BMJ Open

Opti'care protocol: a randomised control trial to evaluate the impact of a mobile antenatal care clinic in isolated rural areas on prenatal follow-up

Anne Debost-Legrand [1,2] Guillaume Legrand,[3] Julie Duclos-Médard,[2] Juliette Thomazet,[2] Marine Pranal [1] Eric Langlois,[4] Charline Mourgues,[5] Françoise Vendittelli[1,2]

For numbered affiliations see end of article.

Correspondence to
Anne Debost-Legrand;
alegrand@chu-clermontferrand.fr

ABSTRACT

Introduction Rural residence appears to be a factor of vulnerability among pregnant women with poor clinical antenatal care. Our principal objective is to assess the impact of an infrastructure for a mobile antenatal care clinic on the completion of antenatal care for women identified as geographically vulnerable in a perinatal network.

Methods and analysis Controlled cluster-randomised study in two parallel arms comparing an intervention group with an open-label control group. This study will concern the population of pregnant women who must live in one of the municipalities covered by the perinatal network and considered to be an area of geographic vulnerability. The cluster randomisation will take place according to the municipality of residence. The intervention will be the implementation of pregnancy monitoring by a mobile antenatal care clinic. The completion of antenatal care between the intervention and control groups will be a binary criterion: 1 will be attributed to each antenatal care that includes all visits and supplementary examinations. Sample size has been estimated to be 330 at least with an 80% participation rate.

The univariate analyses will compare the follow-up rates (with Fisher's exact test), and all individual characteristics collected (Fisher's exact test, Student's t-test) between the two groups. The multivariate analysis will use a mixed linear model analysis and consider the cluster effect as random; the initial model will include known confounders from the literature, confounders identified in univariate analyses, and the clinically relevant prognostic factors. All of these factors will be taken into account in the model as a fixed effect.

Ethics and dissemination The Patient Protection Committee North-West II approved this study on 4 February 2021 (IRB 2020-A02247-32). The results will be the subject of scientific communications and publications.

Trial registration number NCT04823104.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Geolocation was performed to identify the cluster unit.
⇒ A municipality was considered in a vulnerable zone if there was not at least one professional (≤1) or facility that was accessible within 30 min driving time.
⇒ As it is a new intervention, participation rate to the protocol may be less than expected.
⇒ As morbidity and mortality events are rare, there may be a lack of power to test the impact of intervention on those events.

with specialised departments located mainly in urban areas. Difficulties of access to this care have been found to be greatest for families farthest away from them, who must travel long distances and give birth far away from the family home.[1–3]

Moreover, women in rural areas appear to have characteristics different from those of women in urban areas, in particular, they consume more tobacco and alcohol and have higher parity. The number of antenatal consultations may also be lower in this population.[4] The consequences of these factors on maternal and neonatal morbidity have been measured.[4–7] Both gestational hypertension and gestational diabetes, that is, with onset during pregnancy, appeared less frequent among rural women.[5] Inversely, the risk of maternal death or severe disease was higher among them.[4] Authors have underlined that poor clinical antenatal care prevents screening and early management of the most frequent diseases and consequently worsens the mother's health status and puts her at higher risk of severe morbidity.[4 5]

The consequences of this poor management have also been measured on the newborns' health status. The children of

INTRODUCTION

Rural residence appears to be a factor of vulnerability among pregnant women. It has been demonstrated that the distribution of maternity units across France is inegalitarian,

rural inhabitants had a higher risk of preterm birth, with poorer Apgar scores and a greater risk of macrosomia.[4 5] Thus, the risk of perinatal death was greater among these children born in a hospital providing a level of care inappropriate for them.[6]

These risks were highest for those in the most rural areas.[7] Social deprivation in rural areas was also an aggravating factor, especially of neonatal consequences.[8]

