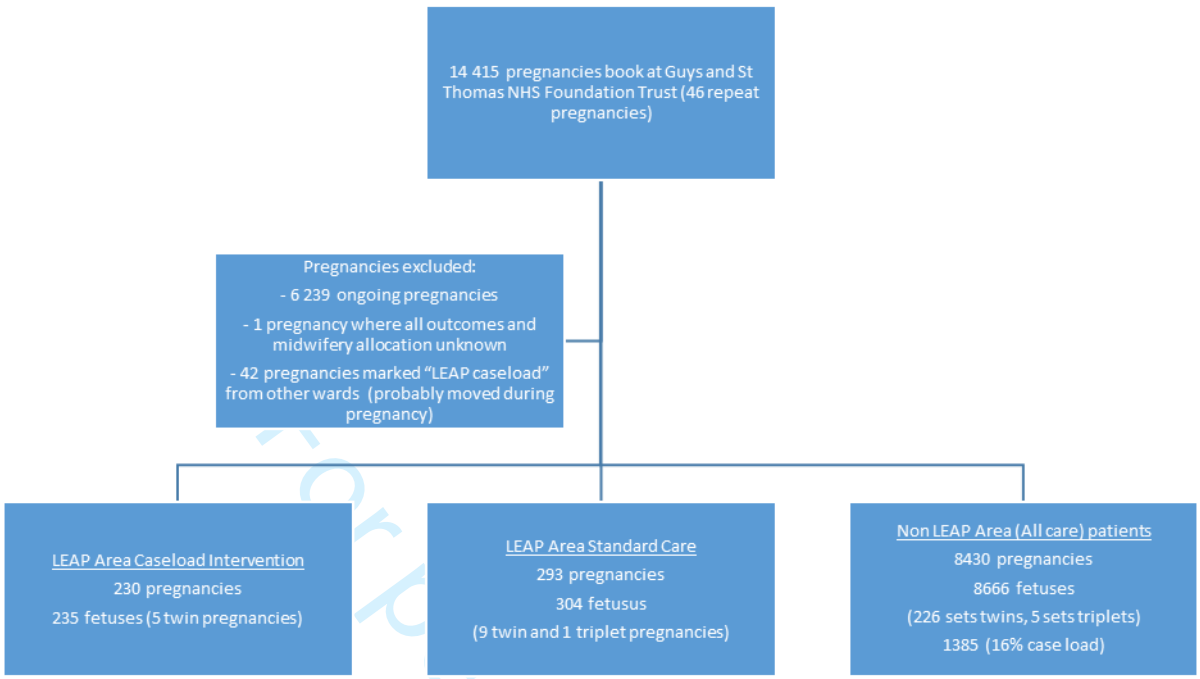


Figure 1. Allocation of women booking at Guys and St Thomas' foundation trust to antenatal care groups for purposes of data analysis.

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 (*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	1-2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up (*b*) For matched studies, give matching criteria and number of exposed and unexposed	5-6
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5-6
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	5-6
Bias	9	Describe any efforts to address potential sources of bias	6
Study size	10	Explain how the study size was arrived at	
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	5-6
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding (*b*) Describe any methods used to examine subgroups and interactions (*c*) Explain how missing data were addressed (*d*) If applicable, explain how loss to follow-up was addressed (*e*) Describe any sensitivity analyses	6
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 (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram	8
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest (c) Summarise follow-up time (eg, average and total amount)	9
Outcome data	15*	Report numbers of outcome events or summary measures over time	9-11

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	9-11
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	9-11
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
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	12-13
Generalisability	21	Discuss the generalisability (external validity) of the study results	13
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	17

*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.

BMJ Open

Can birth outcome inequality be reduced using targeted caseload midwifery in a deprived diverse inner-city population? A retrospective cohort study, London UK

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2021-049991.R2
Article Type:	Original research
Date Submitted by the Author:	07-Sep-2021
Complete List of Authors:	Hadebe, Ruth; Guy's and St Thomas' NHS Foundation Trust, Department of Women's Health Seed, Paul; King's College London, Department of Women and Children's Health Essien, Diana; Guy's and St Thomas' NHS Foundation Trust, Department of Women's Health Headen, Kyle; Guy's and St Thomas' NHS Foundation Trust, Deapartment of Women's Health Mahmud, Saheel; King's College London School of Medicine Owasil, Salwa; King's College London School of Medicine Fernandez Turienzo, Cristina; King's College London, Department of Women and Children's Health Stanke, Carla; National Childrens Bureau, Public Health; Lambeth Early Action Partnership Sandall, Jane; Kings College, London, Department of Women and Children's Health Bruno, Mara; Guy's and St Thomas' NHS Foundation Trust, Department of Women's Health Khazaezadeh, Nina; Guy's and St Thomas' NHS Foundation Trust, Department of Women's Health Oteng-Ntim, Eugene ; guys and st thomas nhs foundation trust, Department of Women's Health; King's College London, Department of Women and Children's Health
Primary Subject Heading:	Obstetrics and gynaecology
Secondary Subject Heading:	Health policy, Obstetrics and gynaecology, Public health
Keywords:	OBSTETRICS, Health policy < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, PUBLIC HEALTH

I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our licence.

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which Creative Commons licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

Can birth outcome inequality be reduced using targeted caseload midwifery in a deprived diverse inner-city population? A retrospective cohort study, London UK

Ruth Hadebe, ST6 obstetrics and gynaecology[1] (0000-0003-4020-8933), Paul T Seed, reader in medical statistics[2] (0000-0001-7904-7933), Diana Essien, clinical fellow obstetrics and gynaecology[1], Kyle Headen ST2 obstetrics and gynaecology[1], Saheel Mahmud, medical student[3], Salwa Owasil, medical student[3], Cristina Fernandez Turienzo, midwife researcher[2] (0000-0002-7393-6593), Carla Stanke, public health specialist[4,5], Jane Sandall, professor of social science and women's health[5] (0000-0002-5384-3744), Mara Bruno, midwife[1], Nina Khazaezadeh, consultant midwife in public health[1], Eugene Oteng-Ntim, professor of obstetrics, [1,2](0000-0001-8867-2909).

Affiliations

1 Guy's and St Thomas' NHS Foundation Trust, Department of Women's Health London, UK,

2 Department of Women and Children's Health, Faculty of Life Science and Medicine, King's College London, London, United Kingdom.

3 King's College London School of Medicine, London, UK,

4 National Children's Bureau, Public Health, London, UK,

5 Lambeth Early Action Partnership

Corresponding Author: Ruth Hadebe, Dept Women's Health, 10th Floor, North Wing, St Thomas Hospital, Westminster Bridge Road, London. SE1 7EH. Email: ruth.hadebe@nhs.net

Abstract

Objectives:

i. To report maternal and newborn outcomes of pregnant women in areas of social deprivation in inner-city London.
ii. To compare the effect of caseload midwifery with standard care on maternal and newborn outcomes in this cohort of women.

Design: Retrospective observational cohort study.

Setting: Four council wards (electoral districts) in inner-city London, where over 90% of residents are in the two most deprived quintiles of the English Index of Multiple Deprivation (2019) and the population is ethnically diverse.

Participants: All women booked for antenatal care under Guys and St Thomas' NHS Foundation Trust after 11/7/2018 (when the Lambeth Early Action Partnership (LEAP) caseload midwifery team[a] was implemented) until data collection 18/6/2020. This included 523 pregnancies in the LEAP area, of which 230 were allocated to caseload midwifery, and 8430 pregnancies from other areas.

Main outcome measures: To explore if targeted caseload midwifery (known to reduce preterm birth) will improve important measurable outcomes (preterm birth, mode of birth, and newborn outcomes).

Results: There was a significant reduction in preterm birth rate in women allocated to caseload midwifery, when compared to those who received traditional midwifery care (5.1% vs 11.2%; risk ratio: 0.41; P=0.02; confidence interval 0.18 to 0.86; number needed to treat: 11.9). Caesarean section births were significantly reduced in women allocated to caseload midwifery care, when compared to traditional midwifery care (24.3% vs 38.0%; risk ratio: 0.64: P=0.01; confidence interval: 0.47 to 0.90; number needed to treat: 7.4) including emergency caesarean deliveries (15.2% vs 22.5%; risk Ratio: 0.59; P=0.03; confidence interval: 0.38 to 0.94; number needed to treat: 10) without increase in neonatal unit admission or stillbirth.

