Title

Reduction in massive postpartum haemorrhage and red blood cell transfusion during a national quality improvement project, Obstetric Bleeding Strategy for Wales, OBS Cymru: an observational study.

Authors

Sarah F Bell*, MBBS, Consultant anaesthetist, Department of Anaesthetics, Intensive Care and Pain Medicine, Cardiff and Vale University Health Board, Cardiff, UK. Sarah.bell3@wales.nhs.uk

Rachel E Collis* MBBS, Consultant anaesthetist, Department of Anaesthetics, Intensive Care and Pain Medicine, Cardiff and Vale University Health Board, Cardiff, UK. Rachel.collis@wales.nhs.uk.

Philip Pallmann PhD, Deputy Director Research Design and Conduct Centre, Centre for Trials Research, College of Biomedical and Life Sciences, Cardiff University, Cardiff UK. pallmannp@cardiff.ac.uk

Christopher Bailey MBChB, Anaesthetic specialist registrar, Department of Anaesthetics, Intensive Care and Pain Medicine, Betsi Cadwaladr University Health Board, Glan Clwyd Hospital, Bodelwyddan, UK. Christopher.bailey@wales.nhs.uk

Kathryn James MBChB, Anaesthetic specialist registrar, Department of Anaesthetics, Intensive Care and Pain Medicine, Cardiff and Vale University Health Board, Cardiff, UK. Kathryn.james2@wales.nhs.uk.

Miriam John MBBCh, Anaesthetic specialist registrar, Department of Emergency Medicine, Aneurin Bevan University Health Board, Newport, UK. Miriam.john2@wales.nhs.uk.

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Kevin Kelly MBChB, Anaesthetic specialist registrar, Department of Anaesthetics, Intensive Care and Pain Medicine, Betsi Cadwaladr University Health Board, Glan Clwyd Hospital, Bodelwyddan, UK. Kevin.kelly@wales.nhs.uk.

Thomas Kitchen MBBCh, Consultant anaesthetist, Department of Anaesthetics, Intensive Care and Pain Medicine, Cardiff and Vale University Health Board, Cardiff, UK. Thomas.kitchen@wales.nhs.uk.

Cerys Scarr MBBS, Obstetric Specialist registrar, Department of Obstetrics and Gynaecology, Cardiff and Vale University Health Board, Cardiff, UK. Cerys.scarr@wales.nhs.uk.

Adam Watkins BA, Information analyst, Improvement Cymru, Public Health Wales, Cardiff, UK. Adam.watkins@wales.nhs.uk.

Tracey Edey MSc, Senior midwife, Department of Midwifery, Singleton Hospital, Swansea, UK. Tracey.edey@wales.nhs.uk.

Elinore Macgillivray RM, Midwife and senior improvement manager, Improvement Cymru, Public Health Wales, Cardiff, UK. Elinore.macgillivray2@wales.nhs.uk.

Kathryn Greaves BSc, Deputy Head of midwife, Department of Obstetrics and Gynaecology, Cwm Taf Morgannwg Health Board, Merthyr Tydfil, UK. Kathryn.greaves@wales.nhs.uk.

Ingrid Volikas MBBS, Consultant anaesthetist, Department of Anaesthetics, Intensive Care and Pain Medicine, Betsi Cadwaladr University Health Board, Glan Clwyd Hospital, Bodelwyddan, UK. Ingrid.volikas@wales.nhs.uk.

James Tozer MBBCh, Consultant anaesthetist, Department of Anaesthetics and Intensive Care, Aneurin Bevan University Health Board, Newport, UK. James.tozer@wales.nhs.uk.

Niladri Sengupta MBBS, Consultant obstetrician, Department of Obstetrics and Gynaecology, Betsi Cadwaladr University Health Board, Glan Clwyd Hospital, Bodelwyddan, UK. Niladri.sengupta@wales.nhs.uk.

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Iolo Roberts MBChB, Anaesthetic specialist registrar, Department of Anaesthetics, Intensive Care and Pain Medicine, Betsi Cadwaladr University Health Board, Glan Clwyd Hospital, Bodelwyddan, UK. Iolo.roberts2@wales.nhs.uk.

Claire Francis MRCOG, Consultant obstetrician, Department of Obstetrics and Gynaecology, Cardiff and Vale University Health Board, Cardiff, UK. Helen.francis2@wales.nhs.uk.

Peter W Collins MD, Professor of haematology, Institute of Infection and Immunity, School of Medicine, Cardiff University, Cardiff, UK. Peter.collins@wales.nhs.uk.

* SFB and REC are joint first authors and contributed equally to the project and manuscript.

Corresponding author

Peter W Collins MD, Institute of Infection and Immunity, School of Medicine, Cardiff University, Cardiff, UK. Email: Peter.collins@wales.nhs.uk

Telephone: 02920744144

Running title

Reduction in postpartum and transfusion during OBS Cyrmu

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Summary

Background

Postpartum haemorrhage (PPH) is a major cause of maternal morbidity and mortality and its incidence is increasing in many countries despite comprehensive management guidelines. A national quality improvement programme called the Obstetric Bleeding Strategy for Wales (OBS Cymru) was introduced in all obstetric units in Wales. The aim was to reduced moderate bleeds (1000 mL) progressing to massive haemorrhage (2500 mL or more) and the need for red blood cell transfusion.

Methods

A PPH care bundle was introduced into all 12 obstetric units in Wales and included all women giving birth in 2017 and 2018 (n=61094). The care bundle consisting of: universal risk assessment, quantitative measurement of blood loss after all deliveries (as opposed to visual estimation), structured escalation to senior clinicians and point-of-care viscoelastometric-guided early fibrinogen replacement. Data were collected at each obstetric unit and submitted to a national database. The main outcome measures were incidence of massive PPH, defined as bleeds of 2500 mL or more and red blood cell transfusion.

Results

There was good uptake of the intervention with use of quantitative blood loss measurement increasing to 98.1% of all maternities. Massive haemorrhage decreased by 1.10 (95% CI 0.28 to 1.92) per 1000 maternities per year (P=0.011). Fewer women progressed from moderate bleeds to massive haemorrhage in the last 6 months, 74/1490 (5.0%), than in the first 6 months, 97/1386 (7.0%), (P=0.021). Units of red blood cells transfused decreased by 7.4 (95% CI 1.6 to 13.2) per 1000 maternities per year (P=0.015). Red blood cells were transfused to 350/15204 (2.3%) and 268/15150 (1.8%) (P=0.001) in the first and last 6 months, respectively. There was no increase in the number of

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women with lowest haemoglobin below 80 g/L during this time period. Infusions of fresh frozen plasma fell and there was no increase in the number of women with haemostatic impairment.

Conclusions

The OBS Cymru care bundle was feasible to implement and associated with progressive, clinically significant improvements in outcomes for PPH across Wales. It is applicable across obstetric units of widely varying size, complexity and staff mixes.

Key words

Postpartum haemorrhage; quality improvement; coagulopathy; blood transfusion; viscoelastometry

Introduction

Bleeding after childbirth (postpartum haemorrhage, PPH) is the leading cause of maternal death worldwide.[1] In resource rich countries PPH causes 80% of severe maternal morbidity and its incidence is increasing in many regions,[2 3] including Wales,[4] despite international guidance.[5-7] In the UK PPH is described as moderate at 1000 mL blood loss and severe at 2000 mL.[6] Massive PPH is defined as 2500 mL or more and, in resource rich countries, is associated with a hysterectomy rate of 6% and intensive care admission in 11.8% of cases.[3] Post-traumatic stress disorder is common after PPH.[8] Multi-professional management of PPH requires the skills of midwives, obstetricians, anaesthetists, healthcare support staff and haematologists working in an effective team. Variations in care are widely reported, with delays in escalation to senior staff a common theme.[9 10] A recent confidential enquiry identified deficiencies in care, compared to guidelines, in 90% of cases.[11]

Bleeding after childbirth may be exacerbated by haemostatic impairment. A Clauss fibrinogen below 2 g/L is associated with progression of bleeding,[12 13] although clinically significant deficiencies of

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other clotting factors and platelets are less common.[14-16] In severe PPH, laboratory coagulation results are often too slow to be useful clinically and guidelines recommend the use of empirical treatment with fixed ratios of red blood cells (RBC), fresh frozen plasma (FFP) and platelets, based on data derived from major trauma[5 6]. This results in many women receiving blood components when haemostasis is normal.[17] Point-of-care haemostasis test results, using viscoelastometry, are available within 10 minutes and can direct timely and targeted replacement of fibrinogen and avoid unnecessary FFP during PPH.[15 18-20]

International PPH quality improvement projects have been undertaken with the aim of standardising care and improving outcomes. Interventions have included risk assessment, quantitative measurement of blood loss and escalation to senior clinicians, although to date all have used empirical, fixed-ratio transfusion therapy.[21-24] OBS Cymru is a national quality improvement project developed by combining lessons learnt during 10-years of research[17] with themes emerging from international PPH quality improvement projects.[21-24] OBS Cymru introduced an integrated care bundle into all obstetric units in Wales.[25] A key and unique feature was the inclusion of viscoelastometric point-of-care haemostatic tests to guide targeted blood component administration.[15 18-20] We report the impact of OBS Cymru over a 2-year period.

