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# Primary care follow-up and measured mental health outcomes among women referred for ultrasound assessment of pain and/or bleeding in early pregnancy: a quantitative questionnaire study

Andrew Moscrop,[1] Sian Harrison,[1] Victoria Heppell,[2] Carl Heneghan,[1] Alison Ward[1]

**To cite:** Moscrop A, Harrison S, Heppell V, *et al*. Primary care follow-up and measured mental health outcomes among women referred for ultrasound assessment of pain and/or bleeding in early pregnancy: a quantitative questionnaire study. *BMJ Open* 2013;**3**: e002595. doi:10.1136/bmjopen-2013-002595

▸ Prepublication history for this paper are available online. To view these files please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2013-002595).

Received 15 January 2013
Revised 18 February 2013
Accepted 13 March 2013



[1]Department of Primary Care Health Sciences, Oxford University, Oxford, UK
[2]Urgent Gynaecology, John Radcliffe Hospital, Oxford, UK

**Correspondence to**
Dr Andrew Moscrop, andrewmoscrop@post.harvard.edu

## ABSTRACT

**Objectives:** To examine the extent of primary care follow-up and mental health outcomes among women referred for ultrasound assessment of pain and/or bleeding in early pregnancy, including those whose pregnancy is found to be viable on ultrasound assessment.

**Design:** Questionnaire study with prospective follow-up.

**Setting:** Urgent gynaecology clinic in secondary care, England.

**Participants:** 57 women participated in the study. Entry criteria: referral to the urgent gynaecology clinic with pain and/or bleeding in early pregnancy; gestation less than 16 weeks (the clinic's own 'cut-off'); no previous attendance at the clinic during the current pregnancy. Exclusion criteria: inability to understand English or to provide informed consent.

**Primary and secondary outcome measures:** Incidence of primary care follow-up among women referred to the urgent gynaecology clinic; incidence of women with measured mental health scores suggesting significant symptoms of distress.

**Results:** Fewer than 1 in 10 women referred for ultrasound assessment of pain and/or bleeding in early pregnancy had follow-up arrangements made with their general practitioner (GP). Most women who had GP follow-up found it helpful and a significant minority of women who did not have GP follow-up felt that it would have been helpful. Following ultrasound assessment, more than one-third of women had significant symptoms of distress. Symptoms of distress, particularly anxiety, were present among those women found to have viable pregnancies, as well as among those with non-viable pregnancies.

**Conclusions:** GPs are advised to consider offering follow-up to all women referred for ultrasound assessment of pain and/or bleeding in early pregnancy. Researchers in this area are advised to consider the experiences of women with pain and/or bleeding in early pregnancy whose pregnancies are ultimately found to be viable on ultrasound scan.

## ARTICLE SUMMARY

### Article focus

- Recent National Institute for Health and Clinical Excellence guidelines recommend that women experiencing early pregnancy loss be offered the option of a follow-up appointment.
- Little is known about the incidence of primary care follow-up after miscarriage or about women's perception of its value.
- Nothing is known about the experiences of those women who are referred for urgent assessment of pain or bleeding in early pregnancy but whose pregnancy is found to be viable.

### Key messages

- Few women are currently offered follow-up in primary care after referral for ultrasound assessment of pain and/or bleeding in early pregnancy.
- Women who are referred for assessment of pain and/or bleeding in early pregnancy may experience significant distress, even if the pregnancy is found to be viable.
- We suggest that GPs should consider offering follow-up to all women who are referred for ultrasound assessment of pain and/or bleeding in early pregnancy. Those working in primary care might find it easiest to make this offer at the time of referral.

### Strengths and limitations of this study

- Among its strengths, this study is the first to focus specifically on the issue of primary care follow-up among women referred with pain and bleeding in early pregnancy. It is also the first study to consider the experiences of those women referred whose pregnancy is found to be viable, as well as those women who experience pregnancy loss. Limitations include a small sample size, a low response rate and a study population that does not reflect the breadth of healthcare users in Britain.

