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PUBLIC SERVICES OMBUDSMAN FOR WALES
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The investigation of a complaint by Ms D against Cardiff and Vale University Local Health Board

A report by the
Public Services Ombudsman for Wales
Case: 201202432

Contents

Introduction

This report is issued under section 16 of the Public Services Ombudsman (Wales) Act 2005.

In accordance with the provisions of the Act, the report has been anonymised so that, as far as possible, any details which might cause individuals to be identified have been amended or omitted. The report therefore refers to the complainant as Ms D.

Summary

Ms D complained that midwives at the University Hospital of Wales (UHW) wrongly informed her that her pregnancy dating scan[1] revealed that she had suffered a 'silent' miscarriage. This error was detected only because Ms D elected to undergo uterine evacuation at a different hospital. There, a more thorough type of scan[2] was performed which detected a healthy, viable foetus.

The Ombudsman upheld Ms D's complaint and found that, at the time of the complaint, the Health Board had failed to implement guidelines issued by the Royal College of Obstetricians & Gynaecologists (RCOG) that were designed to prevent the misdiagnosis of early pregnancy loss. These guidelines require midwives to conduct a TV scan in all such cases. The Ombudsman also found that the initial dating scan had been incompetently conducted and that midwives failed to take account of Ms D's relevant medical history. The Ombudsman recommended :

(a) That the Health Board provides Ms D with a written apology and, in recognition of the inconvenience and expense incurred in obtaining alternative antenatal care, makes a payment to Ms D in the sum of £1,500.

(b) That further to the Health Board agreeing to take immediate steps to implement RCOG guidance in respect of the diagnosis of early pregnancy loss and to promptly notify all relevant clinicians within the Directorate that it has done so, it provides documentary evidence of how this process was accomplished.

(c) That the Health Board provides evidence that it has reviewed/assessed the competence of its midwife sonographers in respect of the diagnosis of silent miscarriage.

(d) That the Health Board shares with the Ombudsman the outcome of its complaint investigation review of this case (its Root Cause Analysis).

[1] A trans-abdominal (TA) pregnancy dating scan.
[2] A trans-vaginal (TV) scan.

The complaint

1. Ms D complained that, following a pregnancy dating scan in July 2012, midwives at UHW mistakenly informed her that she had suffered a missed (or 'silent') miscarriage.

2. Ms D complained that this misdiagnosis came to light only because she elected to attend another hospital for uterine evacuation. There, midwives discovered that Ms D was nine weeks pregnant with a healthy, viable foetus.

3. Ms D complained that this experience left her severely traumatised. It destroyed her confidence in the UHW's maternity service and led her to harbour doubts about the viability and health of her baby throughout her pregnancy.

Investigation

4. Comments and copies of relevant documents were obtained from Cardiff and Vale University LHB (the Health Board), together with medical records from Aneurin Bevan Health Board (where Ms D was subsequently treated), and these were considered in conjunction with the evidence provided by Ms D.

5. Clinical advice was initially obtained from Dr John Orrell Davies, an experienced Consultant in Obstetrics and Gynaecology. At his suggestion, further advice was obtained from Dr Martin James Cameron, a Consultant Obstetrician specialising in antenatal ultrasonography. Both Ms D and the Health Board were given the opportunity to see and comment on a draft of this report before the final version was issued. The Health Board, whilst accepting the report's findings and my recommendations, made a number of specific comments, some of which are reflected in the amendments I have made to the draft report. These amendments appear at paragraphs 12, 13, 50 and 51. I have also added an additional recommendation. Ms D indicated that she was content with the draft report and had no specific comments. A number of abbreviations are used in this report. A list of those abbreviations is attached at Appendix A.

6. I am issuing this report under Section 16 of the Public Services Ombudsman (Wales) Act 2005. I have not included in this report every detail considered in my investigation but I am satisfied that nothing of significance has been overlooked.

