

Variations in the organisation of and outcomes from Early Pregnancy Assessment Units: the VESPA mixed-methods study

Maria Memtsa,¹ Venetia Goodhart,¹ Gareth Ambler,² Peter Brocklehurst,³ Edna Keeney,⁴ Sergio Silverio,^{1,5} Zacharias Anastasiou,² Jeff Round,⁶ Nazim Khan,⁷ Jennifer Hall,¹ Geraldine Barrett,¹ Ruth Bender-Atik,⁸ Judith Stephenson¹ and Davor Jurkovic^{1*}

¹Elizabeth Garrett Anderson Institute for Women's Health, University College London, London, UK

²Department of Statistical Science, University College London, London, UK

³Birmingham Clinical Trials Unit, Institute of Applied Health Research, University of Birmingham, Birmingham, UK

⁴Population Health Sciences, Bristol Medical School, University of Bristol, Bristol, UK

⁵Department of Women and Children's Health, King's College London, St Thomas' Hospital, London, UK

⁶Institute of Health Economics, School of Social and Community Medicine, University of Bristol, Bristol, UK

⁷Modelling and Analytical Systems Solutions Ltd, Edinburgh, UK

⁸The Miscarriage Association, Wakefield, UK

*Corresponding author davor.jurkovic@nhs.net

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Scientific summary

The VESPA mixed-methods study

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Scientific summary

Background

Early pregnancy complications are common and account for the largest proportion of emergency work performed in gynaecology departments across the UK. The early pregnancy assessment unit is a specialised clinical service for women with suspected complications during the first trimester of pregnancy. Although early pregnancy assessment units operate in the majority of acute hospitals in the UK, it is unknown what the best configuration would be to deliver the optimal balance between cost-effectiveness, clinical effectiveness and service- and patient-centred outcomes.

Objectives

The primary aim of our study was to test the hypothesis that the rate of hospital admissions for early pregnancy complications is lower in early pregnancy assessment units with high consultant presence than in units with low consultant presence.

The secondary objectives were to:

- test the hypothesis that increased consultant presence in early pregnancy assessment units improves other clinical outcomes, including the proportion of follow-up visits, non-diagnostic ultrasound scans, negative laparoscopies for suspected ectopic pregnancies and ruptured ectopic pregnancies requiring blood transfusion
- assess the effect of variations in opening hours and service accessibility on the overall admission rates and other clinical outcomes
- determine the optimal skill mix to run an effective and efficient early pregnancy assessment unit service
- examine the cost-effectiveness of different skill mix models in early pregnancy assessment units
- explore patient satisfaction with the quality of care received in different early pregnancy assessment units
- make evidence-based recommendations about the future configuration of early pregnancy assessment units in the UK.

Design

The Variations in the organisations of Early Pregnancy Assessment Units in the UK and their effects on clinical, Service and PATient-centred outcomes (VESPA) study employed a multimethods approach and included:

- a prospective cohort study of women attending early pregnancy assessment units (to measure clinical outcomes)
- a health economic evaluation (including skill mix and cost-utility model development)
- a patient satisfaction survey
- qualitative interviews with service users
- an early pregnancy assessment unit staff survey
- a hospital emergency care audit for women presenting with early pregnancy complications.

Setting

The study was conducted in 44 early pregnancy assessment units across the UK.

Participants

Clinical outcomes in early pregnancy assessment units and workforce modelling

All women (aged ≥ 16 years) who attended the participating early pregnancy assessment units because of suspected early pregnancy.

Emergency hospital care audit

Routine data for all women who attended hospital emergency services because of early pregnancy complications over a period of 3 months, following completion of clinical data collection from the early pregnancy assessment unit.

Patient satisfaction and health economic evaluation

All pregnant women (aged ≥ 16 years) attending early pregnancy assessment units because of suspected early pregnancy complications who agreed to sign a written consent form to participate in the questionnaire arm of the VESPA study.

Staff satisfaction

All members of staff directly involved in providing early pregnancy care were eligible to consent to this data strand.

Qualitative interviews

Women who had taken part in the patient satisfaction survey and who had provided consent to being approached later to participate in a telephone interview formed the sampling frame for the qualitative interviews.

Outcome measures

Main outcome measure

- The proportion of emergency hospital admissions for further investigations and treatment, as a proportion of women attending the participating early pregnancy assessment units.

Secondary outcome measures

- Total number of emergency admissions of women presenting with early pregnancy complications.
- Ratio of new to follow-up visits.
- Rate of non-diagnostic ultrasound scans (pregnancy of unknown location).
- Proportion of laparoscopies performed for a suspected ectopic pregnancy with a negative finding.
- Patient satisfaction with the quality of care received.
- Staff experience of providing care in early pregnancy assessment units.
- Quality-of-life measures, and anxiety levels of women before and after assessment at the early pregnancy assessment unit.
- Cost-effectiveness of different staffing models.

Methods

Data collection

Demographic and routine clinical data were collected from all women attending the early pregnancy assessment units. For women who provided consent to complete the questionnaires, clinical data and questionnaires were linked using the women's study number. The clinical data from women who did not consent were anonymised, and the data collection forms containing any identifiable data remained on the individual hospital premises and were archived locally following the end of the study.

