

**TITLE PAGE****ANXIETY ASSOCIATED WITH DIAGNOSTIC UNCERTAINTIES IN EARLY PREGNANCY**

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## ABSTRACT

**Objectives:** To determine anxiety levels of women presenting to Early Pregnancy Assessment Units (EPAU) with abdominal pain and/or vaginal bleeding and assess how these change over time and according to ultrasonographic diagnosis.

**Methods:** We undertook a prospective cohort study in a EPAU in a large UK teaching hospital. Women with abdominal pain and/or vaginal bleeding in early pregnancy (less than 12 weeks gestation) presenting for the first time were eligible for inclusion in the study. State anxiety levels were assessed using the standardised short form of Spielberger's state-trait anxiety inventory on three occasions (before, immediately after and 48-72 hours after an ultrasound scan). Scores were correlated with ultrasonographic diagnosis. The diagnosis was either certain or uncertain. Certain diagnoses were either positive i.e. a viable intrauterine pregnancy (IUP), or negative i.e. a non-viable IUP or ectopic pregnancy (EP). Uncertain diagnoses included pregnancies of unknown location (PUL) and uncertain viability (PUV). Statistical analysis involved mixed ANOVAs and the post-hoc Tukey-Kramer test.

**Results:** 160 women were included in the study. Anxiety levels decreased over time for women with certain diagnoses (n=128), even when negative (n=64), and increased over time for women with uncertain diagnoses (n=32). Before the ultrasound, anxiety levels were high ( $21.96 \pm 1.11$ ) and there was no significant difference between the five groups. Immediately after the ultrasound, anxiety levels were lower in the viable IUP group (n=64;  $7.75 \pm 1.13$ ) than any other group. The difference between the five groups was significant ( $p < 0.005$ ). 48-72 hours later, women with certain diagnoses had significantly lower anxiety levels than those with uncertain diagnoses ( $10.77 \pm 4.30$  vs  $22.94 \pm 1.65$ ;  $p < 0.005$ ).

**Conclusions:** The experience of abdominal pain and/or vaginal bleeding in early pregnancy is highly anxiogenic. Following an ultrasound, the certainty of the diagnosis affects anxiety levels more than the positive or negative connotations associated with the diagnosis *per se*. All healthcare providers should be aware of this when communicating uncertain diagnoses.

**Keywords:** pregnancy, anxiety, diagnostic uncertainty, Spielberger

## INTRODUCTION

Approximately one in five women experience abdominal pain and/or vaginal bleeding in early pregnancy. This usually prompts referral to an Early Pregnancy Assessment Unit (EPAU). Following a pelvic ultrasound, women may be given a certain or uncertain diagnosis. Certain diagnoses may be positive i.e. a viable intrauterine pregnancy (IUP) or negative i.e. a non-viable IUP or an ectopic pregnancy (EP). Uncertain diagnoses include pregnancies of unknown location (PUL) or uncertain viability (PUV). PUVs are diagnosed in approximately 10% of women attending an EPAU and a further 8-31% of women are diagnosed with a PUL (1). All women with uncertain diagnoses need to be followed up until a definitive diagnosis is made. Follow-up of these uncertainties utilizes limited resources and is often haphazard and protracted and women may deteriorate clinically during the process.

Diagnostic tests, such as ultrasound, inherently harbor uncertainty. Uncertainty, defined as a cognitive state created when an event cannot be adequately structured or categorized because sufficient cues are lacking (2), occurs when the decision-maker is unable to assign definite values to objects and events and/or is unable to accurately predict outcomes (3). It is generated by events characterized as vague, ambiguous, unpredictable, unfamiliar, inconsistent, or lacking information (4). Uncertainty in medicine can be a potent stressor (5) and has been linked to poor coping with health-related issues, as well as poor adaptation and recovery (4).

The Transactional Model of Stress suggests that stress is the result of an interaction between a person and their environment. When an individual finds the environmental demands taxing and/or threatening, and simultaneously feels insufficiently equipped to cope with them due to a lack (actual or perceived) of personal or environmental resources, stress is experienced.