Policy and Guidance

7. The Royal College of Obstetricians and Gynaecologists (RCOG) Green-top Guideline No.25: 'The Management of Early Pregnancy Loss', October 2006 (the 'RCOG Guidelines') provides criteria[3] for establishing, via ultrasound, a diagnosis of Pregnancy of Uncertain Viability[4]. However, the criteria presuppose the use of trans-vaginal (TV) scans to obtain such a diagnosis. There is no suggestion within the RCOG Guidelines that the diagnosis of early pregnancy loss may be made using trans-abdominal (TA) scans (and/or Doppler flow ultrasound) only.

8. In 2011, the RCOG issued an Addendum to Guideline No 25 ('the Addendum'), to the effect that where ultrasound is used to diagnose early pregnancy loss, the use of TV scans should be considered mandatory. The Addendum stated that "with immediate effect…a trans-vaginal ultrasound scan should be performed in all cases" [original emphasis]. This strongly worded injunction reflected the RCOG's concern that "…current definitions used to diagnose miscarriage could lead to an incorrect diagnosis".

9. In February 2011 the Health Board issued a guidance document entitled 'Directorate of Obstetrics and Gynaecology: Ultrasound Guidelines for Obstetric and Gynaecology' (the 'Directorate Protocol'). Whilst the Directorate Protocol offers no specific guidance about diagnosing early pregnancy loss, it provides an electronic link[5] to the RCOG Guidelines.

10. The Directorate Protocol provides further electronic links to key policy and guidance documents. Central to these is the document entitled 'Guidelines For Professional Working Standards: Ultrasound Practice' issued by the United Kingdom Association of Sonographers (UKAS) in 2008. The

[3] Under Section 6.2.
[4] A new diagnostic term designed to replace the term 'indeterminate viability' (which, in 2006, the RCOG considered to be 'confusing'). Arguing for this terminological revision (and not the detailing of the criteria) appears to be the primary function of section 6.2.
[5] Under Section 6.

document sets out a comprehensive regulatory framework for sonography practice in the UK. Under the heading of General Guidelines[6], sonographers are reminded of the requirement to be "…responsive to the relative risks for each application..[and]..to undertake a risk/benefit assessment for each examination". Under the heading of Examination Procedures[7], it is emphasised that "…the sonographer should be aware of…current guidelines of other professional bodies and organisations"; and, under the rubric of Medico-Legal Issues[8], considerable stress is placed on the need to ensure that "…representative images of any abnormal or unusual findings referred to in the written report should be imaged and stored".

11. In December 2012, after the events complained of, the National Institute for Health and Care Excellence (NICE) issued Guideline 154 'Ectopic Pregnancy and Miscarriage'. This document implies that the use of a TA scan in diagnosing early miscarriage should be restricted to those instances where a woman declines a TV scan or where it is contra-indicated due to pelvic pathology.

12. In its response to the draft report, the Health Board referred to the February and May 2011 versions of its Directorate Protocol as "inaccurate and out of date information" which did not reflect the fact that its practice had changed to reflect the RCOG Guidelines and Addendum and the more recent NICE Guidance. The Health Board provided a guidance document entitled 'Guidelines for the Management of Early Pregnancy' which had been in force since September 2012 (and was again updated in September 2013) when it replaced earlier guidelines that had been in place since 2007 (the Early Pregnancy Assessment Unit Guidelines – the EPAU Guidelines). Neither the 2012/13 guidelines nor the 2007 guidelines it replaced had been provided to me during my investigation.

13. The 2012/13 guidelines prominently reproduce the RCOG Addendum (and refer to the 2012 NICE Guidance). However, it appears that the RCOG's Addendum had been in place for nearly 12 months before the Health Board updated its 2007 EPAU Guidelines to take account of it. Moreover, the 2007 EPAU Guidelines do not reflect the stipulation set out in the RCOG's 2006 Green-top Guideline Number 25 document that cases of 'pregnancy of

[6] Section 1.
[7] Page 10.
[8] Section 1.9 Page 17.

uncertain viability' should only be determined as such "...after assessment by TV scan[9]" (original emphasis). It is also notable that, whilst the RCOG's 2006 document clearly identifies the option of performing a TV scan as the starting point in its 'Basic Diagnostic Algorithm for Early Pregnancy Loss[10]', the equivalent algorithm in the 2007 EPAU Guidelines[11] cites the more nebulous 'Perform USS[12]' as the point of departure.