Methods

Intervention

Launched in November 2016, OBS Cymru introduced a PPH care bundle between January and April 2017 into all 12 obstetric units in Wales. These obstetric units support between 500 and 6000 births per year, with about 31,000 births across Wales. The lead research and development office designated OBS Cymru as a quality improvement project and service evaluation according to NHS

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guidance. Consequently ethical approval and individual consent to collect and report data was not required.

Patient and public representatives had provided feedback through local focus groups regarding important outcomes and priorities throughout the programme of research that underpinned OBS Cymru.[17] A James Lind Alliance partnership into bleeding disorders in 2018 had ranked research in the field as the highest priority.[26] Two additional women, representing patients and the public, sat on the OBS Cymru steering committee from its inception and were involved in the design and conduct of the project throughout.

The design, initiation and project interventions have been described in detail previously.[25] OBS Cymru funding provided a Rotem Sigma® point-of-care coagulation device (Instrumentation Laboratories, Werfen, Barcelona, Spain) for use in each obstetric unit. The intervention promoted:

1. Risk assessment of all mothers admitted to delivery suite.
2. Quantitative measurement of blood loss from delivery using volumetric and gravimetric techniques for all births as opposed to visual estimation. Details of the method and validation data supporting quantitative measurement have been published. [4 25 27]
3. Escalation of care to senior clinicians, if not already involved, at specified volumes of blood loss. At the latest, a senior midwife was informed at 500 mL, an obstetrician and anaesthetist were required to attend the mother at 1000 mL and a consultant obstetrician and anaesthetist informed at 1500 mL.
4. Point-of-care tests of haemostasis were taken at 1000 mL or earlier for clinical concern. If required, targeted, early replacement of fibrinogen was administered. The algorithm and recommended dose of fibrinogen or FFP is shown in supplementary material figure 1. Tranexamic acid was infused as soon as abnormal bleeding was recognised and repeated if bleeding continued.[28]

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The intervention was intended for all births and was not limited to those complicated by abnormal bleeding. It was underpinned by a standardised paperwork proforma that prompted management and created a contemporaneous record of findings and actions.[29] An all Wales guideline reinforced the intervention and standardised obstetric management.[30] Antenatal anaemia, cell salvage and transfusion policies were unchanged throughout the project.

The Rotem point-of-care coagulation devices were supported by a validated algorithm[15 17 18 29] and were compliant with internal and external quality assurance. A minor revision of the Rotem interpretation algorithm was introduced in 2018 to emphasise the importance of correcting hypofibrinogenaemia before considering FFP (supplementary material figure 1).[29] Haemostatic impairment was defined as fibrinogen <2 g/L, Fibtem A5 <12 mm or PT or aPTT >1.5 times normal[6 31] (equating to PT >16 or aPTT >50 secs). In autumn 2018 all Rotem devices received a hardware update which was associated with slightly lower Fibtem A5 measurements, the blood product algorthim was not adjusted.

The national team co-ordinated multi-professional training at each unit, as described,[25] this training was front-loaded at the start of the project with top-up training throughout the 2 year period. A lead midwife, obstetrician, anaesthetist and haematologist were appointed at each site to support ongoing training and oversee the project locally with the midwifery time funded by the project. The intervention was introduced during the first 6 month period (January to June 2017) and adopted progressively by obstetric units throughout 2017 and 2018. Training covered quantitative measurement of blood loss, escalation of care and interpretation of Rotem results. The OBS Cymru principles were integrated into PROMPT (PRactical Obstetric Multi-Professional Training) for Wales to support sustainability.[32] Annual multi-professional national meetings allowed dissemination of learning and sharing of good practice.

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Data sources

The Welsh Maternity Indicators Dataset (NHS Wales Informatics Service) provided data regarding number of births and mode of delivery. An all Wales OBS Cymru database was established by Improvement Cymru. Women experiencing bleeds ≥1000 mL or in whom there was concern about abnormal bleeding had a limited dataset collected. Women with bleeds ≥1500 mL or who received a transfusion had more detailed information collected (supplementary figure 2).

In addition, five audits were undertaken to establish the uptake of measured blood loss and use of the paperwork proforma and the risk assessment tool. Audits included up to 30 consecutive women from each obstetric unit, irrespective of blood loss.

Anonymous patient surveys were performed in 2017 (June–December) and 2018 (September). Local teams circulated forms to women experiencing PPH ≥1000mL. Questions explored communication with the mother and her family and areas for improvement in care. A staff questionnaire was circulated to local leadership teams between September and December 2018 to aid understanding of how OBS Cymru had changed local practice, to investigate which components of the intervention were thought to be important and barriers to change.

Analysis

Data are summarised descriptively with continuous variables reported as median, inter-quartile range (IQR) and range and categorical variables as number and percent or per 1000 maternities. Descriptive data were reported in four 6-month periods between January 2017 and December 2018 to show changes across time. The intervention was being implemented during January to June 2017 and this time period is compared to the last 6 month period, after the intervention had been adopted, in some analyses.

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Changes in the proportion of women experiencing massive PPH, the number of units of RBC transfused and intensive care admission were analysed by linear regression using the all Wales monthly data. A simple linear relationship was found to be the best model, with higher-order terms not leading to any substantial improvements in the model. The dependent variables were bleeds ≥2500 mL, units of RBC transfused in Wales and episodes of intensive care and the independent variable was months in each case. Estimates are reported with 95% confidence intervals (CI). Sensitivity analyses using quasi-Poisson regression models with total maternities as offset provided very similar results. Chi square test was used to compare events in the first and last 6 month periods. Data were analysed using SPSS version 23, R version 3.6.0 and ggplot2 version 3.2.0.

Role of funder

The funder had no role in study design; collection, analysis, and interpretation of data; writing of the report; and the decision to submit the paper for publication.

Results

Demographics

Between 1st January 2017 and 31st December 2018, 61094 women gave birth in Wales. Mode of delivery was unassisted vaginal for 62.6%, instrumental vaginal 9.5%, emergency caesarean section 14.4% and non-emergency caesarean section 13.5%. There were 6024 episodes (98.6/1000 maternities) recorded on the OBS Cymru database because of PPH ≥1000 mL or clinical concern of abnormal bleeding. The number of episodes increased during the project, possibly because of better recognition of total blood loss as quantitative measurement replaced visual estimation (Table 1). For PPH ≥1500 mL, 2209 episodes (36.2/1000 maternities) were reported. The mode of delivery, causes of bleeding and first recorded haemoglobin and Clauss fibrinogen remained constant throughout (Table 1).

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Uptake of OBS Cymru intervention

Uptake increased for all components of the OBS Cymru intervention at all sites. Uptake increased progressively across the 2 year period (Table 1 and Figure 1). Quantitative blood loss measurement increased from 83% to 98% for bleeds ≥1000 mL and Rotem analysis increased from 38% to 68% of episodes with ≥1500 mL blood loss. The proportion of women receiving treatment that was compliant with the blood component algorithm increased from 19% to 68% (Table 1). Audit data of consecutive women, irrespective of blood loss volume, showed the variation between sites in the percentage of maternities where blood loss was measured, risk assessment performed and standardised paperwork used (Figure 1). The same information, dependent on mode of delivery, is shown in supplemental figure 3.