Whilst there is an abundance of evidence in the literature regarding the psychological sequelae following miscarriage (6-11) and, to a lesser extent, EP (12), very little is known about how uncertain diagnoses in early pregnancy affect women.

The aim of this study was to: determine anxiety levels of women presenting to EPAU with abdominal pain and/or vaginal bleeding and assess how these change over time and according to diagnosis.

## **HYPOTHESES**

We hypothesized that the five groups (viable IUP, non-viable IUP, EP, PUL and PUV) would not differ significantly on trait anxiety and that levels of state anxiety would not differ significantly between the groups before the ultrasound procedure. Additionally we speculated that immediately after the ultrasound, women with a certain positive diagnosis/viable IUP would have the lowest levels of state anxiety compared to any other group and that 48-72 hours after the ultrasound, women with any certain diagnosis would have lower levels of state anxiety than women with any uncertain diagnosis. Finally, we hypothesized that state anxiety levels would decrease over time for women with certain diagnoses, (especially if they were also positive), and increase over time for women with uncertain diagnoses.

## **METHODS**

### ***Study Design***

All women presenting to the EPAU at the Queen's Medical Centre, Nottingham with abdominal pain and/or vaginal bleeding between 1<sup>st</sup> February 2015 and 30<sup>th</sup> April

2015 were eligible to take part in the study. Upon arrival to the Unit, a brief history was taken using a standardized clerking proforma by a nurse specialist. A pelvic ultrasound scan, performed either transabdominally or transvaginally depending on the estimated gestational age, was then conducted by a trained ultrasonographer. Following the ultrasound, a diagnosis of a viable IUP, non-viable IUP, EP, PUL or PUV was made. A viable IUP was confirmed by the presence of an intrauterine gestation sac with a fetal pole of any length with demonstrable fetal heart pulsations. A non-viable IUP was diagnosed when either there was an empty intrauterine gestation sac with mean sac diameter greater than 25mm or an intrauterine gestation sac containing a fetal pole with crown rump length greater than 7mm with no demonstrable fetal heart pulsations or, in the absence of a viable embryo, there was no significant growth of the gestation sac or fetal pole on two ultrasound scans performed more than 7 days apart. Ultrasonographic appearances strongly suggestive of an EP included an empty endometrial cavity with either an inhomogenous adnexal mass or an empty extra-uterine sac or a yolk sac or fetal pole with or without cardiac activity in an extra-uterine sac. A PUL was reported when, in the presence of a positive urinary pregnancy test, there was no ultrasonographic evidence of an intra- or extra-uterine pregnancy or retained products of conception. A PUV was defined as the presence of an intrauterine gestation sac of less than 25mm mean diameter with no obvious yolk sac or fetal pole or an intrauterine gestation sac containing a fetal pole of less than 7mm with no obvious fetal heart pulsations. Following the ultrasound, women were reviewed by a nurse specialist or a gynaecology doctor, and, if necessary, a plan for further management made according to departmental protocols.

Women were excluded from the study if they had attended the unit previously in the same pregnancy; if they were unable to comprehend the questions asked of them; if

they failed to answer all of the questions on all of the questionnaires: or if they were unable or unwilling to give written consent.

### **Assessment of Anxiety**

Anxiety can be regarded either as a transitory emotional state or a relatively stable personality disposition or trait. Spielberger's State-Trait Anxiety Inventory (STAI) provides operational measures of both state and trait anxiety. It consists of two self-report questionnaires, one for assessing state anxiety and the other for determining trait anxiety. The trait anxiety scale evaluates relatively stable aspects of 'anxiety proneness' including general states of calmness, confidence and security. The questionnaire consists of 20 questions, including anxiety-present and anxiety-absent questions and are rated using a 4-point Likert scale. Responses assess the frequency of feelings 'in general' and include: (1) almost never (2) sometimes (3) often and (4) almost always. Item scores are added. Scoring is reversed for anxiety absent items. Scores range from 20 to 80 and higher scores represent greater levels of anxiety.