Conclusion: This study shows that a model of caseload midwifery care implemented in an inner-city deprived community improves outcome by significantly reducing preterm birth and birth by caesarean section when compared to traditional care. These data trend suggests that when applied to targeted groups (women in higher IMD quintile and women of diverse ethnicity) that the impact of intervention is greater.

Strengths and limitations of this study:

- This study question addresses a clinically and economically important problem (preterm birth and mode of delivery) and first reports caseload midwifery effects in women disadvantaged due to social complexity.
- This study pragmatically represents a clinical setting, including women of all medical risk, with intention to treat analysis, and thus results reflect the reality of intervention in a non-study clinical practice.
- Logistical regression analysis was performed using an established statistical method (inverse probability weighting) to correct for bias in case selection.
- Confounders in caseload allocation and outcome may bias our results.
- Numbers in less common outcomes are small (e.g., Stillbirth and NND), and neonatal deaths may be underreported if they occurred outside the data collection period.

Introduction.

Fetal outcome is affected by social deprivation and parental ethnicity.[1] The English Index of Multiple Deprivation (IMD) comparatively ranks areas according to markers of socioeconomic deprivation using domains of income, employment, education, skills and training, health and disability, crime, barriers to housing services, and living environment. In 2016, 25.9% of all stillbirths in the UK occurred in the most deprived IMD quintile compared with 14.9% in the least, with a similar distribution for neonatal death (25.7% and 15.9% respectively).[2] In 2017, the stillbirth rate for the UK was 3.74 per 1000, however in Black/Black British and Asian/Asian British women, rates were 7.46 and 5.70 per 1000 respectively, with an increase in neonatal mortality (despite a downward trend in the White patient population).[2] Preterm birth is more common in women affected by social deprivation[3], and the combination is associated with developmental problems in the early years.[4,5] Preterm birth negatively impacts maternal mental health, relationships between child and caregiver, and interaction with support services.[6]

Maternal mortality doubles when comparing women in the least deprived IMD quintiles to women in the most deprived (5 to 12 per 100,000).[7] Black women are 5 times more likely to die as a result of pregnancy than White women (38 compared with 7 per 100,000), women of mixed ethnicity 3 times, and women of Asian ethnicity 2 times more likely to die.[7] Mortality is associated with suboptimal utilisation of antenatal services, including late/no booking and nonattendance, (most marked in Black African, Black Caribbean and Middle Eastern women).[8] For each step up in deprivation quintile, women are more likely to receive no antenatal care (25% increase per quintile), to have an unplanned caesarean section (15% per quintile) and any (elective and emergency) caesarean section (4% per quintile)[9]. Women with higher deprivation scores are less likely to be seen in the first trimester and more likely to report dissatisfaction with clarity of communication and respectful treatment by doctors and midwives.[9]

Considering that several causal determinants of adverse infant outcomes that are associated with low socioeconomic status are potentially avoidable, strategies that promise even modest improvements warrant serious consideration. Targeted interventions for vulnerable children in early childhood have been shown to work,[10, 11] to be economically effective,[12] and have been incorporated into standard public health practice.[13] Targeting early childhood alone misses the opportunity to address inequality in-utero and the disparity already present at birth.

Caseload midwifery describes continuity of midwifery care from booking, to the post-natal period, with longer and more frequent antenatal appointments including in the home setting. Continuity of midwifery care has been shown to reduce preterm birth.[14] If these findings are applicable in women whose infants are at greater risk of adverse outcomes, caseload midwifery as an intervention in a socially deprived and ethnically diverse inner-city population, may begin to address this disparity. We aim to investigate caseload midwifery antenatal intervention and its potential for improving pregnancy outcomes in areas of social deprivation in inner-city London.

Objectives:

To report maternal and newborn outcomes of pregnant women in areas of social deprivation.

To compare maternal and newborn outcomes in this cohort of women when exposed to caseload midwifery intervention with standard care.

We hypothesise that in a deprived population cohort, outcomes will be poorer than in the general population. We propose that caseload midwifery will improve important measurable outcomes (in relation to gestational age and mode of birth) and bring them closer to the population mean.

Methods

Study design and data source

This was an observational, cohort study using retrospective data collected at Guys and St Thomas' NHS Foundation Trust, a tertiary level NHS facility in inner-city London. Pregnant women who booked at Guys and St Thomas NHS foundation trust, between 11/7/2018 and 18/6/2020, were allocated to 'traditional' care or 'caseload' care by a screening administration team (following submission of a self or GP referral form). In our main caseload midwifery comparator population, to meet the referral criteria caseload care, women were required to live in a LEAP[a] area (defined by postcode, where more than 90% residents fall in the two most deprived IMD quintile,[15]) and meet the definition of "vulnerable" (*table 1*). Other information on the referral form (see below), was not included in the defined allocation criteria. It was possible for a woman to be transferred from traditional care to caseload care due to an evolving issue later in pregnancy. Twin and triplet pregnancies, repeat pregnancies and patients with complex medical and obstetric histories were included. Ongoing pregnancies on 18/6/2020, women marked "LEAP caseload" with non-LEAP post codes were excluded from the analysis and women with unknown midwifery care pathway.

In caseload care, teams of six midwives care for 18 pregnant women/month. Primigravid and parous women received ten 30-minute appointments in the woman's home or clinic setting as standard. Individualised care pathways allowed frequent and longer visits as required. Two midwives were involved from booking to post-natal care for each patient. Teams were on call for labour and provided extended post-natal care (up to 28 days). Early in antenatal care, a multiagency referral (for support services) form was completed entitled "Safeguarding risks to the unborn", as necessary. The midwifery team have access to social work, health visitors, substance use services and mental health services.

There were two routes for traditional care: 1) Traditional midwifery led care and 2) Consultant led/shared care. The traditional midwifery led care was for low-risk women, managed using the standard NICE guideline pathway (ten 15-minute appointments, mostly in a clinic setting for primiparous and seven for parous).[16] A variable number of midwives were involved antenatally, with a new midwife in labour and a new midwife postnatally. Consultant led/shared care was for women at high medical obstetric risk. The number of appointments was individualised, and appointments were usually 10 to 20 minutes in duration in an antenatal clinic setting. Antenatal midwifery involvement could vary significantly, with a new midwife in labour and a new midwife postnatally.

Non-LEAP area women received a mix of the above three models of care. Outcomes are reported as a guide for antenatal outcome standards in a less deprived, less diverse population.

Data collection

Anonymised data was extracted from maternity records (BadgerNet®) and collated on an Excel spreadsheet. Variables recorded were type of midwifery care provided, post code, age, marital status, BMI, ethnicity, and smoking status at booking and time of birth. Data on newborn outcomes including stillbirths, neonatal death, neonatal admission, gestation of birth, birthweight, breastfeeding at time of birth, and skin to skin contact were recorded. Maternal morbidity including pregnancy induced hypertension (>140/90), pre-eclampsia

(hypertension plus proteinuria[17]), gestational diabetes (GDM: GTT fasting BG of >5.6 and/or post prandial of >7.8 at 120 mins) hospital admission, post-partum haemorrhage (PPH >500mls[18]) and mode of birth were also recorded.

Data were gathered on variables available during decision to allocate the women to caseload or traditional care from self and GP referral forms submitted. This included maternal history of need for interpreter services, learning disability, hearing or sight problems, IVF conception, birth location preference, history of previous live children, preterm births, miscarriages, ectopic pregnancies, stillbirths and neonatal deaths, previous caesarean or assisted birth, thalassaemia or sickle disease, respiratory, diabetic, cardiac, hypertension, renal, liver, neurological or infectious diseases, history of substance abuse, domestic violence, safeguarding issues, and women with the status of refugee or asylum seeker. These questions were "yes/no" on the self-referral form with an opportunity for free text included. On the GP referral if any information was not included, it was assumed to be negative (as this was the information available to the triaging midwife).

Data collection was confidential and adhered to the Kings College London Research Data Management Policy standards.

Analysis:

Three separate groups were analysed:

1) LEAP area women allocated to caseload midwifery care
2) LEAP area women allocated to traditional care
3) Non-LEAP area women (mix of above care models)

Missing documentation was reported and included in statistical analysis. Neonatal outcomes outside the data collection period were not included.