## INTRODUCTION

The experience of early pregnancy loss can have a significant impact upon women's emotional well-being and mental health.[1 2] Many women experiencing pregnancy loss recall disappointment with health service providers,[3] including care provided by general practitioners (GPs).[4] The absence of arrangements for formal clinical follow-up is cited as a source of dissatisfaction,[5–7] with particular emphasis placed upon the lack of psychological or emotional support.[8]

The 'Better Miscarriage Care' campaign organised by 'Mumsnet' in 2011 evidenced dissatisfaction with current care provision. Among other things, the campaign appealed for improved support and routine clinical follow-up for women, and received considerable media attention and endorsement.[9] The National Institute for Health and Clinical Excellence (NICE) released the first ever National Health Service (NHS) guideline dealing with miscarriage and ectopic pregnancy in December 2012. The guidance emphasised the importance of providing women who experience early pregnancy loss with information, support and the 'option of a follow-up appointment with a healthcare professional of her choice', which might include the GP.[10]

At least one of every five women experience pain and/or bleeding during the first trimester of pregnancy (so-called 'threatened' early pregnancy loss): approximately half of these pregnancies remain viable, half do not.[11] History, examination and GP interpretation are poor predictors of pregnancy viability or non-viability[12] so, in order to establish a diagnosis and to confidently exclude gynaecological pathology, referral for ultrasound assessment is required. Evidently, significant proportions of pregnant women experience early pregnancy problems and are referred for assessment; emphasising the importance of establishing appropriate standards of care.

No study has yet been conducted of the extent of primary care follow-up provision for women experiencing early pregnancy loss. Nor have any studies yet included consideration of the needs and experiences of those women who are referred for assessment of pain and/or bleeding in early pregnancy, but whose pregnancy is found to be viable. Furthermore, no study has yet assessed mental health outcomes among this group of women using standard assessment tools (eg, PHQ-9, GAD-7) that will be familiar to most GPs.

## METHODS

### Study design and sample

We conceived an exploratory pilot study in order to assess the feasibility of a larger study of this subject. We received ethical approval for the pilot study from Leicestershire, Northamptonshire and Rutland Research Ethics Committee 2 (REC reference: 11/EM/0121).

Based on a formal sample size calculation performed using STATA and an anticipated response rate derived from previous studies in similar settings, we estimated that some 300 women would need to be asked to participate in the study in order to obtain meaningful results.

We offered sealed study packs (containing an introduction letter, information sheet, consent form, questionnaire and prepaid return envelope) to consecutive women attending the urgent gynaecology clinic at Oxford's John Radcliffe hospital. Study inclusion criteria were: referral with pain and/or bleeding in early pregnancy; gestation less than 16 weeks (the clinic's own 'cut-off'); no previous attendance at the clinic during the current pregnancy. Exclusion criteria were: inability to understand English; inability or unwillingness to provide informed consent.

The information sheet made clear that the aim of the study was to gather anonymous data that could be used to produce a research paper intended to improve the care of women. The questionnaires asked women about how and when they were referred to the clinic, and any plans that had been made for follow-up. Standard demographic questions and mental health assessment tools were also included. Participants' clinical information was obtained from their clinic records once a signed consent form was received.

A follow-up questionnaire was posted to participants in time for it to be completed 6 weeks after the date of their clinic appointment. This follow-up second questionnaire repeated the mental health assessment measures and asked about any contact with the GP since the clinic attendance.

### Measures

Questionnaires included specific enquiries relating to follow-up that were conceived for this study, as well as the following generic mental health assessment tools: the Patient Health Questionnaire 9-item assessment (PHQ-9) depression symptom measure; the Generalised Anxiety Disorder 7-item assessment (GAD-7) measure of anxiety symptoms; and the Impact of Event Scale—Revised (IES-R), post-trauma stress symptom measure (see box 1 for explanations of these measures).

### Analysis

Questionnaire data were analysed using SPSS version 18. Data on primary care follow-up and mental health outcomes were analysed descriptively using percentages to summarise the experiences of women within the sample. We grouped women depending on whether their pregnancy was found to be viable (continuing pregnancy) or non-viable (early pregnancy loss), although the small study numbers prevented statistical comparison of these two groups.

## RESULTS

### Recruitment and sample characteristics

Between November 2011 and May 2012, 300 study-packs were handed out and 57 (19%) women consented to participate. Most women completed the first questionnaire the day after their clinic appointment (time from

**Box 1** Psychological assessment tools

The following measures used in our study are all endorsed by the National Institute for Health and Clinical Excellence (NICE) and exclusively recommended by the NHS program for Improving Access to Psychological Therapies (IAPT).

*PHQ-9, patient health questionnaire, depression symptom measure*. Though the PHQ-9 includes questions on alterations in sleep, appetite weight, energy and concentration (all symptoms that overlap with normative experiences of pregnancy), the measure has been found valid to assess depression among a pregnant population[25] and also for assessment of postpartum depression.[26] The recommended cut-off for the PHQ-9 is a score of 9; anyone scoring 10 or above may be considered to be suffering from clinically significant depressive symptoms. No alterations were made to the PHQ-9: the original questions and introductory text were included in our questionnaires.