The state-anxiety scale evaluates the current state of anxiety, asking how a respondent feels 'right now' using items that measure subjective feelings of apprehension, tension, nervousness, worry and activation/arousal of the autonomic nervous system. Responses for the state anxiety scale assess the intensity of feelings 'at this moment' and include: (1) not at all (2) somewhat (3) moderately so and (4) very much so. Whilst there is a similar 20-question questionnaire to assess state anxiety, one of the benefits of the state anxiety scale over the trait anxiety scale is that it can be used to detect longitudinal change over a relatively short period of time. Completing a 20-question questionnaire several times during a brief clinical encounter would be laborious. Hence there also exists a standardized short-form of

the inventory (STAI-SSF) (13) which consists of only six questions and produces scores ranging from 6 to 24.

### ***Timing of Assessments***

Women were asked to complete the trait anxiety questionnaire and the first of three STAI-SSF questionnaires (State 1) upon arrival to the EPAU. The second STAI-SSF questionnaire (State 2) was completed immediately after the ultrasound scan or as soon after as was considered practical (but always prior to leaving the unit). At this point the questionnaires were returned to a member of the EPAU staff and the ultrasonographic diagnosis recorded. Women were contacted by one of the investigators 48-72 hours (AR) later via telephone or e-mail using contact information provided exclusively for the purpose by the woman to complete the third and final STAI-SSF questionnaire (State 3).

Questionnaires were confidential but not completely anonymous although identifying information was kept to an absolute minimum (appointment date and time) and only used for the purpose of relating the correct ultrasonographic diagnosis to each woman.

### ***Statistical Analysis***

The reliability of the questionnaires was assessed using Cronbach's  $\alpha$ . This is a measure of the internal consistency used to determine how much the items on a scale are measuring the same construct (14). It is commonly used when you have multiple Likert questions in a survey/questionnaire that form a scale or subscale, and you wish to determine if the scale is reliable. It is expressed as a number between 0



and 1. There are different reports about the acceptable values of  $\alpha$ , ranging from 0.70 to 0.95 (15-17).

The Cronbach's  $\alpha$  and the corresponding levels of internal consistency for the trait anxiety questionnaire and the three state anxiety questionnaires are illustrated in Table 1. In the state 1 questionnaire, questions 1 (I feel calm), 4 (I am relaxed) and 5 (I feel content) had zero variance and were removed from the scale resulting in an unacceptable level of internal consistency. This is because  $\alpha$  is affected by the length of the test and if this is too short, the value is reduced. Additionally,  $\alpha$  is grounded in the 'tau equivalent model', which assumes that each test item measures the same latent trait on the same scale. If the number of test items is too small it will also violate the assumption of tau-equivalence and will underestimate reliability (18).

To determine if trait anxiety levels were statistically significant different amongst the different groups, a one-way ANOVA was conducted. To determine if state anxiety levels were statistically significantly different amongst the different groups at the three different time points, a mixed ANOVA was conducted. A post-hoc Tukey-Kramer test was carried out for any statistically significant findings from the ANOVAs. Data are presented as mean  $\pm$  standard deviation unless otherwise indicated. P-values of  $<0.05$  were considered to be statistically significant for all tests.

### ***Ethical Approval***

Ethical approval for this study was obtained from Nottingham 1 Research Ethics Committee (13-EM-0081).

## **RESULTS**

Between 1<sup>st</sup> February 2015 and 30<sup>th</sup> April 2015, 1553 women attended the EPAU at the Queen's Medical Centre, Nottingham. 381 (24.5%) women were excluded because they had visited the Unit previously during the same pregnancy and a further 57 (3.7%) were excluded because they were unable to understand the questions. Of the 1115 women who were eligible to take part in the study: 670 (60.1%) did not return any completed questionnaires; 203 (18.2%) only completed the trait and state 1 questionnaires; 82 (7.4%) only completed the trait, state 1 and state 2 questionnaires. One hundred and sixty women (14.3%) completed all four questionnaires and formed our study sample (Figure 1).