Several French studies have assessed the impact of rural residence on pregnancy outcome. It has been shown that a distance of more than 30 min by car from a maternity ward is a risk factor for neonatal morbidity, in particular, in rural areas, because of the closures of small healthcare facilities.[9] The frequency of hospitalisation around the time of birth has also risen in relation to the longer travel time.[9] The risk of sudden home delivery is also strongly associated with residence in rural zones and with low socioeconomic status.[10] It has also been shown that the choice of maternity ward depends on its proximity to the woman's home, especially for women of low socioeconomic status.[11] Finally, a last study showed that the risk of neonatal morbidity increases with social deprivation, especially in rural areas, thus underlining the difficulties of access to healthcare facilities.[12]

Access to care is difficult for women in rural areas. It has been shown that early and regular antenatal care can reduce maternal morbidity (especially that linked to hypertension and gestational diabetes) but also infant morbidity, by decreasing the number of children born with low birth weight or growth restriction.[13] Interventions for women at home or by mobile healthcare teams have shown improvements in monitoring during pregnancy and delivery, along with a diminution in infant morbidity.[14–16] These supportive interventions have also reduced the prevalence of postpartum depression.[17 18]

Our principal objective is to assess the impact of an infrastructure for a mobile antenatal care clinic on the quality of antenatal care for women identified as geographically vulnerable in a perinatal network.

METHODS AND ANALYSIS
Study design
Controlled cluster-randomised study in two parallel arms comparing an intervention group with an open-label control group.

Study population
This study will concern the population of pregnant women managed by any of the perinatal professionals belonging to the Auvergne regional perinatal network at the first antenatal consultation, confirming the pregnancy.

They must live in one of the municipalities (villages and hamlets) covered by this perinatal network and considered to be an area of geographic vulnerability.

The women must be informed about the study, understand, read and speak French, and must be able to consent to participate in medical research. Women who give birth in a maternity ward outside Auvergne will be excluded, and women from another region giving birth in a maternity ward in Auvergne will not be included.

Study protocol
Recruitment
All health professionals belonging to the perinatal network will identify and recruit pregnant women residing in geographically vulnerable zones during their consultation to confirm the pregnancy from 15 June 2022 to 15 January 2024. For those living in the cluster randomised to intervention, the health professional will suggest to them that they can receive antenatal care throughout their pregnancy through a mobile care infrastructure and will give them both written and oral information about it. For those living in the cluster randomised to control, the health professional also describes the study to women and ask them they would be willing to participate. They would be receiving regular care, and could choose whoever they wanted to see, except the mobile clinic.

For the intervention group, if the woman agrees, the health professional will inform the midwife coordinator of the mobile team, who will contact the woman, include her in the study, collect her consent and give her a schedule for her antenatal care.

For the control group, if the woman agrees, the health professional will inform the midwife coordinator of the mobile team, who will contact the woman, include her in the study and collect her consent.