*GAD-7, generalised anxiety disorder symptom measure*. This 7-item questionnaire uses the same format as the PHQ-9. Although IAPT recommends a cut-off score of 7, it has been suggested that a cut-off of 10 may optimise sensitivity and specificity for detection of individuals suffering from clinically significant anxiety symptoms.[27] We use this higher cut-off in our study. No alterations were made to the GAD-7.

*IES-R, Impact of event scale (revised), post-trauma stress symptom measure*. Originally designed to assess 'the current degree of subjective impact experienced as a result of a specific event'.[28] The revised impact of event scale is a 22-item assessment tool with a maximum score of 88 and a cut-off of 33 or above. In our questionnaire the tool's introductory statement was slightly altered to refer specifically to 'events and experiences of early pregnancy problems and attending the urgent gynaecology clinic' in order that women might complete the assessment with reference to the subject of our study, rather than any other incidental stressful life events.

clinic appointment to completion of first questionnaire: median=1 day; interquartile range=0–6 days). Of the 57 respondents, 56 provided a postal address for us to send the follow-up second questionnaire. Follow-up questionnaires were completed and returned by 42 (74%) women. Most women completing the follow-up questionnaire did so between 6 and 7 weeks after their initial clinic visit (time from clinic appointment to completion of second questionnaire: median=44 days; interquartile range=40–52 days).

Table 1 shows the demographic characteristics of respondents: predominantly white, university-educated, married and/or living with their partner. Mean age was 33, with a range from 21 to 47. Approximately half the participants had at least one child already.

Clinical diagnoses were obtained for 54 of the 57 participants (one participant did not give her consent for this and for two women the eventual diagnosis was unclear from the clinic records). Thirty three women were found to have viable pregnancies; 21 non-viable (miscarriages).

**Table 1** Demographic characteristics of participants

| | Mean=33, range=21–47, SD=5.7 | |
|---|---|---|
| **Age** | **Frequency** | **Per cent** |
| Education | | |
| GCSE | 5 | 8.8 |
| A level | 8 | 14 |
| University degree | 36 | 63.2 |
| Professional | 6 | 10.5 |
| Not recorded | 2 | 3.5 |
| Ethnicity | | |
| White | 49 | 86.0 |
| Asian | 3 | 5.3 |
| Mixed | 2 | 3.5 |
| Other | 1 | 1.8 |
| Not recorded | 2 | 3.5 |
| Relationship status | | |
| Single | 2 | 3.5 |
| Married/partnered | 51 | 89.5 |
| Divorced/separated | 1 | 1.8 |
| Other | 1 | 1.8 |
| Not recorded | 2 | 3.5 |
| Living | | |
| Alone | 1 | 1.8 |
| With spouse/partner | 50 | 87.7 |
| With family | 5 | 8.8 |
| Not recorded | 1 | 1.8 |
| Children | | |
| Yes | 28 | 49.1 |
| No | 27 | 47.4 |
| Not recorded | 2 | 3.5 |
| Self-reported physical health problems | 6 | 10.5 |
| Self-reported mental health problems | 3 | 5.3 |

GCSE, general certificate of secondary education.

## Primary care follow-up

Table 2 shows that the majority of women were referred to the clinic from primary care; either by their 'usual' GP or another doctor at their practice. However, fewer than 1 in 10 women attended the clinic with knowledge of follow-up arrangements being in place with a GP. At the time of completing the first questionnaire, 10 of the 57 women (17%) had, or planned to have, an appointment with their GP to discuss the outcome of their clinic attendance. Overall, 21 of the 57 women (37%) thought such an appointment might be helpful (including 12 women with viable pregnancies and 9 with non-viable pregnancies); only 2 women (4%) thought it would be unhelpful, while the remainder were uncertain or ambivalent. Of the 47 women who had neither seen, nor planned to see, their GP, 13 (28%) thought that seeing their GP would in fact be helpful.