Severity of postpartum haemorrhage

Incidence of massive postpartum haemorrhage

Massive PPH (blood loss of 2500 mL or more) fell from 6.4 to 4.9/1000 maternities between the first and last 6 month periods (Table 2). Regression analysis suggested a progressive fall across the 24 month period with an estimated decrease in massive PPH of 1.10 (95% CI 0.28 to 1.92)/1000 maternities/year (P=0.011) (Fig 2a). The incidence of massive PPH at each obstetric unit during the first and last 6 months is shown in Fig 2b and 2c. These illustrate the overall decrease in massive PPH in Wales and a reduction in the number of obstetric units with massive haemorrhage rates above 10/1000 maternities. More detailed obstetric unit level data are shown in supplementary material table 1. Information about the incidence of massive PPH in Wales before OBS Cymru is shown in supplementary figure 4.

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The all Wales incidence of PPH ≥1000 mL increased, bleeds ≥1500 remained stable and ≥2000 mL fell slightly (Table 2) throughout the 2 year period. There were progressively fewer episodes of moderate PPH (1000 mL) developing into massive haemorrhage throughout the 2 year period; in the first 6 months, 97/1386 (7.0%), second 6 months 92/1480 (6.2%), third 6 months 76/1412 (5.3%) and last 6 months, 74/1490 (5.0%) (P=0.021 comparing first and last 6 months).

Intensive care admission, hysterectomy and length of hospital stay

The estimated decrease in intensive care admission was 0.31 (95% CI: -0.21–0.84)/1000 maternities/year (P=0.23). The total time spent in intensive care fell but this was due mainly to a prolonged stay of 168 hours for one woman in the first 6 months (Table 2). There were 22 hysterectomies in total (0.36/1000 maternities), of which 19 were associated with PPH (0.31/1000) (Table 2). Of these hysterectomies, 11/19 (58%) were for placenta accreta, increta or praevia and are likely to represent appropriate care.[6 7] The eight hysterectomies for PPH that were unrelated to abnormal placentation occurred at 0.13, 0.06, 0.27 and 0.07/1000 maternities in each 6 month period. These numbers are too small for meaningful comparison. The length of hospital stay for women with PPH ≥1500 mL did not change (Table 2).

Transfusion of red blood cells and blood components

The proportion of women transfused RBCs for PPH fell from 350/15204 (2.3%) to 268/15150 (1.8%) between the first and last 6 month periods, (P=0.0010). The total number of units of RBCs transfused in Wales fell from 54.1 to 40.2/1000 (Table 3). Regression analysis estimated that the number of units of RBCs transfused for PPH fell by 7.4 (95% CI 1.6-13.2)/1000 maternities/year, P=0.015 (Figure 3a and table 3). The total number of units of RBC/1000 maternities transfused at each obstetric unit in the first and last 6 months of the project is shown in Fig 3b and 3c. The number of obstetric units that transfused ≥50 units of blood per 1000 maternities fell from 8/12 to 3/12 (P=0.041). Despite the reduction in RBC transfusions, the proportion of women with a lowest haemoglobin <80 g/L did not increase (Table 3).

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The proportion of women receiving FFP fell by 42% (P=0.088) and the use of fibrinogen concentrate increased by 37% (P=0.26) between the first and last 6 months (Table 3). The decrease in FFP usage occurred mainly in the final 6 months after clinicians had been encouraged to correct fibrinogen before infusing FFP.[29] Infusion of cryoprecipitate and platelets was very uncommon (Table 3).

Haemostatic impairment

The number of laboratory coagulation tests reported increased over time and so differences between 6 month periods must be interpreted with caution. Despite this, the restrictive use of FFP was not associated with an increase in haemostatic impairment as demonstrated by the lowest fibrinogen and the longest PT/aPTT (Table 3). The median Fibtem A5 was 3 mm lower and more women had a Fibtem A5 <12 mm in the last 6 months, this is discrepant to the laboratory fibrinogen results and probably reflects the change in Fibtem A5 after the Rotem devices were updated. This may have affected the number of women receiving fibrinogen concentrate which increased in the last 6 months (Table 3).

Maternal and staff feedback

Eight obstetric units collected 47 patient surveys in September 2018, mean (range) blood loss 1716 (1029-5743) mL. In total 66% (31/47) of women remembered being told that they were having abnormal bleeding. Of the women answering a question, 94.8% (37/39) had their questions answered fully and 100% (38/38) felt listened to by staff at the time of the event. Although 95% (39/41) felt well supported during the PPH, 29% (8/28) said that care could have been improved and better communication with mother and partner was suggested. No mother reported that the process of measuring blood loss or the escalating the multi-professional team response to her bleeding had a negative impact on the birth experience.

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Local leadership staff survey, response rate 29/46 (63%), reported that OBS Cymru had changed individual and unit level management of PPH. Table 4 shows the components of the intervention that clinicians thought had led to change.

Discussion

OBS Cymru was a national quality improvement project that aimed to reduce morbidity associated with PPH by introducing a care bundle into all 12 obstetric units in Wales. There were clinically and statistically significant reductions in massive haemorrhage across Wales with a 29% fall in the number of women progressing from moderate to massive PPH. The number of women exposed to RBC transfusion fell by 22% and the number of units of blood transfused for PPH decreased by 26%.

Adoption of the whole care bundle progressively improved throughout the project with quantitative blood loss measurement approaching 100% during the last 6 months. This technique is more accurate than visual estimation, which tends to under-report actual volume, especially for large bleeds.[33-38] The increase in bleeds ≥1000 mL is likely to be a consequence of relative under-reporting during the early stages of OBS Cymru when quantitative measurement was being introduced. Similarly, recognition of massive haemorrhage is likely to have improved over time and so the reduction in the rate of PPHs ≥2500 mL may be an under-estimate.

The main strength of this report is that it represents service change implemented across an unselected real-world national cohort of women. It includes all women giving birth in Wales and all obstetric units irrespective of size, case mix and staffing levels. Women who gave birth in the community and experienced bleeding were transferred to an obstetric unit and are included in the results. The improvements in outcomes are internally consistent and continued throughout the project. The population, mode of delivery and cause of bleeding are similar to many high resource countries making the results widely applicable.

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The quality improvement methodology used means that change over time has been reported and it cannot be known for certain that the improved outcomes were the result of the care bundle. However, improvements of the size observed are very unlikely to have happened simultaneously in multiple centres by chance and progressive improvement in outcomes coincided with the progressive adoption of the intervention. The largest improvements in massive haemorrhage occurred in obstetric units with high initial rates possibly, in part, due to regression towards the mean.

The blood component algorithm emphasised early treatment of hypofibrinogenaemia in line with previous studies and guidelines.[5 6 12 15 18 20 39] In the last 6 month period the Rotem devices had a hardware update associated with a fall in median Fibtem. Clinicians should be wary of variations between and within point-of-care devices and engage local laboratory expertise and monitor local normal ranges.[19]

Quantitative measurement of blood loss alone does not improve outcomes.[40] However, when integrated into a care bundle such as OBS Cymru, real time accurate knowledge of blood loss acts as an enabler to prompt teams to escalate care according to guidelines.[6 39] The changes in massive haemorrhage and concurrent uptake of OBS Cymru interventions suggest that measuring blood loss and using Rotem, facilitated by multi-professional team attendance at the bedside, were important factors. This was supported by feedback from clinicians, with blood loss measurement, team working and point-of-care coagulation tests stated to be the most influential changes to practice.

The rate of hysterectomy for PPH remained low throughout the project (0.31/1000 maternities). Consideration of early hysterectomy in cases of abnormal placentation is advocated by guidelines and 58% of hysterectomies were reported to have abnormal placental implantation.[6 7] Other studies report a hysterectomy rate of 0.6-1/1000 maternities[3 21] demonstrating that hysterectomies were uncommon in Wales before OBS Cymru and this may explain why improvements were not seen.

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The number of women transfused RBCs for PPH fell by 22%, equivalent to about 160 women in Wales avoiding transfusion annually. RBC transfusion fell to 40 units/1000 maternities compared to a UK average of about 100 units/1000 maternities. Despite this, the lowest haemoglobin during a PPH was similar throughout the 2 year period and the proportion of women with haemoglobin below 80 g/L did not increase, suggesting the reduction in transfusion reflected reduced bleeding rather than withholding RBCs inappropriately. Treatment of antenatal anaemia was consistent throughout the project supported by the finding that the first recorded haemoglobin remained unchanged across the 2 year period.