IMD scores and quintiles were derived from patient postcodes using the National Perinatal Epidemiology Unit tool[19]. Data collection began in 2018, but 2019 IMD data was used in significance analysis[20] (rather than 2015), as likely to be most accurately representative of patient circumstance. They are reported in quintiles (rather than deciles) to simplify interpretation.

164 women who had no referral form, for the purpose of analysis, were assumed to be triaged at their booking visit and were included in absolute numbers but excluded from significance analysis. Information in the questionnaire relevant to the decision to allocate to caseload midwifery care was analysed by logistic regression. Adjustment was made for these differences by the inverse probability weighting method[21] to identify and correct the most important sources of bias (*see table 2).* The inverse probability weightings were based on the four strongest predictors in the questionnaire of a decision to caseload: unknown ethnicity, breathing problems, need for an interpreter, and previous delivery by Ventouse. Probabilities were first calculated using logistic regression, and the weighting calculated for each woman as 1/(probability of caseload care) in those allocated to caseload care; and 1/(probability of not caseload care) in the other participants. Subgroup analysis was preformed according to ethnicity and IMD score. Significance analysis was performed by a statistician using Stata statistical package. Significance analysis performed adjusting for those

whose continuity was interrupted due to service disruption e.g. staffing and COVID 19, did not affect our results, however we report the whole dataset as intention to treat analysis.

Patient and Public Involvement statement (PPIE):

No women were directly involved in the design, conduct, reporting, or dissemination plans of this observational study. However the research question was stimulated by the leading request of women in the Better Births[22] report for continuity of care, and the increasing public consciousness and protest to inequality, including the Black Lives Matter movement. LEAP Lambeth has parent representatives who feedback regarding early years services to local stakeholders.

Dissemination declaration:

The study findings will be disseminated to local women through the hospital and university websites, seminars and participant engagement events, NIHR ARC South London PPIE group, and conferences.

Results

A total of 14,415 pregnancies booked at Guys and St Thomas' foundation trust in the study period (11/7/2018 to 18/6/2020). We excluded 6239 ongoing pregnancies, 1 where no midwifery allocation or outcomes were known, and 42 pregnancies recorded as LEAP caseload midwifery care, but from other geographical areas (possibly explained by women moving home during pregnancy). (*fig 1*)

There were a total of 523 pregnancies in women in the LEAP area. Of these, 230 pregnancies (44%) were allocated to caseload midwifery and resulted in 235 fetuses (5 twin pregnancies). 293 pregnancies were allocated to traditional care and resulted in 304 fetuses (9 twin, 1 triplet pregnancy). There were a total of 8430 pregnancies from non-LEAP areas which resulted in 8666 fetuses (226 sets of twins, 5 sets of triplets). Of these, 1385 (16.4%) were allocated to caseload midwifery (non-LEAP team). 46 women had a second pregnancy during the study period, one of which was a twin pregnancy. All were included. (*Fig 1*)

Statistical analysis into decision for caseload midwifery was performed on information available at allocation i.e. data from referral forms. Significant factors that were identified from referral forms in the LEAP area women were women, who needed an interpreter, of unknown ethnicity, with respiratory co-morbidity and previous instrumental birth *(table 2)* and adjusted for in significance analysis. Multifetal pregnancy was not a statistically significant factor in decision making.

Demographics and modifiable lifestyle related risk factors

The LEAP area had a higher representation of BAME[b] women than in other post code areas (e.g. Black ethnicity: 27.8% vs 17.2%) and higher levels of deprivation (IMD quintile 5: 55.6% vs 28.0%) *(table 3).*

The LEAP area also had a higher proportion of single women (35.2% vs 27.0%), teenage women (3.6% vs 1.3%), women who were smokers at time of birth (4.2% vs 2.8%) and obesity (19.5% vs 14.4%) than other areas *(table 4).*

Maternal outcomes:

Primary outcome (mode of birth) in the LEAP area:

Both elective and emergency caesarean section (CS) rates were higher in the LEAP area (16.3% and 22.5% respectively) compared to other areas. In the LEAP area women allocated to caseload midwifery care, when compared to traditional care, had significantly reduced total CS (38.9 vs 24.3%; risk ratio: 0.65, P=0.01 confidence interval: 0.47 to 0.90, number needed to treat: 7.4) and emergency CS (22.5 vs 15.2%; Risk Ratio: 0.59, P=0.03; confidence interval: 0.38 to 0.94; number needed to treat: 10) *(table 5).*

Sub-analysis into vulnerability in the LEAP area

BAME population: There was a significant difference in the CS rate in those allocated to case load midwifery, compared to those allocated to traditional care. In BAME women the total

rate of CS was significantly reduced in those allocated to caseload midwifery compared to those allocated to traditional care (27.8% vs 43.1%; risk ratio: 0.68; P=0.04; confidence interval: 0.47 to 0.99). The statistical significance was similar in White mothers (24.7% vs 39.8%; risk ratio: 0.63; P=0.04; confidence interval: 0.40 to 0.99), but the caesarean rate was higher overall in BAME women. The trend reduction in women allocated to caseload midwifery compared to those allocated to traditional care on emergency caesarean was more marked in BAME women (15.7% vs 26.2%) than White women (16% vs 20.4%) but did not reach statistical significance in small numbers. (P=0.10; confidence interval 0.38 to 1.08 in BAME women). (*Table 6*)

IMD quintile 5: The overall rate of CS was higher in women in IMD 5 compared to others (3rd and 4th quintiles combined) (30.3% vs 24.6%), and the rate of emergency CS was higher (21.2% vs 11.4%). The trend in emergency CS reduction in women allocated to caseload midwifery compared to traditional care in IMD 5 is more marked (24.1% vs 17.8%) than in IMD other (12.9% vs 9.8%) but did not reach statistical significance (risk ratio 0.75; P=0.47; confidence interval: 0.34 to 1.65). This trend was not observed for reduction in total CS rate.

Women who needed an interpreter: There was a statistically significant decrease in emergency CS in women allocated to caseload midwifery compared to traditional care (5.0% (1/20) vs 50.0% (4/8)); risk ratio 0.10; P=0.03; confidence interval: 0.01 to 0.75). There was a non-statistically significant reduction in total caesarean section (30% vs 50%; Risk ratio: 0.57; P=0.28; confidence interval: 0.21 to 1.59).

Teenage women: In the LEAP area, none of the 13 teenage women allocated to caseload midwifery had a CS (0/13). 33% (2/6) of teenage women allocated to traditional midwifery had an emergency CS.

Multifetal pregnancy: In women allocated to caseload midwifery 4/10 (40%) of twin babies were born by elective CS, 1/10 (10%) by emergency caesarean and 5/10 (50%) vaginally. In women allocated to traditional care 11/21 (52.4%) babies were born by elective caesarean, 4/21(19.0%) by emergency caesarean and 6/21 (28.6%) vaginally. Numbers of multifetal pregnancies were small and the impact of caseload midwifery in multifetal pregnancies was similar to singleton in total CS (multifetal risk ratio: 0.57 and singleton risk ratio: 0.65). This reduction remains significant when multifetal excluded (P=0.01; confidence interval: 0.47 to 0.91). Reduction in emergency caesarean sections in those allocated to caseload midwifery compared to traditional care was also comparable in multifetal and singleton pregnancies (multifetal risk ratio: 0.39 and singleton risk ratio: 0.62. Reduction in emergency caesarean remains significant when multifetal excluded P= 0.04; confidence interval: 0.39 to 0.98).

Previous caesarean birth: In women allocated to traditional midwifery care, more had a history of previous caesarean birth than in women allocated caseload midwifery (20.1% vs 14.0%). When mode of delivery was analysed separately in women who had had a CS in a previous pregnancy, the rate of any caesarean birth in women receiving caseload midwifery compared to traditional care (66.7 vs 72.5%; risk ratio: 0.96; P=0.8; confidence interval: 0.60 to 1.5; risk difference: -0.03; number needed to treat: 35.9), did not reach significant difference. Furthermore, the rate of emergency cs was higher in the caseload group (27.3% vs 25.0%).

However, analysis of mode of delivery in women with no history of previous cs, found the rate of any cs birth was significantly less in the women allocated to caseload midwifery compared to traditional care (17.9% vs 32.1%; risk ratio: 0.54; P=0.004; confidence interval: 0.35 to 0.82; Risk difference: 0.16; number needed to treat: 6.2), as was the rate of emergency cs (12.9% vs 21.8%; risk ratio: 0.58; P= 0.04; confidence interval: 0.36 to 0.96; risk difference: 0.10; number needed to treat: 9.6), Interaction test suggests that while the effect of caseload midwifery on mode of delivery is strong in women without previous CS, there is no clear evidence for women with previous CS.