Of these 160 women, 64 (40%) had a viable IUP, 48 (30%) a non-viable IUP, 16 (10%) an EP, 13 (8.1%) a PUL and 19 (11.9%) a PUV diagnosed following the ultrasound. One hundred and twenty-eight (80%) therefore had a certain diagnosis (viable IUP, non-viable IUP or EP) and 32 (20%) had an uncertain diagnosis (PUL or PUV). Of those with a certain diagnosis, 64 (50%) women had a positive diagnosis (viable IUP) and a further 64 (50%) women had a negative diagnosis (non-viable IUP or EP).

The relative frequencies of the different diagnoses were not significantly different amongst women that completed all four questionnaires (i.e. those that formed the final study sample) and women that only completed two (trait and state 1) or three (trait, state 1 and state 2) questionnaires (Table 2).

Similarly, irrespective of the diagnosis, there were no significant differences in the levels of trait or state anxiety amongst those that were included in the final study sample and those that were excluded due to failure to complete all four questionnaires (Table 3).

### ***Anxiety levels in women attending the EPAU with abdominal pain and/or vaginal bleeding***

Trait anxiety levels amongst women presenting to the EPAU with abdominal pain and/or vaginal bleeding were generally fairly low ( $33.28 \pm 7.13$ ).

Overall, the level of state anxiety was  $21.96 \pm 1.11$  before the ultrasound,  $15.89 \pm 6.83$  immediately after the ultrasound and  $13.21 \pm 6.26$  48-72 hours after the ultrasound. State anxiety levels were highest before the ultrasound and lowest 48-72 hours after the ultrasound in women with a: viable IUP; non-viable IUP; certain diagnosis; positive diagnosis; and negative diagnosis. The opposite was true in women with a PUV or uncertain diagnosis. In women with an EP or a PUL, anxiety levels were highest immediately after the ultrasound and lowest 48-72 hours after the ultrasound (Tables 4, 5 and 6 and Figure 2).

### ***Anxiety levels according to diagnosis and timing of assessment***

We first examined whether there were any differences between the groups in the level of trait anxiety. Trait anxiety was found to be modest across all groups and one-way ANOVAs confirmed that there were no significant differences in trait anxiety levels between the groups.

We then went on to assess whether there were any differences between the five specific diagnostic groups in the level of state anxiety prior to the ultrasound, immediately after the ultrasound and 48-72 hours after the ultrasound.

Prior to the ultrasound, state anxiety levels were found to be high across all five specific diagnostic groups and mixed ANOVAs confirmed that there were no

significant differences in state anxiety levels between the specific diagnostic groups at this time (Table 4 and Figure 2).

Immediately after the ultrasound, the mean level of state anxiety was  $15.89 \pm 6.83$  but levels ranged from  $7.75 \pm 1.13$  in women with a viable IUP/positive diagnosis to  $23.00 \pm 0.58$  in women with a PUL (Table 4 and Figure 2). Mixed ANOVAs confirmed that the differences in state anxiety levels between the groups at this time were significant.

Immediately after the ultrasound, women with a viable IUP/certain diagnosis were the least anxious group. Women with non-viable IUPs had significantly higher levels of state anxiety than women with viable IUPs [ $M=12.13$ ,  $SE=0.197$ ,  $p<0.005$ ] and women with EPs had significantly higher levels of state anxiety than women with non-viable IUPs [ $M=2.62$ ,  $SE=0.297$ ,  $p<0.005$ ]. There were no significant differences in state anxiety levels between women in the EP, PUV or PUL groups at this time (Table 4a and Figure 2a). There was a significant difference in state anxiety levels between women with certain diagnoses and women with uncertain diagnoses immediately after the ultrasound [ $F(1,158)=56.361$ ,  $p<0.005$ , partial  $\eta^2=0.263$ ] (Table 4b and Figure 2b). Of those with a certain diagnosis, women with a negative diagnosis had significantly higher levels of state anxiety than women with a positive diagnosis [ $M=12.78$ ,  $SE=0.222$ ,  $p<0.001$ ] and women with an uncertain diagnosis had significantly higher levels of state anxiety than women with a negative diagnosis [ $M = 2.34$ ,  $SE = 0.272$ ,  $p < 0.001$ ] (Table 4c and Figure 2c).