Intervention
The study will include two arms, that is, two groups of women: the intervention group and the control group (see figure 1); the cluster randomisation will take place according to the municipality of residence. The intervention will be the implementation of pregnancy monitoring by a mobile antenatal care clinic. The infrastructure is a vehicle equipped for obstetric consultation, including an ultrasound instrument, so that clinical obstetric and gynaecological examinations, imaging and interviews, as well as the taking of biological samples can all be performed. The vehicle will make trips weekly all year long; its trips will be optimised according to the geolocation of the women included. Communes with geographic vulnerability were grouped into zones based on how close they were, and with a maximum travel time of 1 hour within the zone. The vehicle will visit several municipalities in the intervention group during a single day of visits. There will be 5–10 consultations to be performed each week. The mean consultation time is estimated at 1 hour, in order to perform a clinical examination, take any samples, do any imaging and take the necessary notes for the file. Any supplementary appointment will also be made directly during this consultation. The mobile team will comprise:
► An ultrasonographer authorised to measure first-trimester nuchal translucency for trisomy 21 screening.
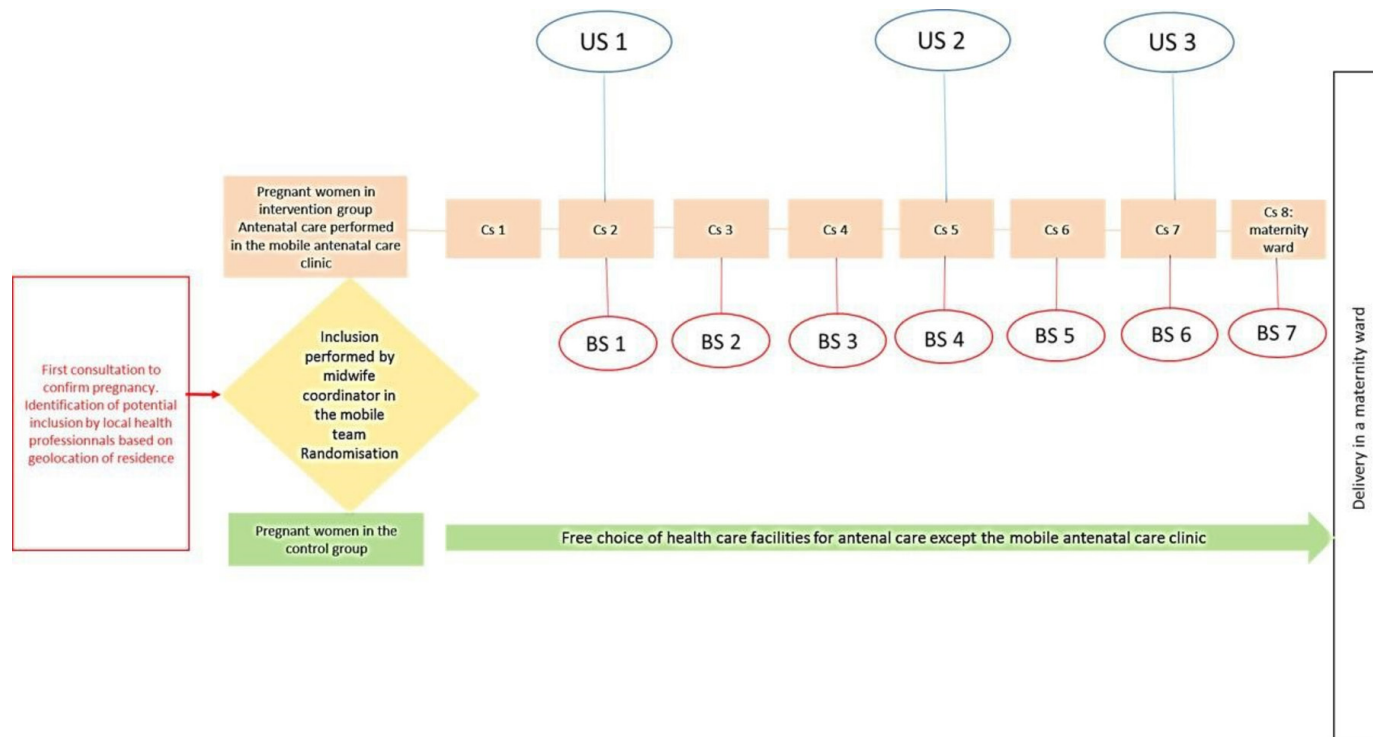
Figure 1 Study protocol, patient's course in the intervention group and in the control group. BS, blood sample; Cs, consultation; US, ultrasound examination.

This professional will also perform the standard ultrasound imaging during pregnancy.

► A midwife: midwives will conduct consultations in the vehicle, especially for physiological pregnancies and can handle/manage/teach the childbirth preparation classes as well.

► A nurse: this health professional will take the blood samples for the mobile team's consultations.

The pregnancy of the women in the intervention group will be managed according to the national guidelines for their risk levels, as close as possible to their home, by the professionals working with this mobile clinic.