Secondary outcomes:

Numbers reported for gestational diabetes and hypertensive disease were small, with no significant difference observed. *(Table 5)* Post-partum haemorrhage was lower by 8.7% in women allocated to caseload midwifery compared to traditional care, but this did not reach statistical significance (Risk ratio: 0.77; P=0.10; confidence interval: 0.57 to 1.04; number needed to treat: 11.6).

Newborn outcomes in LEAP area women:

Primary outcomes (preterm birth):

Preterm birth rate was reduced in women allocated to caseload midwifery before 37 weeks, before 34 weeks and before 24 weeks gestation relative to traditional care. This was statistically significant in births before 37 weeks (5.1% vs 11.2%; risk ratio: 0.41, P=0.02; confidence interval 0.18 to 0.86, number needed to treat: 11.9). There was a trend towards reduction in preterm birth before 34 weeks (1.7% vs 4.3%) which did not reach statistical significance in our small cohort (risk ratio 0.35; P= 0.11; confidence interval 0.97 to 1.28; number needed to treat: 27.7). There were no pre-viable preterm births in the caseload midwifery group *(table 7).*

Sub analysis into vulnerability in the LEAP area

BAME population: Preterm births were reduced by approximately half in BAME women (14.4 to 7.3%) and White women (5.1% to 2.5%) who were allocated to caseload midwifery compared to traditional care. This highlights higher absolute numbers of preterm births in BAME women. There was a more marked trend in reduction in births under 34 weeks in BAME women (7.2% to 1.8%) compared to White women (2.0% to 1.2%) in those allocated to caseload midwifery compared to traditional care. (*Table 6*)

IMD quintile 5: When women in IMD quintile 5 were compared to other IMD quintiles (quintile 3 and 4) there were higher rates of premature births overall (7.0% vs 4.2%). In IMD 5 mothers, births before 37 weeks were reduced by almost half in women allocated to midwifery compared to traditional care (4.4% vs 9.1%; risk ratio 0.48; P 0.37; confidence interval: 0.10 to 2.39) compared to a smaller trend reduction in IMD 4 women (3.7% vs 4.7%).

Women who needed an interpreter: There was a statistically significant reduction in preterm birth rate (before 37 weeks) in those allocated to caseload midwifery compared to traditional

care (5.3% vs 44.4%; risk ratio: 0.11; P=0.03; confidence interval: 0.01 to 0.83). The impact was more marked than in those not needing an interpreter (5.6% vs 9.2%). There was a statistically significant reduction in preterm birth before 34 weeks in those exposed to caseload midwifery compared to traditional care (0 vs 22.2%; risk ratio: 0.25; P=0.03; confidence interval 0.07 to 0.87), which was more marked compared to those not needing an interpreter (2.1% vs 4.1%)

Teenage women: There was only 1 case of preterm birth in teenage women.

Mutifetal pregnancy: In women allocated to caseload midwifery 20% (2/10) twins were born before 37 weeks and none (0/10) before 34 weeks. In women allocated to traditional care 52.4% (11/21) babies were born before 37 weeks and none before 34 weeks (0/21). There were more multifetal pregnancies in the traditional care group, however the trend reduction in those allocated to caseload midwifery was comparable in singleton (risk ratio 0.49) and multifetal pregnancies (risk ratio 0.21).

Secondary outcomes:

In non-LEAP areas, pregnancy resulted in still birth in 0.4% of pregnancies, neonatal death (NND) in 0.7%, and non-registerable death (pre-viable) in 1.2%. In the LEAP area there were no recorded stillbirths or NND in women allocated to caseload midwifery. There was 1 NND in women allocated to traditional care *(table 7).*

Low birthweight (<2.5kg): In LEAP area women allocated to caseload midwifery there was a trend reduction in low birthweight compared to those allocated to traditional care (7.2% vs 12.2%; risk ratio: 0.77; P=0.08; confidence interval: 0.24 to 1.08; number needed to treat: 15.2) *(table 7).*

Neonatal unit (NNU) admission: In LEAP area women allocated to caseload midwifery there was a trend reduction in NNU admission compared to those allocated to traditional care (8.1% vs 11.1%) *(table 7)*.

APGAR scores: There was no significant difference APGAR scores at 1 minute less than 7 or APGAR scores at 5 minutes less than 7 *(table 7).*

Breast feeding rates: In LEAP area women allocated to caseload midwifery there was a trend increase in breast feeding compared to those allocated to traditional care (94.0 vs 92.4%; risk ratio: 1.04; P= 0.29; confidence interval: 0.97 to 1.1) *(table 7)*.

Skin to skin: In LEAP area women allocated to caseload midwifery there was a trend increase in skin to skin contact within 1 hour compared to traditional care (66.8 vs 74.9%; P=0.09: confidence interval: 0.98 to 1.3; number needed to treat: 11.7) *(table 7).*

Discussion:

Principle findings: This study shows that caseload midwifery implemented in a deprived inner-city community improves outcomes by significantly reducing preterm births and birth by caesarean section, without increasing neonatal unit admission or stillbirth. The data also suggest that caseload midwifery had the greatest impact in the highest risk populations (mothers in higher IMD quintiles and from BAME backgrounds). In small numbers our data are suggestive of reduction in low birthweight infants, postpartum haemorrhage, pregnancy induced hypertension and pre-eclampsia, birth before 34 weeks, pre-viable birth, neonatal unit admission and neonatal death with improved breast feeding and skin-to-skin contact. No difference was observed in gestational diabetes mellitus (GDM) and macrosomia.

This study is important due to the potential impact of reducing preterm birth and caesarean rates in vulnerable women and addressing inequality and inequity at birth. Historically, attempts at reducing preterm labour and caesarean birth have been extensive but with limited impact,[23,24] and there are valid concerns regarding safety of reducing caesarean births[25]. Caseload midwifery, already shown to be acceptable [26] and beneficial [14] is not yet standard for all women in the UK (although targeted continuity of midwifery care to BAME and groups and women in living in deprived areas is an NHS Long Term Plan commitments).[27] This may be due to the incomplete understanding of the mechanism of improvement, and the enormity of the task of restructuring a care pathway. By reporting in a targeted group, we can suggest a hopeful starting point for change.

Strengths: This was a pragmatic study that included twin and triplet pregnancies, repeat pregnancies, and women with complex medical and obstetric histories, often excluded from other studies. It analysed a programme of care that has been shown to work in practice in a socially deprived area, rather than recruiting to a research study intervention. We used intention to treat analysis where continuity was affected by provider circumstantial limitations, thus, results reflect the reality of intervention in a non-study clinical practice.

Limitations: As a cohort study, and not a randomised controlled trial, it contains all the limitations of such a design. There may be potential confounders in caseload allocation and outcome which may bias our results. However, women allocated to the caseload midwifery care are anticipated to be at higher risk of adverse outcomes and hence allocated thus, making the improvements demonstrated in their outcomes potentially more significant. The small numbers in less common outcomes (e.g. Stillbirth and NND), allow trends to be only cautiously highlighted. Neonatal deaths outside the data collection period may have occurred in all groups, although numbers are likely to be small. We included multifetal pregnancies because we observed the same trend in main outcomes by caseload midwifery care as in singleton, but it must be considered as a potential confounder. Staffing and COVID 19 disrupted some aspects of continuity. We did not include economic analysis.

Comparison to other studies: To our knowledge, this study is the first to focus on targeting care for vulnerable women based on IMD score and ethnicity, and so is not directly comparable to other studies reporting outcomes of caseload midwifery. Unlike some studies, we did not exclude women with medical/obstetric complications. A Cochrane review of available evidence prior to 2016[14] showed continuity (including caseload midwifery), when compared to standard care, reduced preterm birth (aRR 0.7), but did not reduce caesarean birth, despite a higher vaginal birth rate (aRR 1.05).[14] Our study showed significant reduction in birth before 37 weeks (risk ratio: 0.41) and all caesarean and emergency caesarean birth

rate (risk ratio 0.65 and 0.59 respectively). The POPPIE pilot RCT (2020) of women at high risk for preterm birth, found midwifery continuity of care did not significantly impact gestation, or mode of birth.[28] A prospective cohort study comparing caseload midwifery to standard care in an Aboriginal population in Australia however, found the odds ratio (OR) of preterm birth to be 0.57.[29] A retrospective cohort study of caseload midwifery in vulnerable women with complex social factors in London found a similar reduction in caesarean section (relative risk total caesarean: 0.51 and emergency caesarean: 0.42) and enhanced multidisciplinary support.[30] A previous descriptive analysis of caseload midwifery care in a London population (who were ethnically diversity with high levels of social deprivation), also found low caesarean birth rates of 16%[31].