The background events

Summary of clinical events

14. Ms D was referred by her GP to the Maternity Unit of the University Hospital of Wales (the UHW) on 18 July **2012** for her initial pregnancy dating scan (believing herself to be approximately 10 weeks pregnant).

15. This was Ms D's first viable pregnancy since undergoing surgery for polycystic ovary syndrome (PCOS). Ms D also had a history of endometriosis[13] and displayed symptoms of hyperemesis.[14]

16. A trans-abdominal (TA) ultrasound scan was performed by a midwife sonographer which appeared to reveal a significant discrepancy between the size of the gestation sac (GS) and the foetal crown-rump length (CRL). The GS was measured at 45.8mm (equivalent to a gestation period of 10 weeks and one day) and the CRL at 11.3mm (equivalent to a gestation period of seven weeks and two days). This discrepancy suggested the possibility of an early foetal demise.

17. This possibility was reinforced when the midwife sonographer was unable to detect a foetal heartbeat using Doppler colour flow ultrasound[15].

[9] Despite the 2007 EPAU Guidelines having a sub-section (p13) devoted to 'RCOG Criteria'.
[10] Appendix 1, p14.
[11] Final (unnumbered) page of document.
[12] USS – Ultra Sound Scan
[13] In which the womb lining does not leave the body properly during a period and attaches itself to membranes of the organs of the pelvis.
[14] Severe and intractable morning sickness.
[15] Colour flow Doppler produces a picture of blood flow by converting Doppler sounds into colours that represent the speed and direction of blood flow through the blood vessels.

18. A second midwife sonographer repeated the scan and Doppler flow test and, obtaining the same results, concluded that Ms D had suffered an early pregnancy loss or 'silent' miscarriage.

19. The midwives advised Ms D of the options for managing her post-miscarriage care. Ms D opted for medical (as opposed to surgical or expectant[16]) management. This involves the supervised administration of medication designed to speed up the evacuation of the Retained Products of Conception.

20. An Integrated Care Pathway (ICP) form was completed, together with a consent form and a once-only prescription form. The ICP form recorded a diagnosis of missed miscarriage and made reference to Ms D's history of PCOS. The form also detailed the arrangements that had been put in place for Ms D to undergo uterine evacuation at Llandough Hospital on 21 and 23 July.

21. However, so that she might benefit from the support of her family, Ms D requested that she receive the planned treatment at Nevill Hall Hospital (which falls under Aneurin Bevan Local Health Board). This was arranged by her GP for the following day.

22. On admission to Nevill Hall, Ms D underwent a further TA scan. As there were difficulties in obtaining clear images, a trans-vaginal (TV) scan[17] was carried out. This scan identified a viable intrauterine pregnancy with a CRL measurement of 28.8mm (equivalent to eight weeks and six days gestation). The scan also detected a normal foetal heartbeat. Ms D's symptoms of hyperemesis were identified and, in view of her dehydrated condition, Ms D remained in hospital for several days. In her letter of complaint to my office, Ms D commented that, having been traumatised by these events, she lost confidence in the UHW's maternity service and felt obliged to obtain all further antenatal care from Nevill Hall Hospital.

23. Subsequently, Ms D gave birth to a healthy, full-term baby.

[16] Ie a 'natural' miscarriage process in which 'nature is allowed to take its course'.
[17] An ultrasound imaging technique in which a hand-held device that produces the ultrasound waves is inserted directly into the vagina thus producing a clearer and less distorted image than obtained through transabdominal ultrasound.