Nonetheless, women in the control group will be receiving the usual care provided to women throughout France without direct benefit from using the mobile antenatal care clinic as it will not come in their municipalities. Moreover, the discussion of the study with them may also cause them to adhere more closely than they might normally.

Randomisation, patient allocation and blinding

The cluster unit is the municipality in which the woman resides. There are 220 municipalities in vulnerability zones. A driving time of no more than 30 min is the cut-off defined to qualify a professional or a healthcare facility as accessible.[9] Based on this threshold, we calculated the number of professionals and facilities accessible with a maximum 30 min driving time to each municipality in Auvergne. The professionals and facilities were geolocated according to their postal addresses, and each municipality by its geographic centre as the reference. A

municipality was considered in a vulnerable zone if there was not at least one professional (≤ 1) or facility that was accessible within 30 min driving time. All travel times were calculated by software (Geoclip). A municipality could be included in only one group, to limit the risk of interpenetration. Because the cluster unit is the municipality, the risk of interpenetration between the pregnant women is low because there is no migration flow between municipalities. In these areas, most of the people are owners of their primary home and heir of their lands. Moreover, as those areas are isolated with few job opportunities, there are no migrants. Cluster randomisation will be performed by a minimisation method to take into account both the size of the municipality, its geolocation and the number of pregnancy expected in a year.

OBJECTIVES
Primary objective
To assess the impact of a mobile antenatal care clinic on the completion of the antenatal care of women identified as geographically vulnerable.

Secondary objectives
1. To assess the impact of a mobile antenatal care clinic on the adherence to their antenatal care consultations of women identified as geographically vulnerable.
2. To assess the impact of this mobile clinic on the adherence to their mandatory or recommended antenatal ultrasound and laboratory tests of women identified as geographically vulnerable.

3. To assess the impact of a mobile antenatal care clinic on unfavourable neonatal or maternal outcomes among a geographically vulnerable population.
4. To assess the medical-economic impact of the mobile antenatal care clinic for geographically vulnerable pregnant women.
5. To assess the financial (budget impact analysis) and institutional (optimisation of links between project participants) sustainability of a mobile antenatal care clinic for geographically vulnerable pregnant women.

Study end points

Primary outcome

The completion of antenatal care is defined by: the number of consultations performed in accordance with the relevant French regulations,[19] the performance of paraclinical and ultrasound examinations as recommended by statute and the national guidelines of professional societies. The clinical monitoring of pregnancy and especially the paraclinical monitoring of a normal pregnancy in France are defined by professional associations such as the French National College of Gynaecologists and Obstetricians,[20] as well as the French national authority for health (HAS).[21] In all, eight consultations should take place in a pregnancy that goes to term.[22] The first medical examination must take place before the end of the third month of pregnancy. The other examinations must take place monthly from the first day of the fourth month through delivery. A postnatal medical examination must be conducted within 8 weeks after the woman gives birth. Three systematic or screening ultrasound examinations, one per trimester, are recommended: in the first trimester, between 11 weeks of gestation$^{+0 \text{ days}}$ and 13 weeks $^{+6 \text{ days}}$; in the second trimester, between 20 weeks$^{+0 \text{ days}}$ and 25 weeks$^{+0 \text{ days}}$; and in the third trimester, between 30 weeks$^{+0 \text{ days}}$ and 35 weeks$^{+0 \text{ days}}$. Finally, the guidelines also prescribe the standard laboratory tests and the timing of their performance.

Secondary outcomes

Adherence to antenatal care consultations of women by the mobile antenatal care clinic: adherence to antenatal care consultations will be defined by adherence to the applicable French regulations concerning the term and number of consultations that must be performed until delivery. Adherence will be complete if the first obstetric consultation took place before 15 completed weeks, and then a consultation a month until delivery. Hospitalisations will be taken into account when applicable; 1 month of hospitalisation counts as a consultation. On the other hand, an emergency consultation (not planned) will not be considered a normal antenatal consultation.