Data analysis and reporting of results

Clinical outcomes in early pregnancy assessment units

We investigated the relationship between outcomes and consultant presence, unit volume and weekend opening hours using regression models (i.e. linear models for continuous outcomes, logistic models for binary outcomes and Poisson models for count outcomes). Hierarchical models were used when analysing patient-level data. Unit-level data were analysed using standard regression models. Most of the statistical models were adjusted for final diagnosis, maternal age at initial visit, deprivation score (10 decile groups) and unit policy regarding gestational age. We performed sensitivity analyses by replacing the continuous variables with the corresponding binary or categorical variables.

Emergency hospital care audit

The relationship between emergency admissions from accident and emergency departments and consultant presence, unit volume and weekend opening hours was investigated by fitting multivariable logistic models. Emergency admissions from accident and emergency departments was defined as a binary outcome to indicate whether or not a patient had an emergency admission from the accident and emergency department.

Patient satisfaction

We investigated patient satisfaction by exploring the relationship between the Short Assessment of Patient Satisfaction or the modified Newcastle-Farnworth score and consultant presence, unit volume and weekend opening hours.

Staff satisfaction

The association between staff experience of providing early pregnancy care and consultant presence, unit volume and weekend opening hours was explored.

Qualitative interviews

Thirty-nine interviews were conducted and transcribed verbatim. The data were analysed using a thematic framework analysis, focusing on women's clinical and emotional pathways through their care experience at the early pregnancy assessment unit and how these were influenced by the configuration and practices of the service they used.

The interview transcripts were read in their entirety, to achieve familiarisation with the interviews, and then uploaded to NVivo software (QSR International, Warrington, UK) for management and analytical work up.

All transcripts were coded by two members of the qualitative research team independently. Any discrepancies between researchers were resolved through explanations, debate and revisiting the data, to ensure that they had been completely coded and that the analysis satisfied a psychological, clinical and public health perspective for a dynamic health-care system.

Health economic evaluation

Costs and outcomes were analysed at baseline and at each follow-up time point. Costs were analysed after adjusting for the site-level stratification variables, as were age and final diagnosis. A multilevel model was used to estimate adjusted costs.

The mean total costs and mean quality-adjusted life-years for each configuration type were examined, as was the mean change in anxiety pre and post consultation. A probabilistic sensitivity analysis was also implemented, reflecting uncertainty around the estimates of costs and quality-adjusted life-years. As the probabilistic analysis requires simulated samples from the mean cost and utility estimates, Monte Carlo simulation was performed to obtain 10,000 simulated samples.

For each configuration type, we analysed the expected total utility and expected total cost, averaged over the simulation sample, together with 95% confidence intervals. The net benefit for a given willingness to pay per additional unit of utility, λ (ceiling ratio) was also computed, where net benefit is defined as:

$$\text{net benefit} = \text{utility} \times \lambda - \text{cost.} \quad (\text{a})$$

We allowed for the uncertainty in the optimal unit configuration by plotting the probability that each configuration is the most cost-effective (has highest net benefit) against willingness to pay per quality-adjusted life-year using cost-effectiveness acceptability curves.

The mean total costs, utility and anxiety change were also analysed at the unit level.

Workforce analysis

The workforce analysis calculated the time spent with each type of staff for each visit and interaction, and used this time to calculate the salary cost for each type of staff. The total cost for each type of staff for each unit was amalgamated into configurations. In this way, the staff cost profiles (showing each unit's staff make-up) could be presented by individual unit and configuration per 1000 patients. This also allowed comparisons between salary cost of each type of staff across units and type of configuration.

Results

Clinical outcomes in early pregnancy assessment units

Clinical data were collected from 6606 women who attended the 44 participating early pregnancy assessment units. A total of 2422 (36.7%) women attended units for follow-up visits. Of those who had a follow-up visit, the median number of follow-up visits was 1 (range 1–14). The overall ratio of new visits to all follow-up visits was 6606 to 3512 (1.88). At the initial visit the majority of women (68.9%) were diagnosed with normal or early intrauterine pregnancies. However, the proportion of abnormal pregnancies increased with the number of follow-up visits. The overall proportion of pregnancies of unknown location was 11.3% at the initial visit.

Primary outcome

A total of 205 (3.1%) women were admitted following their early pregnancy assessment unit attendance. The admission rate among units varied between 0.7% and 13.7%. The highest admission rate (64%) was recorded in women diagnosed with ectopic pregnancies. Nearly 10% of women with the final diagnosis of pregnancy of unknown location were also admitted as an emergency. There was no evidence of an association between the admission rate and consultant presence ($p = 0.497$). This relationship was consistent across adjustment models and different definitions of consultant presence.

Secondary outcomes

There was no evidence of an association between the proportion of women attending for multiple follow-up visits with planned consultant time ($p = 0.281$) or weekend opening ($p = 0.443$); however, there was evidence of an association with unit volume ($p = 0.025$). There was no association between pregnancy of unknown location rate and consultant presence ($p = 0.955$); however, there was some evidence of a positive association with unit volume ($p = 0.075$). There was no association between consultant presence and the rate of negative laparoscopies ($p = 0.51$).