Summary of complaint and investigation correspondence

24. On 31 July 2012, Ms D's mother (who I will refer to as Mrs D) submitted a formal written complaint, on behalf of her daughter, to the Health Board's Concerns Team. The main focus of the complaint was that: "…[Ms D] was informed that there was no heartbeat and less than 24 hours later was told that the baby is well and healthy with a strong heartbeat". Mrs D expressed concern that, although the first midwife had commented on the fact that Ms D's bladder was not sufficiently full, both she and the second midwife proceeded to diagnose a silent miscarriage on the basis of images that were, therefore, less than optimal[18]. Mrs D also complained that despite Ms D discussing her history of nausea and vomiting (to which she had attributed her limited urinary output), midwives failed to identify her dehydrated condition. This was subsequently recorded and identified at Nevill Hall Hospital where, during her three day admission, Ms D was diagnosed with hyperemesis and received six units of saline.

25. Mrs D's complaint was acknowledged the following day, 1 August. The Health Board's formal letter of response to the complainant was issued by the Executive Nurse Director (the Nurse Director) on 20 September. The letter began with an apology for the distress caused to Ms D and stated that the response was designed to address each of Mrs D's concerns.

26. Under the heading 'Concerns regarding your daughter's dating scan', the Nurse Director noted Mrs D's comments about Ms D's under-filled bladder but offered the reassurance that "...whilst the midwife noted that [Ms D's] bladder was not completely full, she [the first midwife] was satisfied that the images were clear". This was supported by the second midwife who "...also confirmed that the quality of the images of the ultrasound machine were clear". The Nurse Director went on to state that "...the recorded [GS-CRL] measurements were above the level where, according to our guidelines, it is recommended to offer a rescan or perform a trans-vaginal (TV) scan".

27. The Nurse Director concluded this section of the letter with the comment that: "...while I am clear that normal practice was followed on the day of [Ms D's] scan, I am not able to provide you with any answer as to why the foetal heart beat was not visible on her scan ...this has made us reflect on

[18] The sonographer relies on a distended bladder to optimise images. This is because ultrasound optimally transmits through liquid and a full bladder 'pushes' the uterus out of the pelvis.

our practices and implement some changes. When early pregnancy loss is suspected on the first scan then a second scan and check is now undertaken using a TV scan ...this change should ensure that the risk of what happened to [Ms D] is greatly reduced for women in the future".

28. Under a further heading of 'Gestation', the Nurse Director observed that "...according to [Ms D's] LMP[19] she was 10 weeks plus five days gestation on the day of her appointment, which corresponds with the measurement of the pregnancy". The Nurse Director's letter ended with a reiteration of the Health Board's apology for the anxiety and distress caused to Ms D but also offered the reassurance that the midwives "…acted upon their clinical findings and in accordance with Directorate protocols". The Nurse Director's letter made no reference to Mrs D's complaint about the failure of midwives to identify or treat Ms D's dehydration.

29. When Ms D brought her complaint to my office, I asked the Chief Executive of the Health Board to provide a copy of the Directorate Protocol and to comment on whether it had been amended to take account of the RCOG's Addendum to its Guidelines. I also requested copies of Ms D's ultrasound images taken on 18 July.

30. The Health Board subsequently provided a copy of Ms D's antenatal records, together with the Health Board's complaint file, but was unable to provide digital versions of Ms D's ultrasound images as these had not been retained in any digital archive. This resulted in my Professional Advisers having to rely on paper-based photocopy images of reduced quality.

31. In response to the question of whether the Directorate Protocol had been appropriately amended, the Health Board commented that: "…it [was] reviewed but not amended, as it is not the usual practice of the department to offer a rescan".

32. In view of the apparent contradiction between the assurance given to Mrs D by the Health Board that "...when early pregnancy loss is suspected on the first scan then a second scan and check is now undertaken using a TV scan", and the Health Board's subsequent comment that "...[the Directorate Protocol] was reviewed but not amended", I asked the Health Board to clarify

[19] Last Menstrual Period.

this matter. In an email dated 4 June 2013, I asked: "...could you indicate whether the current ultrasound guidelines have now been amended to reflect this change of practice".