Adherence to antenatal care complementary exams of women by the mobile antenatal care clinic: women's adherence to the performance of the ultrasounds and laboratory tests through delivery will be defined as the performance of all of the recommended ultrasounds at the recommended dates and all of the mandatory or recommended laboratory tests for antenatal care.

Unfavourable maternal or neonatal outcomes: a composite endpoint will be defined by the occurrence of at least one unfavourable outcome during pregnancy or delivery:

► For the mother:
   a. Pregnancy-related hypertension (systolic blood pressure (SBP)≥140 mm Hg and/or diastolic blood pressure (DBP)≥to 90 mm Hg, occurring after 20 weeks, without associated albuminuria and that has disappeared before the end of the sixth week post-partum), and/or
   b. pre-eclampsia (SBP≥140 mm Hg and/or DBP≥90 mm Hg, after 20 weeks, with proteinuria (>0.3 g/24 hours) and, again, that has disappeared before the end of the sixth week postpartum), and/or
   c. gestational diabetes (fasting blood glucose≥0.92 g/L during the first trimester or an oral glucose tolerance test with 75 g of abnormal glucose between 24 and 28 weeks of gestation: fasting blood glucose≥0.92 g/L or 5.2 mmol/L, blood glucose at 60 min≥1.80 g/L or 10 mmol/L, blood glucose at 120 min≥1.53 g/L or 8 mmol/L), and/or
   d. severe postpartum haemorrhage (blood loss>500 mL with vascular embolisation, and/or surgery, and/or blood transfusions>2 units of packed red blood cells), and/or
   e. maternal death (during pregnancy and ≤42 days postpartum), and/or
   f. transfer to intensive care.
► For the child:
   a. Preterm birth<37 weeks), and/or
   b. in utero death (≥ 22 weeks of gestation; and/or≥500 g if term uncertain) or early neonatal death (<7 days), and/or
   c. birth weight<10th percentile or >90th percentile (according to the Audipog curves for gestational age and sex), and/or
   d. immediate or delayed transfer to intensive care or neonatology.

Medical-economic assessment of the programme: cost-effectiveness ratio of the mobile antenatal care clinic from the point of view of health insurance. The costs are available because the prices in insurance perspective are well defined according to the principle of price per activity (T2A) introduced in France in 2005. The economic analysis is carried out from the beginning of the pregnancy follow-up until the birth of the baby.

Assessment of the financial viability of the programme: analysis of budgetary impact to target the largest expenditures (investments in equipment, human resources, depreciation as well as all the charges and products inherent in the project in accordance with the norms of analytic budgetary accounting) and to optimise the management of the project after funding by the Health Ministry. Development of an economic model that can

ensure the sustainability of this mobile antenatal care clinic in integrating it into the region's local care supply policy.

Patient and public involvement

Our hypothesis is that the usual pregnancy follow-up is often delayed or inadequately adhered to in this geographically vulnerable population will be enhanced by this study.

In order to inform the women in the municipality and to facilitate the location of the mobile unit, communities of commune were involved in the information and in the management of the project. Communities of commune have published on their website the information about the project and they also distributed flyers and posters to the population.

For each community, results will be presented to elected municipal officials for their area.

Sample size calculation

According to the national perinatal survey, almost 20% of women have not had the eight antenatal consultations recommended.[23] According to the PRECare study, 50.7% of women did not receive adequate antenatal care, that is, care that corresponds to the HAS guidelines.[24] The objective of the mobile antenatal care clinic is to improve antenatal care so that it meets the national guidelines. Considering the method of randomisation chosen, two indicators must be taken into account: the inflation factor, specific to the cluster, and the level of correlation of the behaviours of subjects in the same cluster. The perinatal health network data suggest that the mean number of women a year who could be included in a cluster is 2.5. Extrapolating from the literature involving pregnant women in cluster-randomised trials, the level of correlation of behaviours ranges from 0.1 to 0.5.[25]

For an alpha risk of 5%, a power of 90% and a success rate for the primary objective of 85% for the intervention group and 70% for the control group, we calculated the number of subjects necessary by considering three correlation coefficient values: 0.1, 0.2 and 0.5. The number of subjects necessary thus ranges between 217 and 330 for an 80% participation rate. Considering previous data in the perinatal health network 300–400 pregnancies occur each year in the municipalities include in the study. Thus, the sample size can be reached considering the time of the study. As it is a new intervention, participation rate may be less than expected, however as the mobile clinic will be as close as possible to women's living place, access to healthcare will be easier for them.