Of the 42 women who completed the 6-week follow-up questionnaire over half (22/42) did not talk to their GP following their referral. Of those 20 women who did talk to their GP afterwards, 14 found it helpful, one found it unhelpful, while the remaining women were uncertain or ambivalent. Nine of the 26 (35%) women with viable

**Table 2** Clinic referral details (results from first questionnaire)

| | Frequency | Per cent |
|---|---|---|
| Who arranged your appointment at the clinic? | | |
| Your 'usual' GP | 23 | 40.4 |
| Another GP at your practice | 24 | 42.1 |
| A&E department | 4 | 7.0 |
| An out of hours GP | 3 | 5.3 |
| Community Midwife | 1 | 1.8 |
| Other | 2 | 3.5 |
| When you attended the clinic, had you already made arrangements or made an appointment with your GP to talk about things afterwards? | | |
| Yes | 5 | 8.8 |
| No | 52 | 91.2 |
| Do you plan to attend, or have you already attended, an appointment with your GP to discuss things following your clinic attendance? | | |
| Yes | 10 | 17.5 |
| No | 43 | 75.4 |
| Not sure | 4 | 7.0 |
| Do you think that discussing things with your GP would be… | | |
| Helpful | 21 | 36.8 |
| Unhelpful | 2 | 3.5 |
| Neither helpful or unhelpful | 29 | 50.9 |
| Not sure | 5 | 8.8 |
| Time between being referred and attending clinic | | |
| Same day | 2 | 3.5 |
| Next day | 11 | 19.3 |
| 2 days | 7 | 12.3 |
| 3 days | 9 | 15.8 |
| 4–7 days | 27 | 47.4 |
| More than 1 week | 1 | 1.8 |

GP, general practitioner.

pregnancies and 5 of the 16 (31%) women with non-viable pregnancies reported that talking to their GP was helpful.

### Mental health outcome measures

Mental health measurements were obtained from 57 women completing the first questionnaire and 42 women completing the second questionnaire.

At the time of the first questionnaire, 35% (20/57) of the participants had scores above the cut-off level for significant symptoms of distress in one or more of the PHQ-9, GAD-7 or IES-R. Notably, none of these 20 women with scores above-cut-off had follow-up arrangements in place with their GP at the time of attending the clinic and only three planned to see their GP subsequently.

Anxiety symptoms captured by the GAD-7 assessment tool were most prevalent, with 12/57 (21%) of all women in our study showing scores above the ≥10 cut-off for significant anxiety symptoms at the initial questionnaire. This is approximately three times greater than the estimated population norm (a large general population self-report survey found 6.7% of women between the ages 25 and 44 had GAD-7 scores of 10 or more).[13] Among women with non-viable pregnancies (actual pregnancy loss) 2/21 (10%) had GAD-7 scores above the cut-off for significant anxiety symptoms at the time of the first questionnaire; among women with viable pregnancies, the prevalence of significant anxiety symptoms was 10/33 (30%).

Significant depressive symptoms, suggested by PHQ-9 scores above the cut-off, were present among 19% (11/57) of women in our study (the female population norm is 5%).[14] Prevalence of above-cut-off PHQ-9 scores was similar among women with non-viable (4/21; 19%) and viable (6/33; 18%) pregnancy outcomes.

Nineteen per cent (11/57) of all women also had IES-R scores above the cut-off suggesting significant symptoms of traumatic stress.

By the time of the follow-up questionnaire, 24% of women (10/42) had scores above cut-off levels in one or more of the PHQ-9, GAD-7 or IES-R (six women had PHQ-9 scores above the cut-off; three had GAD-7 scores above the cut-off and 6 had IES-R scores above the cut-off). Seven of these women were among the 20 women with scores suggestive of significant distress at the initial questionnaire; three women developed above-cut-off scores subsequently. Of the 10 women with above-cut-off scores at the time of the follow-up questionnaire, eight had viable pregnancies, two had non-viable pregnancies.

## DISCUSSION

### Principle findings

Although most women attending the urgent gynaecology clinic for ultrasound assessment of pain and/or bleeding in early pregnancy were referred by GPs, very few arrangements were made between women and GPs to meet again and discuss outcomes of the ultrasound assessment. This might be surprising in view of the potential significance of the referral in revealing either the presence or absence of a viable pregnancy. Some women might not wish to revisit their GP. However, the number of women who thought discussion with a GP would be helpful was greater than the number of women who actually had follow-up arranged. These findings suggest that it would be appropriate to facilitate women's choices by offering them the possibility of a follow-up appointment. Those who feel that follow-up with a GP might be helpful will be able to self-select: women can choose whether or not to take up the offer of follow-up.