33. The Health Board provided a copy of its most recent version of the Directorate Protocol, together with a copy of an internal email in which it was stated that: "... this is the guidance in place. I believe it does include the updated RCOG guidance".

34. However, the Directorate Protocol document was dated May 2011 (some five months before the RCOG Addendum was issued) and, following careful examination, appeared to be identical to the Directorate Protocol document dated February 2011 that the Health Board had provided me with at the outset of my investigation.

Summary of professional advice

35. Advice was obtained from Dr John Orrell Davies, a Senior Consultant Obstetrician & Gynaecologist, and from Dr Martin James Cameron, a Consultant Obstetrician with expertise in ultrasound scan services throughout pregnancy. I refer to the Advisers as the First and Second Advisers respectively. The advice received falls into two discrete areas: the conduct of the TA scans undertaken, including the failure to take account of Ms D's medical history; and the failure to conduct a TV scan in line with RCOG Guidelines. I refer to an additional concern raised by the Advisers at the end of this report under the heading of 'Other Matters'.

36. Both Advisers were critical of the quality of the images obtained by the midwives and both noted that Ms D's bladder was 'poorly filled'. The First Adviser observed that "...the sonographer relies on a distended bladder in order to obtain optimal images" and that, in this case, "...an underfilled bladder may well have resulted in problems in obtaining a satisfactory view". The First Adviser, in reference to Image 2 (from which the CRL measurement was derived), noted that "...the area measured…does [not] demonstrate the best view of the foetus ...there was clearly an under measurement of the CRL...".

37. The Second Adviser agreed that the absence of a full bladder compromised the available images and that, in the case of Image 2, the poorly filled bladder gave rise to an imaging "artefact" that reduced the CRL measurement by half its actual size. The Second Adviser also noted that: "...the image is not optimised – the area where the CRL is taken should have been magnified using the depth and zoom controls. The focus is incorrectly positioned too high in the image and should be at the level of the CRL measurement".

38. With regard to Image 1, the Second Adviser observed that: "...[the] image of the uterus is too small on screen and should have been increased by using depth and zoom..", and, with regard to Image 4 that the: "...image is difficult to understand as no annotation on the scan picture ...again, bladder poorly filled ...no measurements on this image". The Second Adviser concluded that: "...the images appear to be of poor quality and could have been significantly improved".

39. The First Adviser also noted that, whilst Ms D's history of PCOS was recorded by midwives on the ICP form, there was no evidence to suggest that the irregular ovulation associated with the condition was taken into account by either midwife. That is, it was assumed that the GS measurement was consistent with a gestation period that began on the first day of Ms D's LMP, i.e. 4 May 2012. However, the First Adviser noted that "...assessing gestational age from the first day of the LMP assumes that ovulation and therefore conception occurs on day 14 of the cycle. Day 14 of the cycle, in Ms D's case, would have been 17 May …[therefore] ...the gestational age would have been nine weeks and one day, i.e. less than gestation estimated from the GS but more than gestation estimated from the CRL. This should have alerted the team to the possibility that they were dealing with a pregnancy of an earlier gestation than that suggested by the date of the LMP". Thus, the midwives' uncritical acceptance of Ms D's LMP as 4 May made them less inclined to doubt the discrepant nature of the CRL measurement (and more inclined to believe that it indicated a foetal demise). The First Adviser concluded that "…the reason for this discrepancy is likely to have been [Ms D's] polycystic ovary syndrome and this factor was not acknowledged at the time of the initial assessment".

40. The Second Adviser also expressed concern about the use of Doppler: "...Doppler ultrasound is used to help see movement but puts a lot of ultrasound energy through a very small area. There have always been concerns that Doppler in the first trimester may cause thermal heating/injury to the foetus if it is a viable pregnancy. Rather than use Doppler colour flow the sonographer should have asked Ms D to empty her bladder and then perform a trans-vaginal scan – this would have resulted in better images as the ultrasound probe is closer to the foetus but the actual amount of ultrasound would have been less concentrated with no concerns about thermal injury".