Meaning of the study: Due to these varied outcomes, previous study findings suggest a need to consider appropriate targeting and the mechanism of action of caseload care. We need to consider why our study found a reduction in caesarean birth (and so markedly so), why the impact in preterm birth before 37 weeks appears bigger (aRR 0.45) and why our high-risk group responded so differently from those in the POPPIE trial?

The intervention at the crux of caseload midwifery care is providing time, continuity, and communication.[32, 33,34] Time with a women, to build trust and rapport,[35] to observe a woman's surroundings and assess what risks have not been verbalised, to establish solutions that tailor into a woman's framework and community.[36,37]

In the POPPIE pilot trial high risk was identified by history, but also by structural abnormalities and smoking.[28] This is testament to the heterogenicity of preterm labour aetiology[23], and so the solution must also be multifaceted and patient centred. There was minimal change in smoking behaviour in our caseload group. A link between a continuity-based intervention and structural adaptation (i.e. cervix and uterine abnormalities) is not known. Furthermore, continuity was often in a hospital, rather than a community-based setting (like in this study), the importance of which is currently under research.

Mechanisms of spontaneous preterm labour include the premature triggering of the hypothalamic-pituitary axis of the fetus, inflammation, matrix remodelling, abruption of the placenta and mechanical stretch.[38,39] Stress response is incompletely realised, but can physiologically manifest as an endocrine and/or a pro-inflammatory response[40,41]. Pregnancy is a state of relatively reduced systemic cortisol and inflammatory cytokines, however acute and less acute psychosocial stressors in pregnancy can counteract this, and even modulate the development of the fetus' hypothalamic-pituitary-adrenal axis.[40] Stress affects maternal health behaviours such as diet, sleep and exercise, it reduces the effectiveness of the maternal immune response, and it exacerbates mental illness such as anxiety and depression.[40] These stimuli have been shown to have impact early in pregnancy[41] and so must be tackled early.

If evidence exists that psychosocial stress and its associated effects, are linked to pre-term labour and low birthweight[41], it is intuitive to imagine that early impact on these stressors (when the physiological adaptation to pregnancy is so marked and rapid structural and functional development of the fetus is taking place) could be integral to improving outcome. One aspect of caseload midwifery care, is time to identify need for, and access social support services relative to other traditional care[30]. If a multi-agency referral is completed early, from the first trimester, the potential burden of anxiety around visa status, housing, finances etc

(that may be heightened by the impending addition of a new child) may be lightened. Intimate partner violence support, and potential freedom from financial abuse can impact both the stress response and the physical abruption risk associated with pre-term labour. This information may come to light in person, rather than with questionnaire screening, which is why early identification of risk and flexible allocation to caseload midwifery may be important.

From a longer-term perspective, maternal stressors on the fetus in-utero have been linked to neurodevelopmental disorders in children[42]. Preterm birth is associated with anxiety and depression long beyond the perinatal period in caregivers and bonding difficulties in those admitted to NNU (greater at earlier gestations).[43 44 45] A later gestation of birth may avoid a financial implication to the parents and the health care system in early years[46] and in adult hood with reduced disability, chronic illness and increased educational attainment in children born closer to term[47].

CS is a life-saving intervention, but rates above 9-16%[48] have minimal proven benefit, with negative maternal and neonatal consequences[49]. A systematic review has not reported lower caesarean rate to be associated with caseload midwifery[14]. However, deprivation is associated with unplanned CS. Our cohort population, diverse and socioeconomically deprived, are vulnerable to lack of clear communication and failed engagement with services[50]. The impact of communication is clearly illustrated by the risk ratio of 0.10 of caesarean section in mothers who need an interpreter.

It could be anticipated that more and longer antenatal appointments, with continuity of the health care professional may have more impact. Opportunities to address fears regarding labour may reduce antenatal motivation for caesarean birth. Identification of a healthy support structure in labour, may be aided by enhanced knowledge of the family dynamics, through appointments in the family home and prolonged rapport with women. Discussion around women's expectations of what is a normal labour, may impower women in their birth support and analgesia options. A known carer may enhance support to execute birth plans, thereby improving motivation in labour to pursue vaginal birth. Benefits of a vaginal birth extend from the women to health economics, reducing need for additional antenatal appointments, a lower-cost labour location and reduced CS in the next pregnancy[51]. Our results may differ from the POPPIE trial, due to a higher representation of BAME women (in POPPIE trial 58.6% were White vs 34% in LEAP area women) and women affected by deprivation (over 93% of LEAP area women in the 2 most deprived IMD quintiles vs 70% in the POPPIE trial).

Future research: Further research is needed to determine whether the significant improvement seen, will translate to other inner-city populations with similar demographics. Long term follow-up of these women would determine whether there are long-term clinical and economic benefits of caseload midwifery in this population. Further research is needed into the effectiveness of continuity of care in a hospital-based setting for those with high medical obstetric risk.

Conclusion

Before the umbilical cord is cut, paths for inequality in health out-comes have begun and are marked in communities of high socioeconomic deprivation and ethnic diversity.

Justice and equality should be a priority in any health-care setting, and caseload midwifery, may be a part of the solution. Recognising resource limitations, this study demonstrates for the first time how targeting disadvantaged inner city communities may have the most marked effect in reduction of pre-term labour before 37 weeks, all caesarean birth (and emergency caesarean birth) and their subsequent impact.

Further research is needed into the generalisability of this approach in other populations and into its impact on health economics is required. Long term follow-up of these patients is planned.

Footnote:

a: The Lambeth Early Action Partnership (LEAP) programme is a 10-year programme that works with pregnant women and children aged 0-3 years and their families and aims to give them a better start. Part of this programme includes caseload midwifery care. The majority, of women allocated to caseload midwifery in this study were cared for by this team, and the postcode areas/wards are identified as areas of deprivation by the LEAP programme. However, some women received the same package of care under the umbrella of other caseload teams in Guys and St Thomas NHS Foundation trust.

b: In this paper a large group of people are grouped under the umbrella term “Black, Asian and Minority Ethnic (BAME)”, to enable us to quantify and target outcome inequality, rather than ignorance of the diversity within that label. It should not imply uniformity of experience within these communities and does not include White minority communities that may also experience inequality in this instance.

Figure Legend:

Figure 1. Allocation of women booking at Guys and St Thomas’ foundation trust to antenatal care groups for purposes of data analysis.

Acknowledgement: We thank Clare White, Anne Kerrigan, Rachel Erskine and Emily Miller for their thoughtful comments on improving how we communicate to the reader and editing previous drafts. We thank the caseload midwives, in particular the LEAP team, for their ongoing care of women. Most importantly, we thank the women whose experience we have been able to learn from.

Contributor statement:

Eugene Oteng-Ntim conceived the presented study, organised outcome data extraction, methodology and verified the data analysis. He co-wrote the manuscript, approved the final draft and is responsible for the overall content and guarantor for the study.

Ruth Hadebe was lead in curation and analysis of the main data and was lead author of the original draft manuscript. Responsible for incorporating content from co-authors, and for the overall content of the manuscript.

Paul Seed performed statistical analysis of main results. He guided methodology and performed statistical adjustment for data confounders. He supported review and editing of the manuscript.

Dianna Essien, Kyle Headen, Saheel Mahmood and Salwa Owasil curated data regarding women's allocation to caseload midwifery. They reviewed and edited the manuscript.

Christina Fernandez Turienzo, Carla Stankes, Mara Bruno and Jane Sandall, reviewed and edited the manuscript, providing expertise on interpretation of the data set, and clinical application to bettering women's health.

Nina Khadzaezadeh, provided expertise in the study conception.