RBCs, FFP and platelets are often transfused in fixed-ratios for major PPH[5 6 21 24 41-44] based on data derived from major trauma.[45 46] PPH differs from major trauma because at term women have an expanded circulating blood volume and are hypercoagulable[47 48] and can maintain adequate haemostasis despite moderate blood loss.[15 16] Clinically significant deficiency of coagulation factors other than fibrinogen is uncommon in PPH and fixed-ratio transfusion algorithms may result in women receiving FFP with normal coagulation.[17] In OBS Cymru PT/aPTT >1.5 times normal was seen in 1% of women experiencing a PPH ≥1500 mL whilst fibrinogen <2 g/L occurred in about 5%, consistent with other studies.[13 15 16] In OBS Cymru Extem clot time was used to guide FFP infusion, with a 42% reduction in women receiving FFP. This occurred mainly in the last 6 months after the importance of correcting hypofibrinogenaemia before FFP administration was emphasised. During this time fewer women had PT/aPTT >1.5 times normal demonstrating that conservative use of FFP during PPH, guided by point-of-care tests, does not increase haemostatic impairment.[15]

Other large-scale quality improvement projects for PPH have combined risk assessment, measured blood loss, standardised escalation and empirical, as opposed to targeted, blood component resuscitation.[21 22 24] These initiatives have shown that, with high adoption of the interventions, severe morbidity can be reduced.[21] Sites adopting The California Maternal Quality Care Collaborative care bundle reported a 21% reduction in severe maternal morbidity.[24] The Association of Women's

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Health, Obstetric, and Neonatal Nurses PPH Project implemented a care bundle into 58 hospitals over 18 months. There was variable uptake and no statistically significant difference in maternal morbidity.[22] The lack of dedicated multi-professional time was identified as a barrier. The use of multi-professional leadership teams in OBS Cymru, embedded at both a local and national level, with dedicated time to lead change, contributed to the speed, uptake and success of the project.

The integrated care bundle introduced universal risk assessment to identify mothers of increased risk of PPH, whilst quantitative measurement of blood loss enabled early recognition of abnormal bleeding and progression. This facilitated escalation to more experienced midwives and obstetricians to treat the underlying cause of bleeding earlier whilst anaesthetists focused on timely resuscitation. Point-of-care tests identified cases of hypofibrinogenaemia, allowing targeted and rapid correction of coagulopathy whilst avoiding inappropriate FFP in the majority. Early identification of normal coagulation facilitated escalation of obstetric measures to control bleeding.

Conclusions

A care bundle for the management of PPH, that included point-of-care tests of coagulation to guide the treatment of coagulopathy, was introduced as a national quality improvement project involving more than 30000 maternities annually. Clinically significant improvements in PPH outcomes, including rates of massive haemorrhage and RBC transfusion are achievable on a national level using quality improvement methodology. Obstetric units of all size and case mix implemented and benefitted from the care bundle with improved national outcomes. These results suggest that trends towards increasing incidence of severe PPH seen over recent years can be reversed by structured multi-professional team interventions. A cluster randomised trial is needed to investigate whether the OBS Cymru care bundle improves outcomes for PPH compared to standard care.

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List of abbreviations

PPH: Postpartum haemorrhage

RBC: red blood cells

FFP: fresh frozen plasma

Declarations

Ethical approval and consent to participate:

In the UK, the need for submission to an ethics committee is governed by the Health Research Authority. The data published in this paper complies with the definition of service evaluation and, therefore, according to the rules in the UK, it did not require research ethics committee review or individual consent to report data, information available at http://www.hra-decisiontools.org.uk/research/docs/DefiningResearchTable_Oct2017-1.pdf (accessed 5th Feb 2021). It is the role of the lead research and development office to determine whether a project fulfils the criteria for research or service evaluation. In this case the lead research and development office was at the Cardiff and Vale University Health Board and they concluded that the OBS Cymru quality improvement project was service evaluation according to NHS guidance. Email confirmation of this decision is included in supplementary materials.

Consent for publication:

Not applicable

Availability of data and materials:

The datasets generated and/or analysed during the current study are not publicly available because there are held on a quality improvement database hosted by Cardiff and Vale University Health Board. Anonymised data are available from the corresponding author on reasonable request.

Competing interests:

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All other authors have no conflicts of interest to declare.

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Werfen loaned 10 Rotem Sigma devices to sites in Wales for the duration of the project and subsidised reagents required to perform assays. Werfen provided technical support, maintenance and annual service of all 12 Welsh devices, funded through the Welsh Government grant.

Authors contributions:

SFB: designed OBS Cymru, obtained funding, led the quality improvement project, analysed data and co-wrote the first draft of the manuscript

REC: led the research under-pinning OBS Cymru, designed OBS Cymru, obtained funding, led the quality improvement project, analysed data and co-wrote the first draft of the manuscript.

PP: analysed data and revised the manuscript

CB: designed OBS Cymru, managed the quality improvement project, collected data and revised the manuscript

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KJ: designed OBS Cymru, managed the quality improvement project, collected data and revised the manuscript

MJ: designed OBS Cymru, managed the quality improvement project, collected data and revised the manuscript

KK: designed OBS Cymru, managed the quality improvement project, collected data and revised the manuscript

TK: designed OBS Cymru, managed the quality improvement project, collected data and revised the manuscript

CS: designed OBS Cymru, managed the quality improvement project, collected data and revised the manuscript

AW: designed and developed the OBS Cymru database, analysed data and revised the manuscript

TE: designed OBS Cymru, managed the quality improvement project, collected data and revised the manuscript

EM: designed OBS Cymru, managed the quality improvement project, collected data and revised the manuscript

KG: designed OBS Cymru, managed the quality improvement project, collected data and revised the manuscript

IV: designed OBS Cymru, managed the quality improvement project, collected data and revised the manuscript

JT: designed OBS Cymru, managed the quality improvement project, collected data and revised the manuscript

NS: managed the quality improvement project, collected data and revised the manuscript

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IR: managed the quality improvement project, collected data and revised the manuscript

CF: designed OBS Cymru, managed the quality improvement project, collected data and revised the manuscript

PWC: led the research under-pinning OBS Cymru, managed the quality improvement project, analysed data and co-wrote the first draft of the manuscript.

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Singleton Hospital, Swansea: C Harris, S Williams, M Garry, N Jenkins, L Mukhopadhyay, D Apsee, H Saitch and A Benton

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626 Table 1. Demographics of women experiencing postpartum haemorrhage in Wales and uptake of the
627 OBS Cymru intervention