This study confirms the findings of earlier studies showing that some women experience significant distress after early pregnancy loss. However, our results call into question the apparent assumption of earlier researchers that it is only actual pregnancy loss that is associated with distress. We found that distress was experienced by some women who ultimately had a viable pregnancy revealed by ultrasound. Experiencing the uncertainty of threatened pregnancy loss may itself be a cause of

distress until the ultrasound scan findings reveal whether the pregnancy is viable or not. Our results also suggest that even after a viable pregnancy has been demonstrated on ultrasound, the experience of threatened pregnancy loss may not be rendered emotionally neutral or insignificant: distress or upset may persist.

### Study strengths

Our study is the first to provide evidence of the extent of primary care follow-up among women referred for assessment of pain and/or bleeding in early pregnancy. Ours is also the first study to consider the experiences of all women referred for assessment—including those women whose pregnancy is revealed to be viable—and to demonstrate that some of those women who experience threatened pregnancy loss with a viable outcome also experience significant distress. We are also the first researchers in this area to utilise the NICE-endorsed, Improving Access to Psychological Therapies (IAPT)-recommended battery of mental health measurement tools that will be familiar to those working in primary care.

### Study limitations

The low response rate left us with a small sample size and considerable potential for selection bias among study participants: participants may have been more inclined to respond to questionnaires asking about symptoms of distress if they were experiencing such symptoms. We cannot therefore claim that the incidence rates of distress found in our study accurately reflect the incidence among women who did not participate. However, we can claim with confidence that our findings at least represent the experiences of some women. The small sample size also prevented statistical comparison of psychological outcomes between women with viable and non-viable pregnancies. Because we were unable to conduct pre-event assessment of participants, we cannot attribute causality with certainty; that is, we cannot claim that any psychological or emotional disturbances were definitely caused by the experience of actual or threatened pregnancy loss. It was not possible or appropriate to define the precise point after events at which women completed the questionnaires and there was some variability. Clinical records did not consistently record reproductive history so we could not include this information in our study. Our study population consisted predominantly of white, well-educated women and this may limit the generalisability of our findings.

Because of our difficulty in recruiting women for this study and the consequent limitations of our numerical results, future researchers in this area might consider adopting a qualitative method. This approach would potentially offer important insights into women's experiences.

### Context of other studies

The potential distress associated with early pregnancy loss has been amply demonstrated. A review paper in 2007 cited 87 articles and concluded: 'As many as 50% of miscarrying women suffer some form of psychological morbidity in the weeks and months after loss'.[15]

The first ever NHS guideline dealing with early pregnancy loss was published by NICE at the end of 2012.[10] The guideline emphasises psychological support, information giving and advises that all women experiencing early pregnancy loss be offered a follow-up appointment. The guideline authors recognise that not all women will need or want follow-up; however, the offer alone may have a beneficial effect, and some women might value the opportunity to ask questions or seek support. The guideline also acknowledges that returning to the location where a pregnancy loss was diagnosed might be upsetting for some women, while a rapport with a known GP might make follow-up in primary care preferable. However, the NICE guideline does not mention the needs of those women who experience pain and/or bleeding in early pregnancy but whose pregnancy is found to be intact.

Meanwhile, our study findings suggest that primary care practice may have altered little since 1989 when Trevor Friedman, writing on the subject of early pregnancy loss in the then *Journal of the Royal College of General Practitioners*, highlighted the lack of primary care follow-up for women; the associated distress and dissatisfaction and the 'mismatch between the patients' and the doctors' perceptions of patients' needs'.[16]

Since then, a role for GPs has been endorsed by the finding that women in a study of postmiscarriage interventions experienced less anxiety over time if they attended follow-up with the GP; the authors stated: 'Although (GP) follow-up consultations offered little more than the general discussions concerning the health of the women and the impact of miscarriage on future pregnancies, together with the expression of general care and support, it appears that such follow-up may lead to lowering of women's anxiety postmiscarriage'.[17]

Our findings are consistent with those of earlier studies conducted using the Hospital Anxiety and Depression Score, which suggest that anxiety, rather than depression, may be more prevalent following early pregnancy loss.[1 17 18] However, the reliability of the Hospital Anxiety and Depression Scale (HADS) in early pregnancy has been questioned[19] and the HADS is known to be used by only a minority of GPs.[20 21] Other studies of women experiencing early pregnancy loss have used psychological measures that are likely to be much less familiar to GPs. Often too these measurement tools appear to have implied presuppositions on the part of the researchers about the nature and impact of the experience (for instance, trauma scales have been used by those viewing the process as traumatic; measures of grief by those likening the loss to bereavement). Our purpose in utilising our chosen mental health measures was not to endorse any particular presupposed psychological outcome of threatened or actual pregnancy loss, still less to impart psychiatric diagnoses or define mental

illness. Rather, we sought to highlight the degree of distress using scales that will be familiar and meaningful to practitioners. The problems of medicalising (and, specifically, mental-health-pathologising) motherhood are understood,[22] but we suggest that this concern may be outweighed here by the problem of inadequately acknowledging a personally meaningful experience that has already been brought within the remit of medical care.