Statistical analysis

Main outcome

The principal objective is to compare the quality of antenatal care between the intervention and control groups. This is a binary criterion: 1 will be attributed to each antenatal care that includes all visits and supplementary examinations (ultrasound and laboratory tests).

The univariate analyses will compare not only the follow-up rates (with Fisher's exact test), but also all individual characteristics collected (Fisher's exact test, Student's t-test with correction for inequality of variance when applicable).

The objective of the multivariate analysis is, beyond an adjusted estimate of the association between the intervention and the quality of the antenatal care, to identify potential independent factors that favour or impede this quality. The multivariate analysis will use a mixed linear model analysis and consider the cluster (municipality) effect as random; the initial model will include known confounders from the literature, confounders identified in univariate analyses (p values≤0.2) and the clinically relevant prognostic factors. All of these factors will be taken into account in the model as a fixed effect.

The first-order interactions will also be introduced initially. If any significant interaction is found between the principal criterion (the intervention) and one or more individual characteristics, a stratified analysis will be envisioned. The final model will be obtained by manual backward stepwise selection, with the principal criterion forced into the model.

Secondary outcomes

Women's adherence

The women's adherence to their antenatal care will be compared between the intervention group and the control group for two aspects: the number of consultations performed and the number of examinations performed.

This is again a binary criterion: antenatal care will be considered correct if all of the acts recommended during pregnancy are performed, at the correct time: both the number of consultations and the supplementary ultrasound and laboratory tests. The groups will be compared by univariate analyses (Fisher's exact test, Student's t-test with correction for inequality of variance when applicable). A mixed linear model analysis, considering the cluster effect (municipality) as random and the confounding factors identified in the univariate analyses (p values≤0.2) as fixed effects, will be performed. The final model will be obtained by manual backward stepwise selection.

Unfavourable pregnancy outcomes

Unfavourable pregnancy outcomes will be analysed in two separate subanalyses: one of the mother's health and the other of the child's health.

For each subanalysis, the frequency of unfavourable outcomes will be compared between the intervention and the control groups. The groups will be compared by univariate analyses (Fisher's exact test, Student's t-test with correction for inequality of variance when applicable). A mixed linear model analysis, considering the cluster effect (municipality) as random and the confounding factors identified in the univariate analyses (p values≤0.2) as fixed effects, will be performed. The

final model will be obtained by manual backward step-wise selection.

This secondary outcome implies rare events, as the sample size is based on the main outcome, analysis may not reach significant statistical power, descriptive analysis will provide prevalence so that it can be compared with literature.

Economic analysis

The cost-effectiveness ratio will be conducted differentially by using the incremental cost-effectiveness ratio (ICER). It will be calculated as follows: $ICER = (C_C - C_I)/(E_C - E_I)$,

with $_C$ represents the women in the control group, $_I$ represents the women in the intervention group, C the cost data (in €) and E the efficacy criterion is modelled on the main outcome (completion of antenatal care between the intervention and control groups).

The results will be presented in terms of cost-effectiveness.

In a second sub-analysis, the sustainability of the economic model underlying the programme will be modelled as spreadsheets with low, median and high hypotheses for the model parameters that may vary over time (demography, care supply, etc).

A two-variable sensitivity analysis will be performed by modulating the percentage of women's adherence to the programme and the percentage of maternal and neonatal complications calculated as a result of the project evaluation based on empirical observations in both groups. We will use the SD observed in the study to modulate the programme adhesion rate and the maternal and neonatal complication rate.