	Jan-Jun 2017	Jul-Dec 2017	Jan-Jun 2018	Jul-Dec 2018
Total number of maternities in Wales	15204	15986	14754	15150
Episodes with ≥1000 mL blood loss or clinical concern of abnormal bleeding N (/1000 maternities)	1448 (95.2)	1519 (95.1)	1499 (101.6)	1558 (102.8)
Episodes with ≥1500 mL blood loss N (/1000 maternities)	547 (36.0)	588 (36.8)	530 (35.9)	544 (35.9)
Mode of delivery				
Unassisted vaginal: n (%)	211 (38.6)	228 (38.8)	203 (38.3)	184 (33.8)
Instrumental vaginal: n (%)	115 (21.0)	116 (19.7)	123 (23.2)	147 (27.0)
Non-emergency caesarean section: n (%)	181 (33.1)	194 (33.0)	170 (32.1)	161 (29.6)
Emergency caesarean section: n (%)	40 (7.3)	50 (8.5)	34 (6.4)	51 (9.4)
Not recorded: n (%)	0 (0)	0 (0)	0 (0)	1 (0.2)
Cause of bleeding for episodes with ≥1500 mL blood loss N (%) (NB many bleeds had multiple causes)				
Uterine atony	323 (59.0)	352 (59.9)	276 (52.1)	315 (57.9)
Surgery related	142 (26.0)	142 (24.1)	135 (25.5)	161 (29.6)
Genital tract trauma	175 (32.0)	185 (31.5)	178 (33.6)	189 (34.7)
Extragenital bleeding only	6 (1.1)	1 (0.2)	12 (2.3)	5 (0.9)
Uterine rupture	4 (0.7)	4 (0.7)	1 (0.2)	0 (0.0)
Placenta praevia	16 (2.9)	8 (1.4)	15 (2.8)	10 (1.8)
Placenta accrete	5 (0.9)	7 (1.2)	5 (0.9)	5 (0.9)
Amniotic fluid embolus	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)
Uterine inversion	1 (0.2)	1 (0.2)	0 (0.0)	1 (0.2)
Placental abruption	17 (3.1)	14 (2.4)	17 (3.2)	23 (4.2)
Retained products	63 (11.5)	46 (7.8)	57 (10.8)	45 (8.3)
No cause reported	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)
First blood test after recognition of haemorrhage for bleeds ≥1500 mL				
Haemoglobin g/L: Med (IQR), range	104 (93-114) 62-156	104 (94-115) 57-164	103 (93-115) 60-146	102 (92-113) 52-144
Clauss fibrinogen g/L: Med (IQR)	4.2 (3.6-5) 0.3-7.9	4.2 (3.6-4.9) 0.6-7.4	4.3 (3.7-4.9) 0.3-8.3	4.3 (3.7-4.9) 0.4-9.8
Uptake of OBS Cymru intervention				
Risk assessment completed. All Wales: n (% of all episodes ≥1000 mL)[1]	23 (1.6)	399 (26.2)	931 (62.1)	1003 (64.4)
Percent completion in individual units: Med (IQR) range[1]	0.8 (0-1.7) 0-3.3	25 (22-40) 16-59	82 (74-90) 36-96	88 (68-97) 37-99
Paperwork completed. All Wales: n (% of all episodes ≥1000 mL)[1]	28/1166 (2.4)	503/1274 (39.5)	724/1210 (59.8)	802/1262 (63.5)
Percent completion in individual units: Med (IQR), range[1]	1.6 (0-3.1), 0-6.1	45.4 (24.0-53.2), 10.2-66.4	53.3 (40.6-79.7) 18.1-97.2	62.4 (45.9-85.1) 10.9-97.6
Blood loss quantitatively measured All Wales: n (% of all episodes ≥1000 mL)	1204 (83)	1409 (93)	1404 (93.7)	1530 (98.2)
Percent blood loss measurement in individual units: Med (IQR) range	76.7 (81.9-90.2) 38-98	93.6 (88.6-97.6) 86-100	93.7 (88.8-98.5) 85-100	99.1 (98.3-99.6) 95-100
Rotem analysis performed: n (% of episodes with bleeds ≥1500 mL)	206 (37.7)	346 (58.8)	380 (71.7)	371 (68.2)[2]
Percent Rotem analyses performed in individual units: Med (IQR) range	24.9 (16.2-44.9) 10-88	57.2 (39.0-74.4) 9-88	59.2 (67.5-83.0) 39-100	85.2 (75.3-90.6)[2] 16-96
Rotem analysis requiring intervention and acted on according to algorithm: n (%)	3/16 (19)	18/35 (51)	19/29 (65)	25/37 (68)[2]

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Legend: [1]One obstetric unit did not report any data for this intervention and has been excluded from the analysis and [2]two obstetric units did not return Rotem data between July and December 2018. A more complete dataset was collected for episodes ≥1500 mL.

Table 2 Bleed volume, admission to intensive care, hysterectomy and length of stay

	Jan-Jun 2017	Jul-Dec 2017	Jan-Jun 2018	Jul-Dec 2018
Bleeds ≥1000 mL: n (/1000 maternities)	1386 (91.2)	1480 (92.6)	1412 (95.7)	1490 (98.3)
Bleeds ≥1500 mL: n (/1000 maternities)	547 (36.0)	589 (36.8)	530 (35.9)	544 (35.9)
Bleeds ≥2000 mL: n (/1000 maternities)	228 (15.0)	232 (14.5)	228 (15.5)	209 (13.8)
Bleeds ≥2500 mL: n (/1000 maternities)	97 (6.4)	92 (5.8)	76 (5.2)	74 (4.9)
Admission to intensive care for PPH: n (/1000 maternities)	10 (0.66)	12 (0.75)	9 (0.61)	6 (0.40)
Hours in intensive care for PPH: n (/1000 maternities)	322.3 (21.2)*	290 (18.1)	180 (12.2)	124 (8.2)
Hysterectomy associated with PPH: n (/1000 maternities)	5 (0.33)	3 (0.19)	8 (0.54)	3 (0.20)
Length of hospital stay (days) for women with PPH ≥1500 mL: Med (IQR), range	2.09 (1.37-3.27) 0.08-13.3	2.01 (1.29-3.22) 0.02-13.3	2.12 (1.45-3.23) 0.12-26.6	2.11 (1.44-3.20) 0.05-28.9

Legend: The change in number of women with moderate and severe PPH throughout the project is shown. The number of bleeds between 1000 and 1499 mL/1000 maternities was 55.2, 55.7, 59.8 and 62.4 in each six month period. * one woman spent 168 hours on intensive care between January and June 2017.

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655 Table 3. Transfusion and haematological results for postpartum haemorrhage

	Jan-Jun 2017	Jul-Dec 2017	Jan-Jun 2018	Jul-Dec 2018
Transfusion of red blood cells and blood components				
Number of women transfused red blood cells: n (/1000 maternities)	350 (23.0)	270 (16.9)	278 (18.8)	268 (17.7)
Total number of units of red blood cells transfused: n (/1000 maternities)	823 (54.1)	656 (41.0)	636 (43.1)	609 (40.2)
Number of women transfused ≥5 units red blood cells: n (/1000 maternities)	16 (1.1)	14 (0.9)	14 (1.0)	11 (0.7)
Number of women transfused FFP: n (/1000 maternities)	26 (1.7)	20 (1.3)	21 (1.4)	15 (1.0)
Total number of units of FFP transfused: n (/1000 maternities)	87 (5.7)	78 (4.9)	74 (5.0)	37 (2.4)
Number of women transfused fibrinogen: n (/1000 maternities)	22 (1.5)	19 (1.2)	17 (1.2)	30 (2.0)
Total number of grams of fibrinogen transfused: n (/1000 maternities)	94 (6.2)	103 (6.4)	89 (6.0)	137 (9.0)
Number of women transfused cryoprecipitate: n (/1000 maternities)	6 (0.4)	3 (0.2)	2 (0.1)	5 (0.3)
Total number of units of cryoprecipitate transfused: n (/1000 maternities)	14 (0.9)	8 (0.5)	4 (0.3)	9 (0.6)
Number of women transfused platelets: n (/1000 maternities)	12 (0.79)	8 (0.50)	6 (0.41)	7 (0.46)
Total number of units of platelets transfused: n (/1000 maternities)	20 (1.3)	13 (0.8)	10 (0.7)	9 (0.6)
Haematological results				
Lowest Clauss fibrinogen All Wales: Med (IQR), range	4.2 (3.4-5), 0.3-9.2	4.1 (3.4-4.8), 0.5-8.1	4.2 (3.5-4.7), 0.3-8	4.2 (3.5-4.8), 0.3-9.8
Number with lowest fibrinogen ≤2 g/L n/reported results (% of reported results)	24/383 (6.3)	18/399 (4.5)	17/435 (3.9)	22/459 (4.8)
Longest PT All Wales: Med (IQR), range	10.7 (10.3-11.3), 9.2-22.4	10.6 (10.3-11.1), 9.1-80	10.4 (10.1-10.9), 8.3-18.4	10.4 (10-10.9), 9-19.5
Number with longest PT >16 secs n/reported results (% of reported results)	5/384 (1.3)	5/388 (1.3)	5/434 (1.2)	4/458 (0.9)
Longest aPTT All Wales: Med (IQR), range	25.9 (24.1-27.6), 20-84	25.6 (23.9-27.5), 19.5-143	25.1 (23.7-27.2), 19.3-105	24.9 (23.5-26.8), 18.7-42.5
Number with longest aPPT >50 secs n/reported results (% of reported results)	4/384 (1.0)	3/388 (0.8)	2/435 (0.5)	0/458 (0.0)
Lowest Fibtem A5 All Wales: Med (IQR), range	21 (18-25), 4-49	21 (17-24), 2-63	22 (19-25), 2-55	18 (16-21)*, 0-60
Number with lowest Fibtem A5 <12 mm n/reported results (% of reported results)	14/205 (6.8)	26/344 (7.6)	23/378 (6.1)	30/369 (8.1)*
Longest Extem CT All Wales: Med (IQR), range	57 (52-62), 17-120	57 (52-63), 38-147	56 (52-61), 30-300	55 (51-61), 11-481
Number with longest Extem CT >75 secs n/reported results (% of reported results)	8/205 (3.9)	15/344 (4.4)	19/378 (5.0)	9/369 (2.4)
Lowest haemoglobin All Wales: Med (IQR), range	91(71-100), 46-135	89 (80-100), 54-139	88 (78-98), 47-137	88 (79-100), 52-137
Number with lowest haemoglobin <80 g/L n/reported results (% of reported results)	55/203 (27.1)	99/327 (30.3)	82/353 (23.2)	55/306 (18.0)

656 Legend: * Median lowest Fibtem A5 was lower in the last 6 month period compared to the previous
657 18 months and there were more women with Fibtem A5 <12 mm. This is likely to be due to the
658 Rotem machine hardware update because the equivalent results for the lowest laboratory Clauss
659 fibrinogen were similar between the first and last 6 months.