Emergency hospital care audit

This analysis is based on 29 units (5464 patients). In total, 1445 (26.4%) patients had an emergency admission from an accident and emergency department. The percentage of emergency admissions from an accident and emergency department ranged from 7% to 58%, with the majority of the units having an emergency admission rate of between 10% and 30%. There was some evidence of an association between the emergency admissions from an accident and emergency department and weekend

opening ($p = 0.037$). A 1-hour increase in the weekend opening hours was associated with 2.4% (95% confidence interval 0.1% to 4.7%) lower odds of an emergency admission from an accident and emergency department. However, there was no evidence of an association with unit volume ($p = 0.647$) or planned consultant time ($p = 0.280$).

Patient satisfaction

There were variations in patient satisfaction between units. Satisfaction rates in some units are in excess of 95%, whereas in other units the rates could be as low as 66%. There was no evidence of a significant association with consultant presence ($p = 0.075$).

Staff satisfaction

There was a large observed difference, of 17%, in the percentage of staff who 'witnessed potentially harmful errors, near-misses or incidents in the last month' between the units with and without consultant presence. The proportion of staff reporting excessive pressure at work was 17% higher in units that are closed at weekends than in units providing weekend services.

Qualitative interviews

Our thematic framework had four main areas: (1) early pregnancy assessment unit and current pregnancy, (2) emotional responses to experiences, (3) experiences of early pregnancy assessment unit services and (4) recommendations for early pregnancy assessment unit services. We found that women who attended low-volume early pregnancy assessment units were more likely to have a poor or mixed experience of 'sensitive patient management'. Women were particularly concerned when the early pregnancy assessment unit waiting area was shared with women at more advanced stages of pregnancy. They were also worried about privacy issues when personal information was discussed in a confined space in which the early pregnancy assessment unit was run. Desire for a separate early pregnancy assessment unit waiting area or building to maintain privacy was one of the dominant findings. Women also stressed the need for better access to the early pregnancy assessment units, including the provision of out-of-hours, weekend and bank holiday services.

Health economic evaluation

The analysis included costs associated with ultrasounds, blood tests, admissions and staff time, for which data were available for 6531 patients. Total costs take into account repeated tests and admissions, as well as staff salary costs. The mean total cost per patient was £225 (standard deviation £537). The main contributor to total costs was surgical admissions, followed by ultrasounds. Lower-volume units and no consultant presence were associated with lower costs than their alternatives. Lack of weekend opening was also associated with lower mean total cost.

We observed very small differences in expected quality-adjusted life-years at 4 and 18 weeks post early pregnancy assessment unit visits, which indicated that different organisational set-ups could be clinically equivalent. In view of this, a decision regarding optimal configuration should be based on minimising total costs.

Workforce analysis

The salary costs for each unit were expressed per 1000 patients. The average cost across all units was £13,500. The lowest salary cost was £7530 and the highest salary cost £23,310, but the overall variation was not statistically significant. There was a significant difference between the strata when grouped as consultant present compared with consultant not present ($p = 0.037$).

Conclusions

Implications for health care

Our study has shown that consultant presence in early pregnancy assessment units has limited impact on the clinical outcomes measured (i.e. the proportion of women who are admitted as emergencies,

pregnancy of unknown location rates, ratio of new to follow-up visits, negative laparoscopy rate and patient satisfaction). In two-thirds of the units the actual recorded consultant presence was < 5%. This relatively low level of consultant involvement in direct clinical care could possibly explain their lack of significant impact on the quality of care.

We found that low-volume units with < 2500 visits per year tend to perform better than high-volume units in terms of the quality of the ultrasound diagnostic service and patient satisfaction. Low-volume units were also associated with lower costs, particularly when run without direct consultant presence. Workforce analysis indicated that consultant-delivered care would probably be more cost-effective in high-volume units, as the consultants' time may not be well utilised in low-volume units.

All data strands indicate that low-volume units run by senior or specialist nurses and supported by sonographers and consultants may represent the optimal early pregnancy assessment unit configuration in terms of quality of care, cost-effectiveness and patient satisfaction.

There are several limitations of our study that need be acknowledged. The overall proportion of time that consultants spent in the units was low and we were unable to determine the amount of time that consultants should spend in the units to deliver optimal patient care. Other limiting factors were the inconsistent use of clinical care pathway protocols, a lack of information regarding the competencies of ultrasound operators, variations in case-mix complexity, and the relatively low response rates to the health economics and patient satisfaction questionnaires.

Recommendations for research

- An assessment of the potential impact of enhanced clinical and ultrasound training on the performance of consultants working in early pregnancy units.
- A national study looking at the factors contributing to the high rates of negative laparoscopies for suspected ectopic pregnancies and the strategies to reduce them.
- An investigation of the impact of the organisation and staffing configurations of early pregnancy assessment units on the use of different management strategies to treat miscarriage and ectopic pregnancy.

Trial registration

This trial is registered as ISRCTN10728897.

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