Until now, no research has looked at the group of women who experience pain and/or bleeding in early pregnancy (threatened early pregnancy loss), but whose pregnancy is in fact found to be viable on ultrasound assessment. Nothing at all has been known of the experiences and outcomes of this group of women. This is despite the fact that even in cases where the pregnancy remains viable there may be pain, bleeding and hospitalisation, which might cause distress. Conceivably too, the experience might heighten anxieties by means of undermining the apparent certainties of pregnancy outcomes. Our findings challenge the assumptions of earlier researchers and suggest that future research might include all women experiencing pain and bleeding in early pregnancy: those with threatened as well as actual pregnancy loss.

The small scale of our study and the potential for selection bias among participants suggests that further work will be needed to endorse our findings. However, in the absence of any other studies addressing our research questions, we feel our findings represent the best available evidence.

### Clinical implications

GPs are unable to diagnose early pregnancy loss on the basis of history and examination alone; necessitating a referral for ultrasound assessment of pain and/or bleeding in early pregnancy. Acknowledging the uncertainty of ultrasound findings at the point of referral; the potential distress that we have found may be experienced by some women irrespective of the eventual ultrasound findings and the inherent responsibility of the GP to those patients whom he/she refers for further investigation; we suggest that GPs referring women for ultrasound assessment of pain and/or bleeding in early pregnancy should consider discussing follow-up arrangements with all women as a matter of routine best practice. This might be most conveniently done at the time of referral.

If a woman chooses to take up the offer of a follow-up appointment after the ultrasound investigation this could provide an opportunity for GPs to answer any questions that the woman or her partner might have about the experience, or about modifiable risk factors.[23] The GP might also help with meaning-making; encouraging and enabling more helpful interpretations of events. With women who experience pregnancy loss, the GP might facilitate a conversation about whether or when to try again (perhaps bearing in mind recent evidence suggesting that women who conceive earlier after miscarriage may have better pregnancy outcomes and fewer complications).[24] A follow-up appointment might also be a useful opportunity to ensure that women are aware of organisations offering further information and support such as the Miscarriage Association.

## CONCLUSION

We found evidence that some women experience significant distress after pain and/or bleeding in early pregnancy (threatened early pregnancy loss); also that the finding of a viable pregnancy on ultrasound assessment may not resolve this distress for some women; and some women who felt that GP follow-up would have been helpful did not get any such follow-up. Despite the limitations of this evidence owing to our study's small sample size and potential for selection bias, we feel that an approach based on some evidence is better than one based on no evidence at all. Current practices—in which primary care follow-up is not routinely offered—are not based on evidence, but derived from habit and historical precedents that may not be helpful. The evidence that we provide is all that exists in this area.

The value of primary care follow-up after ultrasound assessment of pain and/or bleeding in early pregnancy, and the experiences of those women whose pregnancy is found to be viable on scan, are subjects worthy of future research (qualitative work might be especially appropriate). Meanwhile, a change in current primary care practice is proposed. We suggest that GPs should consider routinely offering follow-up to all women who are referred for assessment of pain and/or bleeding in early pregnancy. It might be easiest to make this offer at the time of referral. Women can chose to take up the offer if they feel it would be helpful.

**Acknowledgements** We would like to thank Linda Portman, Robin Collins, Julie Storey, Louise Finch, Vic Rai, Claire Goyder, Ana Nikcevic and the study participants.

**Contributors** AM designed the study protocol, analysed the results and drafted the final paper. SH advised on the protocol design, steered the study through ethics and R&D committees and oversaw the questionnaire distribution and collection. VH assisted with the design of the study and its implementation in the clinic. CH and AW supervised the study throughout, ensuring ethical and scientific rigour. All authors have read and approved the final manuscript.

**Funding** Department of Primary Health Care, University of Oxford.

**Competing interests** None.

**Ethics approval** Leicestershire, Northamptonshire and Rutland Research Ethics Committee 2.

**Provenance and peer review** Not commissioned; externally peer reviewed.

**Data sharing statement** Extradata can be accessed via the Dryad data repository at http://datadryad.org/ with the doi:10.5061/dryad.3tr8d

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