The costs will discount to take into account the economic principle of preference for the present.

Data monitoring safety committee

The investigator guarantees the authenticity of the data collected as part of the study and accepts the legal provisions authorising the study sponsor to set up quality control.

Quality control inspection will be performed at regular intervals by the clinical research assistant. During these inspections, the following elements will be reviewed according to the predefined monitoring plan:
1. Informed consent.
2. Compliance with the study protocol and the procedures defined there.
3. Quality of the data collected in case report forms: accuracy, missing data, consistency of data with the 'source' documents (medical files, appointment books, originals of laboratory results, etc).

Data storage and management

All of the consultations, any possible hospitalisations, examinations and their results will be reported in the shared computerised regional antenatal care files (ICOS is the web shared obstetrical file used) according to the specifications of Audipog, a non-profit organisation under the French law of 1901; Audipog D31 file, with structured data. Similarly, all of the data concerning the delivery and the health status of the newborn will be reported in the file in a structured manner. The computerised data files are recorded in a regional database, which is stored in a data server authorised to store medical data. The extraction of relevant data will be performed according to the patient's network file number.

ETHICS AND DISSEMINATION

The patients who wish to participate in the study will sign an informed consent document. A consent will also be signed to authorise the registration of their computerised record, and a file number will be attributed. The Patient Protection Committee North-West II approved this study on 4 February 2021 (IRB 2020-A02247-32). The protocol was registered as Clinical Trial NCT04823104.

The data will be divulged only after the joint accord of the principal investigator and the sponsor. The results will be the subject of scientific communications and publications. The authorship eligibility will follow the Recommendations for the Conduct, Reporting, Editing and Publications of Scholarly Work in Medical Journals, 2015.

Author affiliations
[1]CHU Clermont-Ferrand, CNRS, Clermont Auvergne INP, Institut Pascal, Université Clermont Auvergne, Clermont-Ferrand, France
[2]Réseau de Santé en Périnatalité d'Auvergne, CHU Clermont-Ferrand, Clermont-Ferrand, France
[3]Centre Hospitalier Sainte Marie de Clermont-Ferrand, Association Hospitalière Sainte-Marie, Chamalieres, France
[4]UMR Territoires, AgroparisTech, INRA, Irstea, VetAgro Sup, Universite Clermont Auvergne, Clermont-Ferrand, France
[5]Direction de la Recherche Clinique et de l'Innovation, CHU Clermont-Ferrand, Clermont-Ferrand, France

ORCID iDs
Anne Debost-Legrand http://orcid.org/0000-0002-1706-599X
Marine Pranal http://orcid.org/0000-0002-7698-3715