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Table 4. Contribution of intervention to practice change during OBS Cymru

Intervention	Importance to practice change Median (IQR)
Quantitative measurement of blood loss	5 (4-5)
Team working	5 (3-5)
Point-of-care testing of coagulation	5 (3-5)
Paperwork proforma	4 (1-4)

Legend: The importance of interventions that led to practice change were scored by OBS Cymru local champions (n=29) (1- not important, 5- most important). Responses were from 37.9% midwifery, 37.9% anaesthesia, 17.2% obstetrics, 6.9% haematology. Free text responses that described how OBS Cymru had changed individual practice included 'awareness of ongoing blood loss', 'proactive rather than reactive', 'consistent management', 'appropriate product administration', 'communication and team-working'. Barriers to implementation of OBS Cymru were reported by 69% (20/29) with the most common theme being reported as training in 70% (14/20). This was also the leading response for overcoming barriers 53.5% (8/15).

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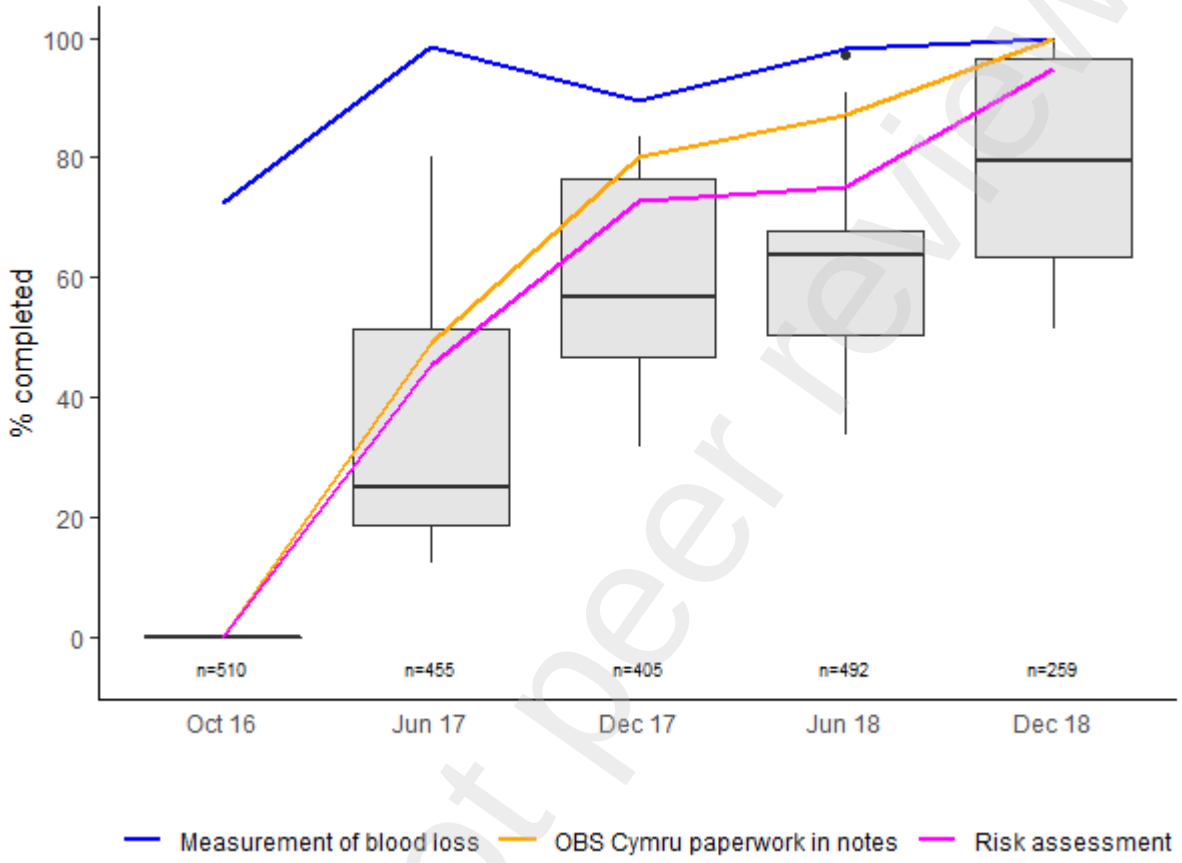
Figure titles and legends

Figure 1. Uptake of OBS Cymru interventions



Audits were performed at five time points throughout the quality improvement project to assess the uptake of the OBS Cymru intervention. The data indicate the percentage of cases where interventions were performed or paperwork completed in consecutive women, irrespective of blood loss. Audit data was provided by all 12 obstetric units in October 2016 (n=510), June 2017 (n=455) and June 2018 (n=492), from 11 units in December 2017 (n=405), and from seven units in December 2018 (n=259). The blue, orange and pink lines refer to the rate of blood loss being quantitatively measured, paperwork proforma being present in the notes and risk assessment tool completed, respectively. Box plots with median, interquartile range and range refer to the combination of paperwork being present in the notes, the risk assessment having been completed and measured blood loss being performed. October 2016 was before OBS Cymru started and no obstetric unit had access to the paperwork or risk assessment tool, therefore, all units had zero compliance for the combined interventions at this time.

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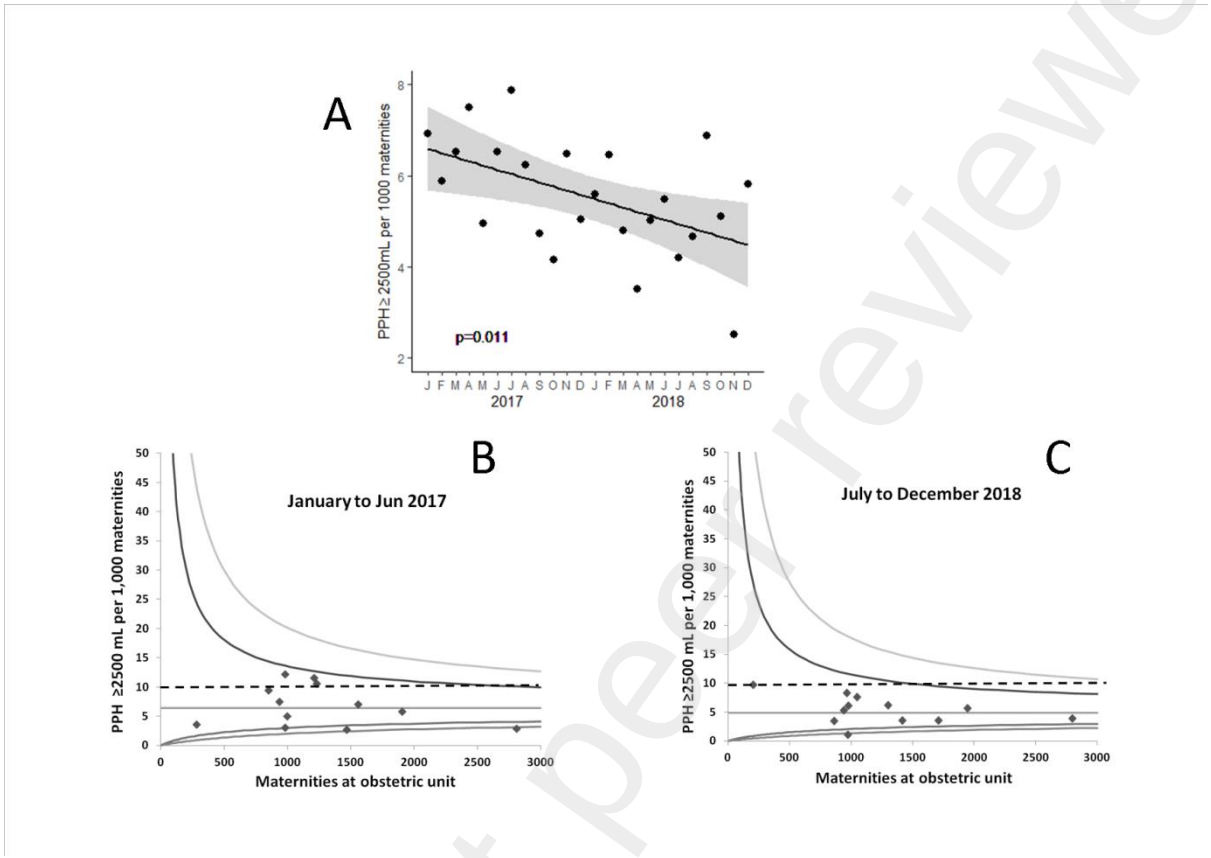
Figure 2. Change in incidence of postpartum haemorrhage during OBS Cymru