Transparency declaration : Ruth Hadebe and Eugene Oteng-Ntim affirm that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

Competing interests: All authors have completed the ICMJE uniform disclosure form and declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

Funding: The Lambeth Early Action Partnership (LEAP) programme is a 10-year programme that works with pregnant women and children aged 0-3 years and their families and aims to give them a better start. LEAP received £36 million from the National Lottery Community Fund as part of the national 'A Better Start programme.' Part of this programme includes caseload midwifery. The majority, but not all women allocated to caseload midwifery were cared for by this team. No funding was received specifically for this study. The funders had no role in the study design, data collection, analysis and interpretation of data, writing of the report, or the decision to submit the paper for publication.

Jane Sandall at King's College is an NIHR Senior Investigator and with Cristina Fernandez Turienzo are supported by the National Institute for Health Research (NIHR) Applied Research

Collaboration South London (NIHR ARC South London) at King's College Hospital NHS Foundation Trust. The views expressed are those of the author[s] and not necessarily those of the NIHR or the Department of Health and Social Care

Data sharing statement: The complete de-identified patient data set and analytical/Statistical code will be available on request form the corresponding author ruth.hadebe@nhs.net from date of publication.

Ethics statement: Ethical approval was granted by the London School of Hygiene and Tropical Medicine Ethics committee. The study was based on routinely collected hospital data. Individual patient consent was not obtained; all patient records were anonymised and de-identified prior to analysis.

Tables:

Table 1. Agreed definition of vulnerability from LEAP service plan.

Women who find services hard to access	**Women needing multi-agency services**
Socially isolated women Those living in poverty / deprivation / who are homeless Refugees / asylum seekers Non-native language speakers Victims of abuse Sex workers Young mothers Unsupported mothers Women within travelling communities	Women who are subject of safeguarding concerns Women with substance and/or alcohol abuse issues Women with physical / emotional and/or learning disabilities Women who have been victims of female genital mutilation Women who are HIV positive

Table 2. Decision to caseload from booking survey. Summary of significant and important factors that were corrected for by inverse probability weighting in statistical analysis. (Women who did not complete a booking survey excluded as interview allocation subject to bias).

Variable reported	Caseload midwifery	Traditional care	Unadjusted Risk Ratio (95% CI)	P
Interpreter needed	20/165 (12.1%)	9/210 (4.3%)	2.83 (1.32 to 6.05)	0.005
Unknown ethnicity	29/165 (17.6%)	57/210 (27.1%)	0.65 (0.43 to 0.96)	0.029
Respiratory co-morbidity	10/165 (6.1%)	26/210 (12.4%)	0.49 (0.24 to 0.99)	0.039
Previous instrumental birth	13/165 (7.9%)	8/210 (3.8%)	2.07 (0.88 to 4.87)	0.089

Table 3 Comparison of ethnic diversity and IMD scores in LEAP area women allocated to caseload midwifery and traditional care, and women in other post code areas (all care models).

	Other areas		LEAP area caseload midwifery		LEAP area traditional care	
Ethnicity	N 8430	(%)	N (230)	(%)	N (293)	(%)
White (British, Irish, Other)	4030	47.8	81	35.2	98	33.4
Black (African, Caribbean, other)	1452	17.2	66	28.7	79	27.0
Asian (including Bangladeshi, Indian, Pakistani, Asian other)	638	7.6	6	2.6	11	3.8
Chinese	200	2.4	3	1.3	2	0.7
Mixed (including White-Black, white-Asian, mixed other)	357	4.2	14	6.1	16	5.5
Other ethnic group	536	6.4	21	9.1	17	5.8
Not recorded	1253	14.9	39	17.0	70	23.9
IMD quintile						
1 (least deprived)	241	2.9	0	0	0	0
2	528	6.3	0	0	0	0
3	1151	13.7	3	1.3	4	1.4
4	3288	39.0	89	38.7	105	35.8
5 (most deprived)	2361	28.0	121	52.6	170	58.0
unknown	861	10.2	17	7.4	14	4.8

Table 4. Risk factors relating to pregnancy in women in the LEAP area allocated to case load midwifery and traditional care, and women in other post code areas.

	Other areas		LEAP area caseload midwifery		LEAP area traditional care	
	N 8430	%	N 230	%	N 293	%
Smoker at booking	324	3.8	14	6.0	10	3.4
Non-smoker at booking	7767	92.1	207	90.0	274	93.5
Status not recorded at booking	339	4.0	9	3.9	9	3.1
Smoker at time of birth	233	2.8	14	6.0	8	2.7
Non smoker at time of birth	7899	93.7	206	89.6	267	91.1
Status not recorded at time of birth	298	3.6	10	4.3	18	6.1
Age </+19	112	1.3	13	5.7	6	2.0
Age >/=40	738	8.8	14	6.1	19	6.5
Age not recorded	0	0	0	0	0	0
Single/separated/divorced/widowed	2276	27.0	87	37.8	97	33.1
Married/co-habiting/partner	4863	57.7	114	49.6	146	49.8
Relationship status not recorded	1291	15.3	29	12.6	50	17.1
BMI 30-39 (all ethnicities)	1213	14.4	47	20.4	55	18.8
BMI>40 (all ethnicities)	145	1.7	1	0.4	10	3.4
BMI not recorded	624	7.4	30	13.0	22	7.5
BMI 23-27.49 and BAME population	985	11.6	29	12.6	33	11.3
BMI >27.5 and BAME population	1054	12.5	37	16.1	50	17.1

Table 5 *Maternal outcomes in LEAP area women allocated to caseload midwifery and traditional care and women in other post code.*

	Other areas	LEAP area Caseload midwifery	LEAP area traditional care	Comparison of caseload midwifery and traditional care in LEAP area[a]			
	N 8430 (%)	N 230 (%)	N 293 (%)	Risk Ratio (95% CI)	Interaction test P value	Risk difference	Number needed to treat[b]
Mode of Birth							
Any Caesarean section	3061 (36.3)	56 (24.3)	114 (38.9)	0.65 (0.47-0.90)	0.01	-0.14	7.4
Elective Caesarean	1317 (15.6)	21 (9.1)	48 (16.3)				
Emergency Caesarean	1744 20.7)	35 (15.2)	66 (22.5)	0.59 (0.38-0.94)	0.03	-0.11	10
Assisted vaginal birth (forceps/ventouse)	1205 (14.3)	34 (14.8)	31 (10.6)				
Normal vaginal birth	4035 (47.9)	138 (60)	143 (48.8)				
Breech vaginal	43 (0.5)	2 (0.9)	2 (0.7)				
Unknown	86 (1.0)	0 (0)	3 (1.0)				
Gestational diabetes	960 (11.4)	22 (9.6)	29 (9.9)				
Pregnancy induced hypertension	141 (1.7)	3 (1.3)	8 (2.7)				
Pre-eclampsia	205 (2.4)	5 (2.2)	7 (2.4)				
Postpartum Haemorrhage (>501mls)	3289 (39.0)	67 (29.1)	111 (37.8)	0..77 (0.57-1.04)	0.10	-0.09	11.6
Inpatient admission							
<24 hours	1148 (13.6)	27 (11.1)	38 (13.0)				
>5 days (121 hours)	1387 (16.5)	32 (13.9)	41 (14.0)				
Admission not documented	120 (1.4)	5 (2.2)	5 (1.7)				

a Comparisons carried out using inverse probability weighting to minimise potential bias

b NNT: Number of women who need to be treated to prevent one bad outcome

Table 6. Comparison of primary maternal and newborn outcomes in the LEAP area following introduction of caseload midwifery in women of White and women of BAME ethnicity.

	White Ethnicity Caseload midwifery	White Ethnicity Traditional care	Comparison of caseload midwifery and traditional care in LEAP area[a]		BAME ethnicity Caseload midwifery	BAME ethnicity Traditional care	Comparison of caseload midwifery and traditional care in LEAP area[a]	
			Risk ratio (95% CI)	P value			Risk ratio (95% CI)	P value
Maternal outcomes								
Any caesarean section	24.7%	39.8%	0.63 (0.40-0.99)	0.04	27.8%	43.1%	0.68 (0.47-0.99)	0.04
Emergency caesarean section	16.0%	20.4%	0.76(0.42-1.44))	0.42	15.7%	26.2%	0.64 (0.38-1.08)	0.10
Neonatal outcomes								
Birth Before 37 weeks	2.5%	5.1%	0.45 (0.08-2.31)	0.23	7.3%	14.4%	0.49 (0.21-1.09)	0.08
Birth before 34 weeks	1.2%	2.0%	0.66 (0.07-7.2)	0.7	1.8%	7.2%	0.24 (0.05-1.12)	0.07

a Comparisons carried out using inverse probability weighting to minimise potential bias

Table 7 Newborn outcomes in LEAP and non-LEAP areas following the introduction of LEAP case-loading intervention.