The mean level of state anxiety 48-72 hours after the ultrasound was  $13.21 \pm 6.26$  but levels ranged from  $6.67 \pm 0.59$  in women with a viable IUP/positive diagnosis to  $23.89 \pm 0.32$  in women with a PUV (Tables 4, 5 and 6 and Figure 2). Mixed ANOVAs

confirmed that the differences in state anxiety levels between the groups at this time were significant.

There was a significant difference in state anxiety levels between women with a certain diagnosis and women with an uncertain diagnosis [ $F(1,158)=245.855, p<0.005, \text{partial } \eta^2=0.609$ ] 48-72 hours after the ultrasound (Table 4b and Figure 2b). Of those with a certain diagnosis, women with a positive diagnosis had the lowest levels of state anxiety. Women with a negative diagnosis had significantly higher levels of state anxiety than women with a positive diagnosis [ $M=8.20, SE=0.236, p<0.001$ ] and women with an uncertain diagnosis had significantly higher levels of state anxiety than women with a negative diagnosis [ $M=8.06, SE=0.290, p<0.001$ ] (Table 4c and Figure 2c). More specifically, women with a viable IUP were the least anxious group 48-72 hours after the ultrasound. Women with non-viable IUPs had significantly higher levels of state anxiety than women with viable IUPs [ $M=7.47, SE=0.179, p<0.005$ ] and women with EPs had significantly higher levels of state anxiety than women with non-viable IUPs [ $M=2.92, SE=0.270, p<0.005$ ]. Unlike immediately after the ultrasound, at this time women with PULs had significantly higher levels of state anxiety than women with EPs [ $M=4.48, SE=0.350, p<0.005$ ] and women with PUVs had significantly higher levels of state anxiety than women with PULs [ $M=2.36, SE=0.337, p<0.005$ ] (Table 4a and Figure 2a).

Finally we examined how state anxiety levels altered over time depending on the diagnosis. State anxiety levels were found to differ over time in women with a certain diagnosis [ $F(2,254)=350.762, p<0.0005, \text{partial } \eta^2=0.734$ ]. State anxiety levels decreased significantly after the ultrasound [ $M=-7.828, SE=0.593, p<0.001$ ] and continued to do so over the next 48-72 hours [ $M=-3.367, SE=0.223, p<0.001$ ] (Table 4b and Figure 2b). In women with a positive diagnosis/viable IUP, state anxiety levels decreased significantly after the ultrasound [ $M =-14.281, SE=0.169, p<0.001$ ] and

continued to do so over the next 48-72 hours [ $M = -1.078$ ,  $SE=0.140$ ,  $p<0.001$ ] (Table 4c and Figure 2c). In women with a negative diagnosis, state anxiety levels also decreased significantly after the ultrasound [ $M=-1.375$ ,  $SE=0.259$ ,  $p<0.001$ ] and continued to decrease over the next 48-72 hours [ $M=-5.656$ ,  $SE=0.122$ ,  $p<0.001$ ] but to a much lesser extent than that observed with a positive diagnosis (Table 3 and Figure 1c). More specifically, in women with non-viable IUPs, state anxiety levels decreased significantly immediately after the ultrasound [ $M=-2.042$ ,  $SE=0.259$ ,  $p<0.005$ ] and continued to do so over the next 48-72 hours [ $M=-5.729$ ,  $SE=0.132$ ,  $p<0.005$ ] whilst in women with EPs, the level of state anxiety increased very slightly [ $M=0.625$ ,  $SE=0.375$ ,  $p<0.349$ ] immediately after the ultrasound but then decreased significantly [ $M=-5.438$ ,  $SE=0.288$ ,  $p<0.005$ ] over the next 48-72 hours (Table 4a and Figure 2a).