41. The Advisers concurred that a TV scan should have been conducted. The First Adviser quoted from the RCOG's Addendum which stated that "...we recommend adoption of the following interim guidance **with immediate effect**: ...a trans-vaginal ultrasound scan should be performed in <u>all</u> cases" [original emphases].

42. The First Adviser commented that: "...the [RCOG] has made a recommendation and have highlighted in bold that this should be with immediate effect and the second recommendation is that trans-vaginal scans to be performed in all cases. The Addendum has taken the step of underlining the word 'all' ...this was an extremely strongly worded recommendation and as far as I can see Cardiff has not given any reasons as to why they have not implemented this ...this recommendation should have been known to any sonographer undertaking early pregnancy assessments".

43. The Second Adviser concurred: "...for any health professional (midwifery, nurse, radiographer or doctor) performing early pregnancy scans in July 2012 I would have expected them to follow the guidance from RCOG ...and its Addendum ...given that a diagnosis of missed/silent miscarriage was being made a trans-vaginal scan should have been performed. The sonographers should not have relied on a TA scan for diagnosis of miscarriage, particularly in the setting of a poorly filled bladder".

44. Finally, both Advisers expressed concern at the Health Board's failure to retain/archive Ms D's ultrasound images. The Second Adviser commented that: "...it is good practice that images taken at pregnancy ultrasound are archived, ideally digitally, using a system such as PACS. This allows images

to be retrieved and reviewed at a later date. It is disappointing that the Board cannot supply original images". I return to this issue at the end of this report under 'Other Matters'.

Analysis and conclusions

45. In reaching my conclusions I have been assisted by the advice and explanations of my Clinical Advisers, which I accept in full. The investigation has considered two broad areas of complaint and I will address each of them in turn.

Failures in the conduct of the dating scan that Ms D received

46. I share, with the First Adviser, concern at the apparent failure of both midwives to take account of Ms D's clinical history of PCOS. Whilst a reference to PCOS appears on the ICP form, there is no evidence to suggest that the irregular ovulation associated with the condition was taken into account by either midwife in the calculation of the gestation period.

47. Both Advisers are of the view that the midwives' decision to proceed with Ms D's dating scan in spite of her under-filled bladder was a departure from standard practice that, in itself, may have compromised the clarity and the reliability of the images. Whilst I note that, in her complaint response letter to Mrs D, the Nurse Director defended this decision by arguing that both midwives were satisfied that the images were clear, this assertion is difficult to reconcile with the Second Adviser's extensive criticisms of the poorly optimised images.

48. I also note the Second Adviser's concern that "...Doppler in the first trimester may cause thermal heating/injury to the foetus" and that, in this case, Doppler ultrasound may have been used incautiously. Whilst this is disquieting in its own right, I am additionally concerned to note the Adviser's view that resorting to Doppler ultrasound (with its attendant risks) as a way of assessing foetal viability would not have been necessary had the midwives conducted a TV scan in accordance with RCOG Guidelines[20].

[20] However, I note the point made by the Health Board's Clinical Director for Obstetrics and Gynaecology (within the Health Board's response to the draft report) that there is a place for Doppler ultrasound in the first trimester in (exceptional) cases where doubt about the viability of a pregnancy remains *after* a second TV scan has been conducted.

49. In sum, I consider that the Advisers' criticisms of the operational conduct of the TA scans that Ms D received indicate a clear and concerning failure by both midwife sonographers to act in accordance with well-established clinical guidance. The assumption that an early silent miscarriage could be reliably diagnosed without reference to a TV scan was a fundamental error that was compounded by the failure to take account of the impact of Ms D's PCOS on her LMP; the failure to ensure that Ms D's bladder was full; the failure to optimise images and allow for imaging artefacts and, finally, the potentially dangerous use of Doppler ultrasound. Were it not for the fortunate circumstance of Ms D seeking her post-miscarriage care at an alternative hospital, it seems likely that these failings would have resulted in the medical termination of a healthy, viable pregnancy. I therefore **uphold** this part of the complaint.