Outcome	Other areas	LEAP area Caseload midwifery	LEAP area Traditional care	Comparison of caseload midwifery and traditional care in LEAP area[a]			
	N 8666 (%)	N 235 (%)	N 304 (%)	Risk Ratio (95% CI)	Interaction test P value	Risk Difference	NNT[b]
Stillbirth	37 (0.4)	0 (0)	0 (0)				
Neonatal death	59 (0.7)	0 (0)	1 (0.3)				
Non-registerable birth	106 (1.2)	0 (0)	3 (1.0)				
Not recorded	1 (0.01)	0 (0)	0 (0)				
Neonatal unit admission	889 (10.3)	19 (8.1)	34 (11.1)				
Not documented if NNU admission	1 (0.01)	0 (0)	0 (0)				
Apgar score <7 (1 min)		15 (6.4%)	27 (8.9%)	0.68 (0.35-1.33)	0.26	-0.04	
Apgar <7 (5 min)		6 (2.6%)	3 (1.0%)	3.9 (0.79-19.3)	0.10	0.03	
Apgar not fully recorded		5 (2.1%)	8 (2.6%)				
All births <37 weeks	912 (10.5)	12 (5.1)	34 (11.2)	0.41 (0.18-0.86)	0.02	-0.07	11.9
All births <34 weeks	417 (4.8)	4 (1.7)	13 (4.3)	0.35 (0.97-1.28)	0.11	-0.04	27.7
Birth 12-23+6 weeks	134 (1.5)	0 (0)	4 (1.3)				
Birth 24- 33+6 weeks	283 (3.3)	4 (1.7)	9 (3.0)				
Birth 34-36+6 weeks	495 (5.7)	8 (3.4)	21 (6.9)				
Gestation of birth not recorded	0 (0)	0 (0)	0 (0)				
Birth weight <2.5kg	967 (11.1)	17 (7.2)	37 (12.2)	0.77 (0.24-1.08)	0.08	-0.07	15.2
Birthweight >4.5kgs	60 (0.7)	1 (0.4)	1 (0.3)				
Birth weight not recorded	2 (0.02)	0 (0)	0 (0)				
Breast fed (at all)	7832 (90.4)	221 (94.0)	281 (92.4)	1.04 (0.97-1.11)	0.29	0.03	30.9
Not recorded if breastfed	214 (2.5)	0 (0)	4 (1.3)				
Skin to skin within 1 hour	5827 (67.2)	176 (74.9)	203 (66.8)	1.12 (0.98-1.30)	0.09	0.09	11.7

a Comparisons carried out using inverse probability weighting to minimise potential bias

b NNT: Number of women who need to be treated to prevent one bad outcome

References

1. National Institute for Health and Clinical Excellence. *Pregnant Women With Complex Social Factors: a model for service provision*. www.nice.org.uk.
2. *MBRRACE-UK Perinatal Mortality Surveillance report. UK Perinatal Deaths for Births from January to December 2016*. https://www.npeu.ox.ac.uk/downloads/files/mbrrace-uk/reports/MBRRACE-UK Perinatal Surveillance Full Report for 2016 - June 2018.pdf (2018).
3. Taylor-Robinson, D. *et al.* Quantifying the Impact of Deprivation on Preterm Births: A Retrospective Cohort Study. *PLoS One* **6**, e23163 (2011).
4. Ene, D. *et al.* Associations of Socioeconomic Deprivation and Preterm Birth With Speech, Language, and Communication Concerns Among Children Aged 27 to 30 Months. *JAMA Netw. Open* **2**, e1911027 (2019).
5. Beauregard, J. L., Drews-Botsch, C., Sales, J. M., Flanders, W. D. & Kramer, M. R. Preterm Birth, Poverty, and Cognitive Development. *Pediatrics* **141**, e20170509 (2018).
6. Henderson, J., Carson, C. & Redshaw, M. Impact of preterm birth on maternal well-being and women's perceptions of their baby: a population-based survey. *BMJ Open* **6**, e012676 (2016).
7. MBRRACE-UK. *Saving Lives, Improving Mothers' Care*. (2019).
8. Health, C. E. into M. and C. *Saving Mothers Lives: Reviewing maternal deaths to make motherhood safer*. (2007).
9. Lindquist, A., Kurinczuk, J., Redshaw, M. & Knight, M. Experiences, utilisation and outcomes of maternity care in England among women from different socio-economic groups: findings from the 2010 National Maternity Survey. *BJOG An Int. J. Obstet. Gynaecol.* **122**, 1610–1617 (2015).
10. Conti, G., Heckman, J. J. & Pinto, R. The Effects of Two Influential Early Childhood Interventions on Health and Healthy Behaviour. *Econ. J.* **126**, F28–F65 (2016).
11. Frank Porter Graham Child Development Institute. The Abecedarian Project. *https://abc.fpg.unc.edu/abecedarian-project*.
12. Barnett, W. S. & Masse, L. N. Comparative benefit–cost analysis of the Abecedarian program and its policy implications. *Econ. Educ. Rev.* **26**, 113–125 (2007).
13. *Health Matters:giving every child the best start in life*. https://www.gov.uk/government/publications/health-matters-giving-every-child-the-best-start-in-life/health-matters-giving-every-child-the-best-start-in-life (2016).
14. Sandall, J., Soltani, H., Gates, S., Shennan, A. & Devane, D. Midwife-led continuity models versus other models of care for childbearing women. *Cochrane Database Syst. Rev.* (2016) doi:10.1002/14651858.CD004667.pub5.
15. *Demography Factsheet: Lambeth:- 'a diverse and changing population'*. https://www.lambeth.gov.uk/sites/default/files/ssh-demography-factsheet-2017.pdf

(2017).

16. Excellence, N. I. or H. C. *Clinical Guideline 62: Antenatal Care for uncomplicated pregnancies*. https://www.nice.org.uk/guidance/cg62.

17. National Institute for Health and Clinical Excellence. *NICE Guideline 133: Hypertension in pregnancy: diagnosis and management*. https://www.nice.org.uk/guidance/ng133/chapter/Recommendations#management-of-pre-eclampsia.

18. Royal College of Obstericians and Gynaecologists. *Green Top Guideline 52: Postpartum Haemorhage, Prevention and Management*. (2016).

19. NPEU. IMD tool | NPEU Tools. http://tools.npeu.ox.ac.uk/imd/.

20. No Title. http://imd-by-postcode.opendatacommunities.org/imd/2019.

21. Cattaneo, M. D. Efficient semiparametric estimation of multi-valued treatment effects under ignorability. *J. Econom.* **155**, 138–154 (2010).

22. Professor Sir Cyril Chantler *et al.* Better births Improving outcomes of maternity services in England. A five year View for maternity care . *Natl. Matern. Rev. found https//www.england.nhs.uk/wp-content/uploads/2016/02/national-maternity-review-report.pdf* (2015).

23. Medley, N., Vogel, J. P., Care, A. & Alfirevic, Z. Interventions during pregnancy to prevent preterm birth: an overview of Cochrane systematic reviews. *Cochrane Database Syst. Rev.* (2018) doi:10.1002/14651858.CD012505.pub2.

24. World Health Organisation. *Non-Clinical Interventions to Reduce Unnecessary Caesarean Sections*. (2018).

25. Ockenden, D. *Ockenden Report: Emerging Findings and Reccommendations form the Independent Review of Maternity Services at the Shrewsbury and Telford Hospital NHS Trust*. https://www.donnaockenden.com/downloads/news/2020/12/ockenden-report.pdf (2020).

26. Tracy, S. K. *et al.* Caseload midwifery care versus standard maternity care for women of any risk: M@NGO, a randomised controlled trial. *Lancet* **382**, 1723–1732 (2013).

27. *The NHS Long Term Plan*. https://www.longtermplan.nhs.uk/wp-content/uploads/2019/01/nhs-long-term-plan-june-2019.pdf (2019).