In women with an uncertain diagnosis, state anxiety levels were also found to differ over time [ $F(2,62)=7.267$ ,  $p<0.001$ , partial  $\eta^2=0.190$ ] but here state anxiety levels increased significantly after the ultrasound [ $M = 0.969$ ,  $SE = 0.252$ ,  $p = 0.002$ ] and then remained fairly constant over the next 48-72 hours [ $M=0.063$ ,  $SE=0.317$ ,  $p>0.05$ ] (Table 4b and Figure 2b). More specifically, in women with PULs, the level of state anxiety increased very slightly [ $M=1.000$ ,  $SE=0.376$ ,  $p=0.062$ ] immediately after the ultrasound but then decreased significantly [ $M=1.462$ ,  $SE=0.462$ ,  $p<0.05$ ] over the next 48-72 hours to levels which were not dissimilar to those observed prior to the ultrasound [ $M=-0.462$ ,  $SE=0.501$ ,  $p=1.000$ ] and in women with PUVs, state anxiety levels increased significantly [ $M=0.947$ ,  $SE=0.346$ ,  $p<0.05$ ] immediately after the ultrasound and continued to do so over the next 48-72 hours [ $M=1.105$ ,  $SE=0.215$ ,  $p<0.005$ ] (Table 4a and Figure 2a).

## DISCUSSION

Our results demonstrate that the propensity for anxiety, as measured by the Spielberger trait anxiety inventory, in women presenting to EPAU with abdominal pain and/or vaginal bleeding, was fairly low. Of interest however is that despite this general tendency towards low levels of anxiety, very high levels of state anxiety were reported by women in all groups prior to the ultrasound. All women scored 20 or more at this time indicating that the experience of abdominal pain and/or vaginal bleeding in early pregnancy is highly anxiogenic. For women with certain diagnoses following the ultrasound, whether associated with positive or negative connotations, anxiety levels significantly decreased but for women with uncertain diagnoses, especially a PUV, anxiety levels increased. Hence it appears to be the certainty of diagnosis that affects anxiety levels rather than the positive or negative connotations associated with it *per se*.

Unsurprisingly, women with a viable IUP described feeling only very slightly anxious 48-72 hours after the ultrasound. It is interesting that in the non-viable IUP group, state anxiety levels also decreased following the ultrasound. However, Spielberger's STAI only measures anxiety. The high Cronbach  $\alpha$  coefficient reflects this. The fact that these women have been given a certain diagnosis, albeit a negative one, appears to have abated their initial anxiety, which has perhaps been replaced by other feelings, for example grief, sadness and depression, which are well-documented amongst women who have miscarried (6-11).

Given the threats to health and future fertility, it is unsurprising that state anxiety levels in the EP group increased following the ultrasound. What is surprising is that this was not significant. This may be because there were only sixteen women in this group and their anxiety levels were already high, or it may be indicative of the general naivety of the population towards the diagnosis, or a reflection of the communication skills of those imparting the diagnosis. Most EPs are treated within 48-

72 hours of diagnosis which explains the significant decrease in anxiety levels observed at this time. Again, it is worth remembering that the STAI does not measure constructs such as sadness and depression. There is very little evidence regarding the psychological sequelae following an EP (12), which, for many women is considered in the same light as a miscarriage. It is, after all, a pregnancy that will never result in a child.

In the PUL group, state anxiety levels increased slightly initially and then decreased significantly over the next 48-72 hours, most likely because serial serum  $\beta$ hCGs were taken, the results of which may have provided clarification. However, whilst anxiety levels have significantly decreased, they were still high.

In women with a PUV, there was a significant increase in anxiety levels immediately after the ultrasound and again 48-72 hours after. In the UK, PUV protocols only advocate a repeat ultrasound 7-10 days after the initial scan (19). Since no other investigations were performed, no additional information was available to alter anxiety levels. Even if further investigations are not definitive, there is evidence to suggest that women would benefit psychologically from tests that give them an indication of what a subsequent ultrasound might show (20).