Panel A shows the monthly all Wales incidence of massive postpartum haemorrhage (≥2500 mL) with a statistically significant fall across the 24 month period. The plots show the monthly rates and for massive haemorrhage and the fitted regression line with 95% confidence interval shaded in grey. Funnel plots show the incidence of massive postpartum haemorrhages at each obstetric unit in the first (B) and last (C) 6 month periods of the quality improvement project. The line represents the mean and the limits shown are 2 and 3 standard deviations. The dashed line indicates a massive haemorrhage rate of 10/1000 maternities. The plots demonstrate the rate of massive haemorrhage at each centre during each time period, the incidence of massive postpartum haemorrhage across Wales fell from 6.4 to 4.9 per 1000 maternities and fewer units had an incidence of massive haemorrhage of more than 10/1000. The increase in massive postpartum haemorrhage reported by the smallest obstetric unit was due to two events in the final 6 months compared to one event in the first 6 months.

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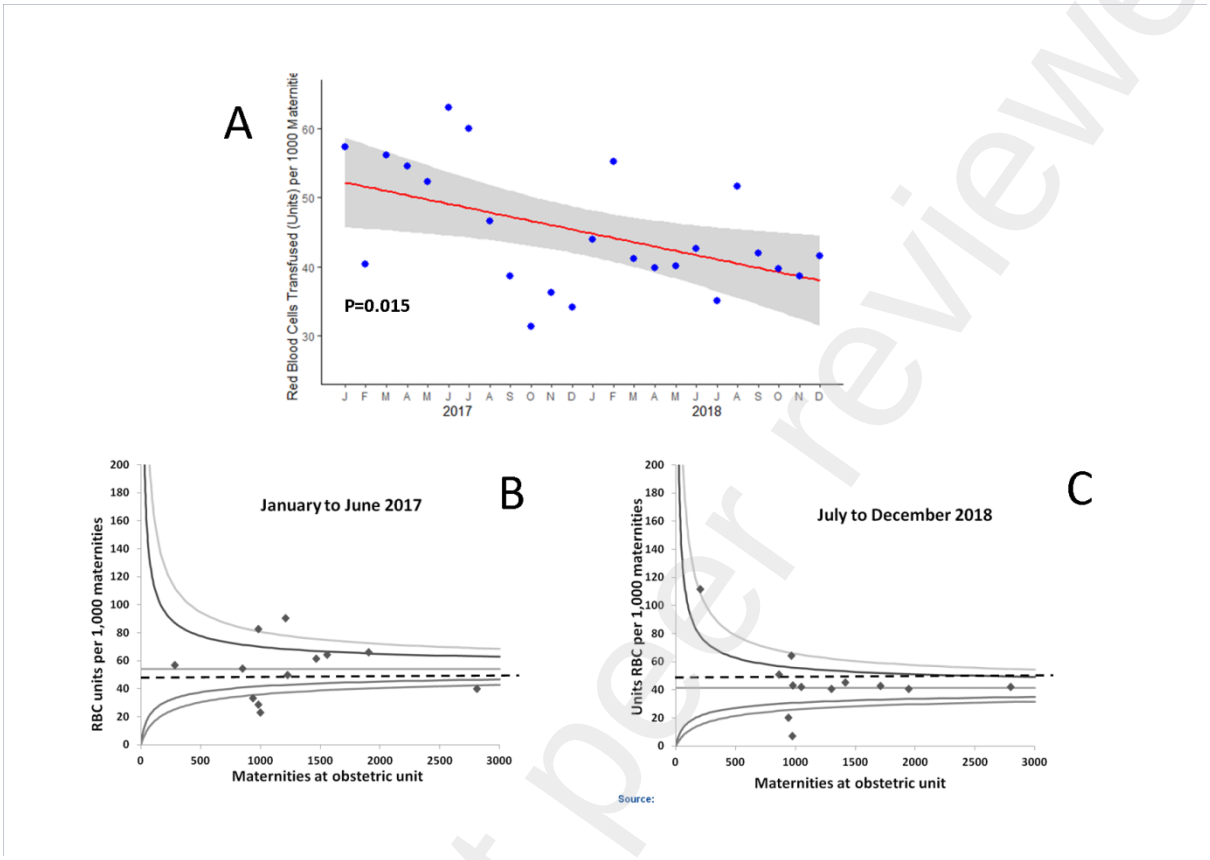
Figure 3. Change in incidence of red blood cell transfusion during OBS Cymru



Panel A shows the monthly all Wales incidence of red blood cell (RBC) transfusion for postpartum haemorrhage during the quality improvement project. There was a statistically significant fall in the monthly rate of transfusion across the 24 months. The plot shows the monthly rates and the fitted regression line with 95% confidence interval shaded in grey. Funnel plots show the incidence of RBC transfusion for postpartum haemorrhages at each obstetric unit in the first (B) and last (C) 6 month periods of the quality improvement project. The line represents the mean and the limits shown are 2 and 3 standard deviations. The dashed line represents a RBC transfusion rate of 50 units/1000 maternities. These demonstrate that the total number of units of RBC transfused for postpartum haemorrhage across Wales fell from 54.1 to 40.2/1000 maternities. There was a reduction in the number of centres with RBC transfusion rate more of than 50 unit/1000 maternities between the first and last 6 months of the project from 8/12 to 3/12 (P=0.041).