28. Fernandez Turienzo, C. *et al.* Midwifery continuity of care versus standard maternity care for women at increased risk of preterm birth: A hybrid implementation–effectiveness, randomised controlled pilot trial in the UK. *PLOS Med.* **17**, e1003350 (2020).

29. Kildea, S. *et al.* Reducing preterm birth amongst Aboriginal and Torres Strait Islander babies: A prospective cohort study, Brisbane, Australia. *EClinicalMedicine* **12**, 43–51 (2019).

30. Rayment-Jones, H., Murrells, T. & Sandall, J. An investigation of the relationship between the caseload model of midwifery for socially disadvantaged women and

childbirth outcomes using routine data – A retrospective, observational study. *Midwifery* **31**, 409–417 (2015).

31. Homer, C. S., Leap, N., Edwards, N. & Sandall, J. Midwifery continuity of carer in an area of high socio-economic disadvantage in London: A retrospective analysis of Albany Midwifery Practice outcomes using routine data (1997–2009). *Midwifery* **48**, 1–10 (2017).

32. Kennedy, H. P. A Model Of Exemplary Midwifery Practice: Results Of A Delphi Study. *J. Midwifery Womens. Health* **45**, 4–19 (2000).

33. Davis, J. A. P. Midwives and Normalcy in Childbirth: A Phenomenologic Concept Development Study. *J. Midwifery Womens. Health* **55**, 206–215 (2010).

34. Phillippi, J. C. & Avery, M. D. The 2012 American College of Nurse-Midwives Core Competencies for Basic Midwifery Practice: History and Revision. *J. Midwifery Womens. Health* **59**, 82–90 (2014).

35. Rayment-Jones, H., Silverio, S. A., Harris, J., Harden, A. & Sandall, J. Project 20: Midwives' insight into continuity of care models for women with social risk factors: what works, for whom, in what circumstances, and how. *Midwifery* **84**, 102654 (2020).

36. ten Hoope-Bender, P. *et al.* Improvement of maternal and newborn health through midwifery. *Lancet* **384**, 1226–1235 (2014).

37. McRae, D. N. *et al.* Is model of care associated with infant birth outcomes among vulnerable women? A scoping review of midwifery-led versus physician-led care. *SSM - Popul. Heal.* **2**, 182–193 (2016).

38. Robinson, J. N., Regan, J. A. & Norwitz, E. R. The epidemiology of preterm labor. *Semin. Perinatol.* **25**, 204–214 (2001).

39. Georgiou, H. M., Di Quinzio, M. K. W., Permezel, M. & Brennecke, S. P. Predicting Preterm Labour: Current Status and Future Prospects. *Dis. Markers* **2015**, 1–9 (2015).

40. Coussons-Read, M. E. Effects of prenatal stress on pregnancy and human development: mechanisms and pathways. *Obstet. Med.* **6**, 52–57 (2013).

41. Shapiro, G. D., Fraser, W. D., Frasch, M. G. & Séguin, J. R. Psychosocial stress in pregnancy and preterm birth: associations and mechanisms. *J. Perinat. Med.* **41**, (2013).

42. KINSELLA, M. T. & MONK, C. Impact of Maternal Stress, Depression and Anxiety on Fetal Neurobehavioral Development. *Clin. Obstet. Gynecol.* **52**, 425–440 (2009).

43. Trumello, C. *et al.* Mothers' Depression, Anxiety, and Mental Representations After Preterm Birth: A Study During the Infant's Hospitalization in a Neonatal Intensive Care Unit. *Front. Public Heal.* **6**, (2018).

44. Ionio, C. *et al.* Mothers and fathers in NICU: The impact of preterm birth on parental distress. *Eur. J. Psychol.* **12**, 604–621 (2016).

45. Pace, C. C. *et al.* Evolution of Depression and Anxiety Symptoms in Parents of Very

Preterm Infants During the Newborn Period. *JAMA Pediatr.* **170**, 863 (2016).

46. Jacob, J. *et al.* Cost effects of preterm birth: a comparison of health care costs associated with early preterm, late preterm, and full-term birth in the first 3 years after birth. *Eur. J. Heal. Econ.* **18**, 1041–1046 (2017).

47. Lindstrom, K., Winbladh, B., Haglund, B. & Hjern, A. Preterm Infants as Young Adults: A Swedish National Cohort Study. *Pediatrics* **120**, 70–77 (2007).

48. Betran, A. P. *et al.* What is the optimal rate of caesarean section at population level? A systematic review of ecologic studies. *Reprod. Health* **12**, 57 (2015).

49. Sandall, J. *et al.* Short-term and long-term effects of caesarean section on the health of women and children. *Lancet* **392**, 1349–1357 (2018).

50. Modder, J. *et al. CEMACH: Perinatal Mortality 2007*.

51. Royal College of Obstericians and Gynaecologists. *Green Top Guideline No 45. Birth After Previous Caesarean Section*. (2015).

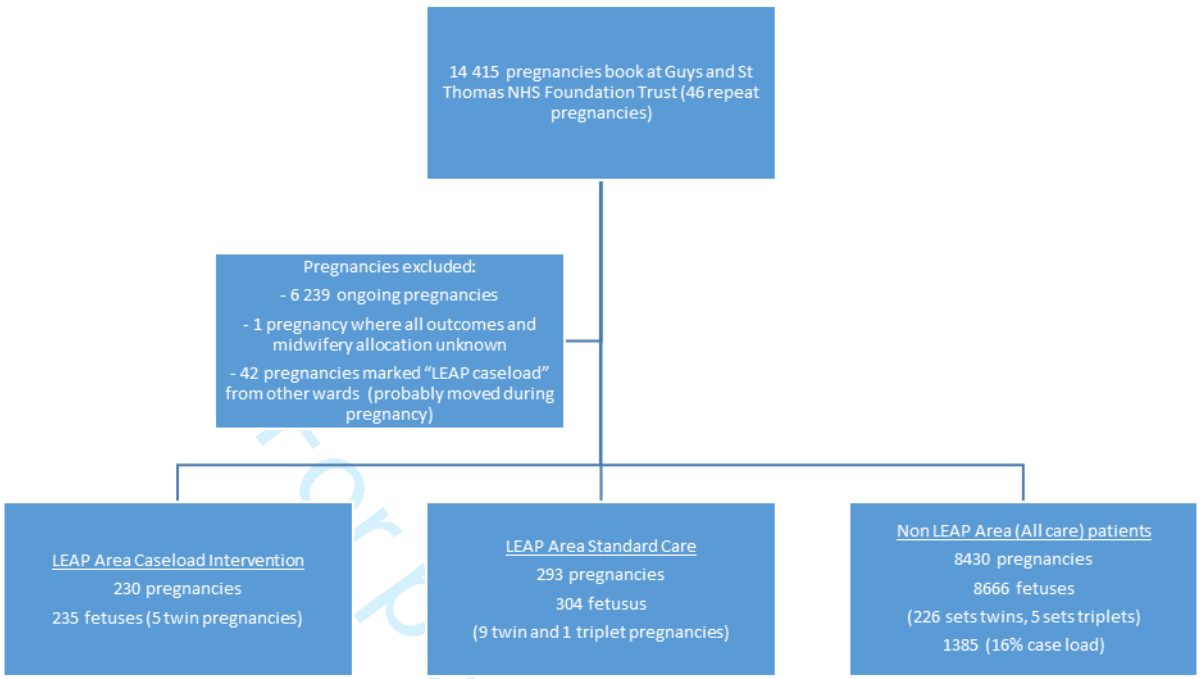


Figure 1. Allocation of women booking at Guys and St Thomas' foundation trust to antenatal care groups for purposes of data analysis.

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 (*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	1-2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up (*b*) For matched studies, give matching criteria and number of exposed and unexposed	5-6
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5-6
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	5-6
Bias	9	Describe any efforts to address potential sources of bias	6
Study size	10	Explain how the study size was arrived at	
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	5-6
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding (*b*) Describe any methods used to examine subgroups and interactions (*c*) Explain how missing data were addressed (*d*) If applicable, explain how loss to follow-up was addressed (*e*) Describe any sensitivity analyses	6
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 (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram	8
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest (c) Summarise follow-up time (eg, average and total amount)	9
Outcome data	15*	Report numbers of outcome events or summary measures over time	9-11

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	9-11
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	9-11
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
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	12-13
Generalisability	21	Discuss the generalisability (external validity) of the study results	13
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	17

*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.