The failure of the Health Board to implement changes to clinical guidelines that require midwives to conduct a TV scan in the diagnosis of early pregnancy loss

50. Whilst it is clear that the Health Board failed to amend its Directorate Protocol or its 2007 EPAU Guidelines in response to the RCOG's Addendum in 2011, it appears that the additional criticisms of the Health Board that I set out in the draft report in relation to its failure to revise and update its clinical guidelines in 2012 once this omission had been brought to the Health Board's attention (by Ms D and, subsequently, my office), stemmed from the Health Board providing me with information that it later described as "inaccurate and out of date ...[and] ...which did not reflect the fact that our practice had changed to reflect the RCOG Guidelines and Addendum and the more recent NICE Guidance". I consider that this error (made on two occasions during my investigation) compounds other failings identified in this report. I have therefore included an additional recommendation that the Health Board should, in due course, share with my office the outcome of the Root Cause Analysis of the investigation processes that it has commissioned.

51. I have identified a number of related policy and procedure failings which I summarise as follows:

- The Directorate Protocol sets out the minimal imaging and reporting requirements for a pregnancy dating scan[21]. It makes no reference to early pregnancy loss or its diagnosis.

- Conversely, the 2012/13 Guidelines for the Management of Early Pregnancy make no reference to dating scan procedure or to other routine applications of ultrasound in antenatal care.

- In view of the Health Board's description of the Directorate Protocol as "inaccurate and out of date..." it is not clear whether the policy frameworks governing routine sonography practice within the Directorate that the Protocol contained (and which do not appear to have been incorporated into the revised 2012/13 Guidelines) remain in force and/or whether they await updating or further revision.

- Notwithstanding the updating of the Health Board's 2007 EPAU Guidelines (in 2012) to incorporate the RCOG's 2011 Addendum, the RCOG's 2006 Green-top Guideline Number 25 presupposed that a pregnancy of uncertain viability should only be diagnosed "...after assessment by TV scan" (original emphasis). I can see no reflection of this in the Health Board's 2007 EPAU Guidelines.

- I have seen nothing in any of the guidance documentation to indicate that an early miscarriage may be diagnosed by reference to a TA scan (and/or Doppler ultrasound) only.

- In her letter to Mrs D, the Nurse Director commented that "…the recorded measurements were above the level where, according to our guidelines, it is recommended to offer a rescan or perform a TV scan". Whether the Nurse Director's reference to 'guidelines' relates to the Directorate Protocol or to the Health Board's 2007 EPAU Guidelines, I have been unable to identify any suggestion within either document that there is a 'level' beyond which the 'recorded [GS-CRL] measurements' preclude either a TV scan being performed or a rescan being offered.

[21] Section 3.5.1.

- I have been unable to reconcile the contents of the Directorate Protocol (or the 2007 EPAU Guidelines) with the Nurse Director's comment that the midwives, in this case, acted in accordance with its provisions. They clearly did not. I also share the First Adviser's view that it was unacceptable[22] for the Health Board to state that, as a result of Ms D's complaint: "...[the Guidelines] were reviewed but not amended".

- The Nurse Director's comment to Mrs D that "…when early pregnancy loss is suspected on the first scan then a second scan and check is now undertaken using a TV scan..." contradicts the Health Board's subsequent comment to me that "the guidelines were reviewed but not amended" and suggests that, prior to Ms D's complaint (since at least 2007), clinicians had been systematically failing to perform TV scans (and/or 'checks') on women with suspected early pregnancy loss.