It is extremely important that the psychological wellbeing of women undergoing investigation for abdominal pain and/or vaginal bleeding in early pregnancy is not overlooked. Our study has demonstrated that the experience of these symptoms alone is highly anxiogenic and that for some women, particularly those given uncertain diagnoses, anxiety levels remain elevated for at least 48-72 hours. This is concerning since women who feel anxious in the first trimester of pregnancy have a much higher risk of miscarriage than those who do not (21).



This is the first study to assess anxiety levels of women presenting to EPAU with abdominal pain and/or vaginal bleeding and to determine how this changes over time with different types of diagnoses. The study was prospective, included a considerable number of women and utilised a widely adopted, validated and reliable measure of anxiety.

Although only 14.3% of eligible women were sampled, the proportions of the different diagnoses were representative of the population hence there should not be any sampling bias. Additionally, due to the rarity of diagnosis, the numbers of women in the EP, PUL and PUV groups were small. However, since the statistical analyses took this into consideration and the results were extremely significant reflected by p-values of  $<0.005$ , this should not affect the validity of our results or conclusions drawn.

Whilst we collected very little specific demographic and clinical data, all participants were of reproductive age and presented with abdominal pain and/or vaginal bleeding in early pregnancy. Although perhaps interesting to collect more data, our remit was to determine *how* anxious women were, not *why* they were this anxious. Furthermore, we wanted to make the questionnaires as brief as possible to encourage participation.

A further weakness of our study is that follow-up was only for 48-72 hours. This is because we wanted to focus on the impact of the diagnosis itself on anxiety levels and felt that with longer follow-up other factors might come into play for example, anxiety about further management and future reproductive performance.

In conclusion, this study has proven that women who present to EPAU with abdominal pain and/or vaginal bleeding in early pregnancy and who are subsequently given an uncertain diagnosis have significantly higher levels of anxiety than their counterparts

who are given certain diagnoses, even if those certain diagnoses are not associated with an ongoing pregnancy. Healthcare providers should be aware of this when communicating uncertain diagnoses. Women with non-viable IUPs, and to a lesser extent those with EPs, have access to different support groups. Women with uncertain diagnoses have no such psychological support and this must be addressed if we are to improve the holistic nature of care provided to women with complications of early pregnancy. Further research should focus on reducing the number of women given uncertain diagnoses in early pregnancy and/or minimizing the duration of uncertainty.

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### **DISCLOSURE OF INTERESTS**

No conflict of interest is declared. No financial relationships with any organization that might have interest in the submitted work in the previous 3 years are declared. No other relationships or activities that could appear to have influenced the submitted work are declared. All authors had full access to all of the data in the study and can take full responsibility for the integrity of the data and the accuracy of the data analysis. The University of Nottingham is the sponsor for the study.

### **CONTRIBUTION TO AUTHORSHIP**

Conception, AR, NRF, BC and KV; design, AR and KV; data acquisition, AR; analysis and interpretation, AR and KV; input into drafting the article, AR and KV; revision and final approval of the article, AR, NRF, SD, BC and KV.

## DETAILS OF ETHICS APPROVAL

Ethical approval for this study was obtained from Nottingham 1 Research Ethics Committee (13-EM-0081).

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#### TABLE/FIGURE CAPTION LIST

Table 1: Internal consistency associated with each of the questionnaires

Table 2: Relative frequencies of the different diagnoses according to the number of questionnaires completed

Table 3: Anxiety levels according to diagnosis, timing of assessment and number of questionnaires completed

Table 4: State anxiety levels according to (a) specific diagnosis (b) type of diagnosis and (c) certainty of diagnosis and timing of assessment

Figure 1: A flow chart to demonstrate movement of participants through the different phases of the study

Figure 2: State anxiety levels according to (a) specific diagnosis (b) certainty of diagnosis and (c) type of diagnosis and timing of assessment