REFERENCES

1 Rolfe MI, Donoghue DA, Longman JM, *et al*. The distribution of maternity services across rural and remote australia: does it reflect population need? *BMC Health Serv Res* 2017;17:163.
2 Kozhimannil KB, Casey MM, Hung P, *et al*. Location of childbirth for rural women: implications for maternal levels of care. *Am J Obstet Gynecol* 2016;214:661.
3 Malouf RS, Tomlinson C, Henderson J, *et al*. Impact of obstetric unit closures, travel time and distance to obstetric services on maternal and neonatal outcomes in high-income countries: a systematic review. *BMJ Open* 2020;10:e036852.
4 Lisonkova S, Haslam MD, Dahlgren L, *et al*. Maternal morbidity and perinatal outcomes among women in rural versus urban areas. *CMAJ* 2016;188:E456–65.
5 Luo Z-C, Wilkins R. Degree of rural isolation and birth outcomes. *Paediatr Perinat Epidemiol* 2008;22:341–9.
6 Haraldsdottir S, Gudmundsson S, Bjarnadottir RI, *et al*. Maternal geographic residence, local health service supply and birth outcomes. *Acta Obstet Gynecol Scand* 2015;94:156–64.
7 Hillemeier MM, Weisman CS, Chase GA, *et al*. Individual and community predictors of preterm birth and low birthweight along the rural-urban continuum in central Pennsylvania. *J Rural Health* 2007;23:42–8.
8 Auger N, Authier M-A, Martinez J, *et al*. The association between rural-urban continuum, maternal education and adverse birth outcomes in Québec, Canada. *J Rural Health* 2009;25:342–51.
9 Combier E, Charreire H, Le Vaillant M, *et al*. Perinatal health inequalities and accessibility of maternity services in a rural french region: closing maternity units in burgundy. *Health Place* 2013;24:225–33.
10 Blondel B, Drewniak N, Pilkington H, *et al*. Out-Of-Hospital births and the supply of maternity units in France. *Health Place* 2011;17:1170–3.
11 Pilkington H, Blondel B, Drewniak N, *et al*. Choice in maternity care: associations with unit supply, geographic accessibility and user characteristics. *Int J Health Geogr* 2012;11:35.
12 Bertin M, Viel J-F, Monfort C, *et al*. Socioeconomic disparities in adverse birth outcomes in urban and rural contexts: a French mother-child cohort. *Paediatr Perinat Epidemiol* 2015;29:426–35.
13 Villar J, Bergsjø P. Scientific basis for the content of routine antenatal care. I. philosophy, recent studies, and power to eliminate or alleviate adverse maternal outcomes. *Acta Obstet Gynecol Scand* 1997;76:1–14.
14 Doyle O, McGlanaghy E, Palamaro-Munsell E, *et al*. Home based educational intervention to improve perinatal outcomes for a disadvantaged community: a randomised control trial. *Eur J Obstet Gynecol Reprod Biol* 2014;180:162–7.
15 Issel LM, Forrestal SG, Slaughter J, *et al*. A review of prenatal home-visiting effectiveness for improving birth outcomes. *J Obstet Gynecol Neonatal Nurs* 2011;40:157–65.
16 Hollowell J, Oakley L, Kurinczuk JJ, *et al*. The effectiveness of antenatal care programmes to reduce infant mortality and preterm birth in socially disadvantaged and vulnerable women in high-income countries: a systematic review. *BMC Pregnancy Childbirth* 2011;11:13.
17 Kenyon S, Jolly K, Hemming K, *et al*. Lay support for pregnant women with social risk: a randomised controlled trial. *BMJ Open* 2016;6:e009203.
18 Dennis C-L, Dowswell T. Psychosocial and psychological interventions for preventing postpartum depression. *Cochrane Database Syst Rev* 2013:CD001134.
19 Legifrance. Code de la santé publique. Available: https://www.legifrance.gouv.fr/loda/id/JORFTEXT000000540419/ [Accessed 24 Jan 2017].
20 Recommendations for clinical practice
. Available: http://www.cngof.fr/pratiques-cliniques/recommandations-pour-la-pratique-clinique [Accessed 29 Aug 2017].
21 Haute Autorité de Santé. Évaluation & Recommandation. n.d. Available: https://www.has-sante.fr/portail/jcms/fc_1249601/fr/evaluation-recommandation
22 Vendittelli F, Janky E. Clinical and paraclinical monitoring of a normal pregnancy. *J Gynecol Obstet Biol Reprod (Paris)* 2001;30:51–8.
23 ENP2016_rapport_complet. Available: http://www.xn--epop-inserm-ebb.fr/wp-content/uploads/2017/11/ENP2016_rapport_complet.pdf [Accessed 8 Feb 2018].
24 Linard M, Blondel B, Estellat C, *et al*. Association between inadequate antenatal care utilisation and severe perinatal and maternal morbidity: an analysis in the precare cohort. *BJOG* 2018;125:587–95.
25 Pagel C, Prost A, Lewycka S, *et al*. Intracluster correlation coefficients and coefficients of variation for perinatal outcomes from five cluster-randomised controlled trials in low and middle-income countries: results and methodological implications. *Trials* 2011;12:151.