- Finally, and despite the Health Board's provision of guidance documentation that I had not previously seen and which did not inform my preparation of the draft report, I have seen no evidence from the Health Board to counter my concern that, since at least 2011 (but possibly since 2006 and beyond), the clinical practices of midwives at UHW in respect of the use of TV scans in the diagnosis of early miscarriage have been potentially flawed. I anticipate that women who, in recent times, received a TA scan-based diagnosis of early miscarriage at the UHW (and subsequently underwent uterine evacuation) will find this extremely disturbing[23].

For these reasons, I **uphold** this part of the complaint.

[22] And, as it transpired, factually incorrect, given that, in September 2012, the 2007 EPAU Guidelines were significantly amended.
[23] For this reason (and in view of its role in matters relating to patient safety) I have taken the unusual step of forwarding a copy of this report, at draft stage, to the Health Inspectorate Wales.

Recommendations

52. I recommend that, within one month of the final report being issued:

a. The Health Board provides a fulsome, written apology to Ms D that recognises the practice and policy-implementation failings I have identified and which acknowledges the psychological distress caused to Ms D as a result.

b. The Health Board, in recognition of that distress and in recognition of the considerable inconvenience and expense that Ms D incurred in accessing alternative antenatal care, makes a payment to Ms D in the sum of £1,500.

c. That further to the Health Board agreeing to take immediate steps to implement RCOG guidance in respect of the diagnosis of early pregnancy loss and to promptly notify all relevant clinicians within the Directorate that it has done so, it provides documentary evidence of how this process was accomplished.

d. The Health Board takes immediate steps to amend/appropriately modify its Directorate Protocol to reflect updated RCOG (and recently published NICE) guidance in regard to the use of TV scans in the diagnosis of early pregnancy loss.

53. I further recommend that within three months of the final report being issued:

e. The Health Board provides evidence that it has appropriately reviewed and updated the CPD Portfolios of its midwife sonographers in regard to:
    - The RCOG Guidelines and Addendum (and recent NICE guidance) concerning the diagnosis of early pregnancy loss
    - The theory and practice of conducting TV scans
    - The use of Doppler ultrasound in early pregnancy
    - The optimising of TA/TV images
    - Taking account of clinically relevant conditions (such as PCOS) in calculating gestational age and in diagnosing miscarriage
    - Recognising hyperemesis.

f. The Health Board shares with the Ombudsman the outcome of its complaint investigation review of this case (its Root Cause Analysis).

54. I am pleased to note that, in commenting on the draft of this report, the Health Board has agreed to implement these recommendations. I am also pleased to note that, in response to a request that I made when I issued the draft version of this report, the Health Board has already taken steps to implement recommendations c. and d. In addition, the Health Board has also undertaken to implement recommendation e. within one month of the date of this final report rather than the three months that I initially proposed. Finally, I have added to my draft recommendations the further one that the Health Board, in due course, shares with my office the outcome of its Root Cause Investigation report.

Other matters: Archiving images

55. Both Advisers expressed concern at the failure of the Health Board to retain Ms D's dating scan images in a digital archive. In its 'Guidelines for Professional Working Standards' document, UKAS state that: "…for dating examinations the images displaying the measured embryonic or foetal sections referred to in the written report should be taken and stored". I therefore **further recommend** that the Health Board reviews its digital archiving policy in respect of antenatal sonography and considers implementing a system such as PACS[24] (if it has not already done so).

Peter Tyndall
Ombudsman 18 October 2013

[24] Picture Archiving and Communication System

Appendix A

Abbreviations used in this report

CPD	Continuous Professional Development
CRL	Crown Rump Length
EPAU	Early Pregnancy Assessment Unit
GS	Gestation Sac
ICP	Integrated Care Pathway
LMP	Last Menstrual Period
NICE	National Institute For Health and Care Excellence
PACS	Picture Archiving and Communication System
PCOS	Polycystic Ovary Syndrome
RCOG	Royal College of Obstetricians and Gynaecologists
TA (scan)	Trans Abdominal
TV (scan)	Trans Vaginal
UHW	University Hospital of Wales
UKAS	United Kingdom Association of Sonographers
USS	Utrasound scan

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