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Supplementary material

Figure 1. Rotem blood product algorithm

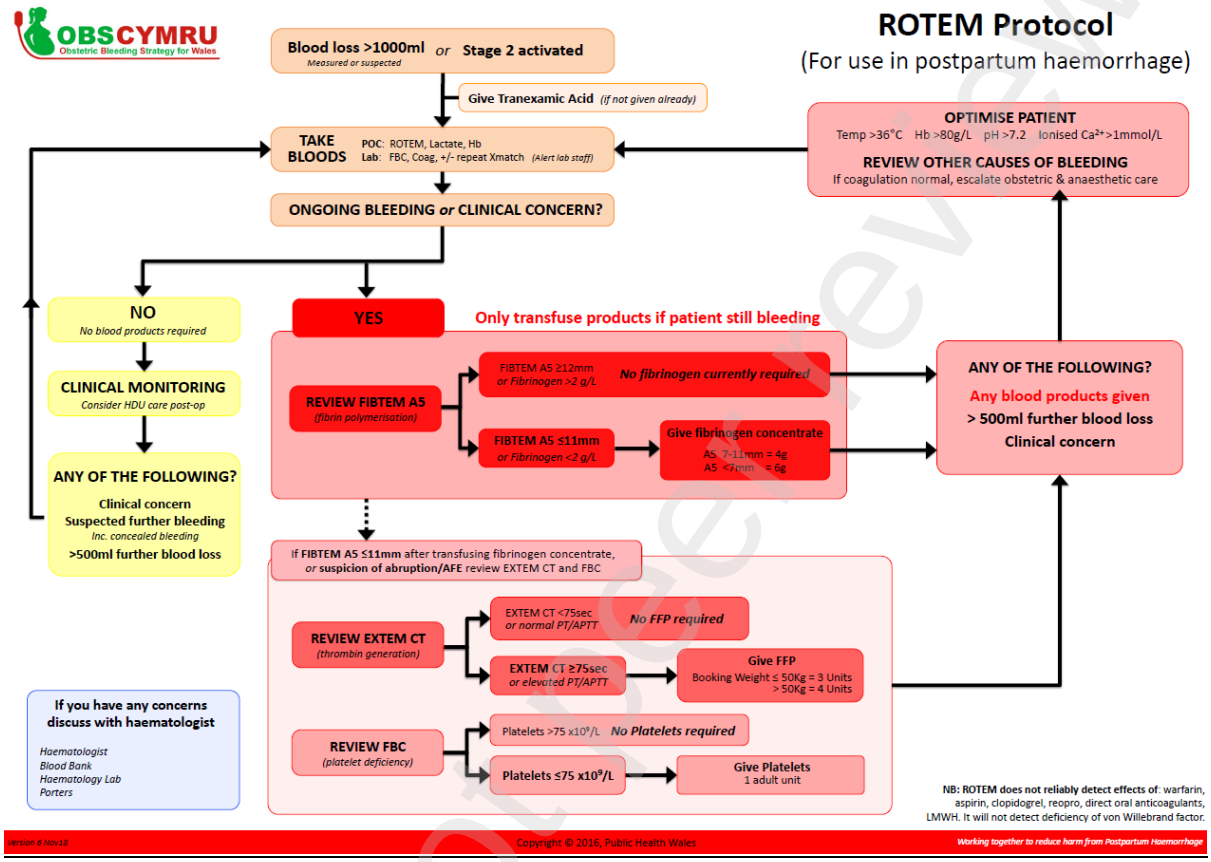

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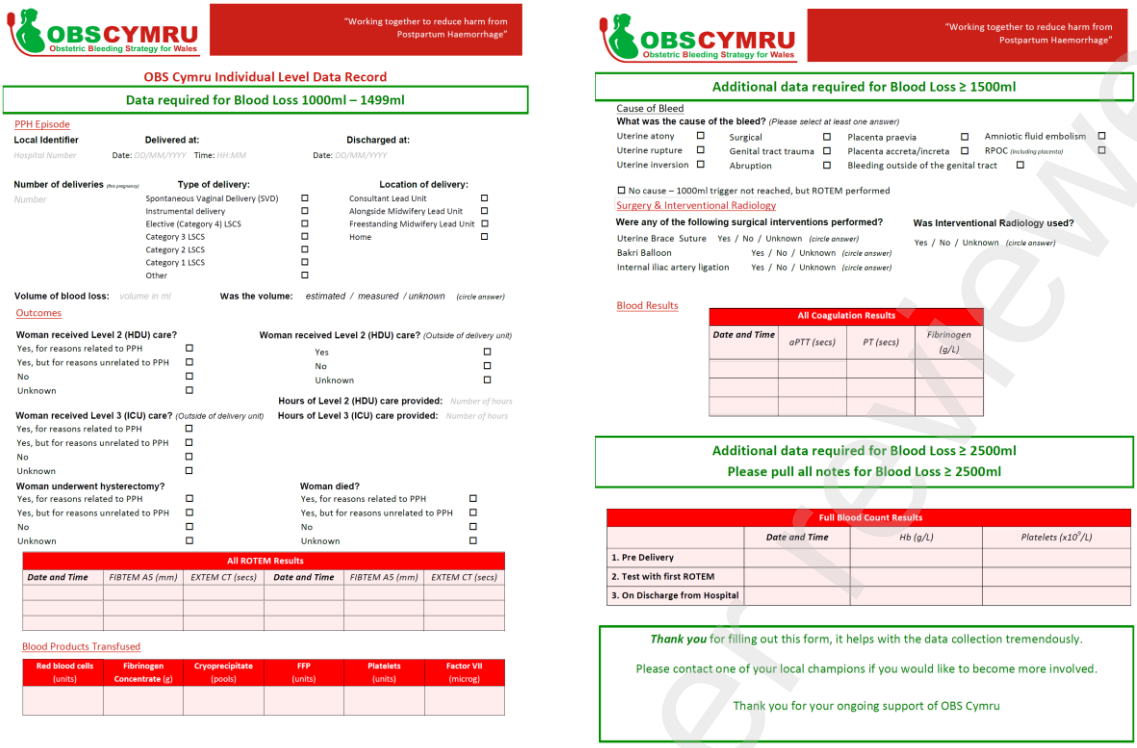
Figure 2. Data collection proforma for postpartum haemorrhage of 1000 mL and 1500 mL



OBSCYMRU
Obstetric Bleeding Strategy for Wales

"Working together to reduce harm from Postpartum Haemorrhage"

OBS Cymru Individual Level Data Record

Data required for Blood Loss 1000ml – 1499ml

PPH Episode

Local Identifier — Delivered at: — Discharged at:

Hospital Number — Date: DD/MM/YYYY Time: HH:MM — Date: DD/MM/YYYY

Number of deliveries (this pregnancy) — Number

Type of delivery:
- Spontaneous Vaginal Delivery (SVD) ☐
- Instrumental delivery ☐
- Elective (Category 4) LSCS ☐
- Category 3 LSCS ☐
- Category 2 LSCS ☐
- Category 1 LSCS ☐
- Other ☐

Location of delivery:
- Consultant Led Unit ☐
- Alongside Midwifery Lead Unit ☐
- Freestanding Midwifery Lead Unit ☐
- Home ☐

Volume of blood loss: volume in ml — Was the volume: estimated / measured / unknown (circle answer)

Outcomes

Woman received Level 2 (HDU) care?
- Yes, for reasons related to PPH ☐
- Yes, but for reasons unrelated to PPH ☐
- No ☐
- Unknown ☐

Woman received Level 2 (HDU) care? (Outside of delivery unit)
- Yes ☐
- No ☐
- Unknown ☐

Hours of Level 2 (HDU) care provided: Number of hours

Woman received Level 3 (ICU) care? (Outside of delivery unit)
- Yes, for reasons related to PPH ☐
- Yes, but for reasons unrelated to PPH ☐
- No ☐
- Unknown ☐

Hours of Level 3 (ICU) care provided: Number of hours

Woman underwent hysterectomy?
- Yes, for reasons related to PPH ☐
- Yes, but for reasons unrelated to PPH ☐
- No ☐
- Unknown ☐

Woman died?
- Yes, for reasons related to PPH ☐
- Yes, but for reasons unrelated to PPH ☐
- No ☐
- Unknown ☐

All ROTEM Results

Date and Time	FIBTEM A5 (mm)	EXTEM CT (secs)	Date and Time	FIBTEM A5 (mm)	EXTEM CT (secs)

Blood Products Transfused

Red blood cells (units)	Fibrinogen Concentrate (g)	Cryoprecipitate (pools)	FFP (units)	Platelets (units)	Factor VII (microg)

OBSCYMRU
Obstetric Bleeding Strategy for Wales

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Additional data required for Blood Loss ≥ 1500ml

Cause of Bleed

What was the cause of the bleed? (Please select at least one answer)
- Uterine atony ☐
- Uterine rupture ☐
- Uterine inversion ☐
- Surgical ☐
- Genital tract trauma ☐
- Abruption ☐
- Placenta praevia ☐
- Placenta accreta/increta ☐
- Bleeding outside of the genital tract ☐
- Amniotic fluid embolism ☐
- RPOC (including placenta) ☐

☐ No cause – 1000ml trigger not reached, but ROTEM performed

Surgery & Interventional Radiology

Were any of the following surgical interventions performed?
- Uterine Brace Suture Yes / No / Unknown (circle answer)
- Bakri Balloon Yes / No / Unknown (circle answer)
- Internal iliac artery ligation Yes / No / Unknown (circle answer)

Was Interventional Radiology used? Yes / No / Unknown (circle answer)

Blood Results

All Coagulation Results

Date and Time	aPTT (secs)	PT (secs)	Fibrinogen (g/L)

Additional data required for Blood Loss ≥ 2500ml
Please pull all notes for Blood Loss ≥ 2500ml

Full Blood Count Results

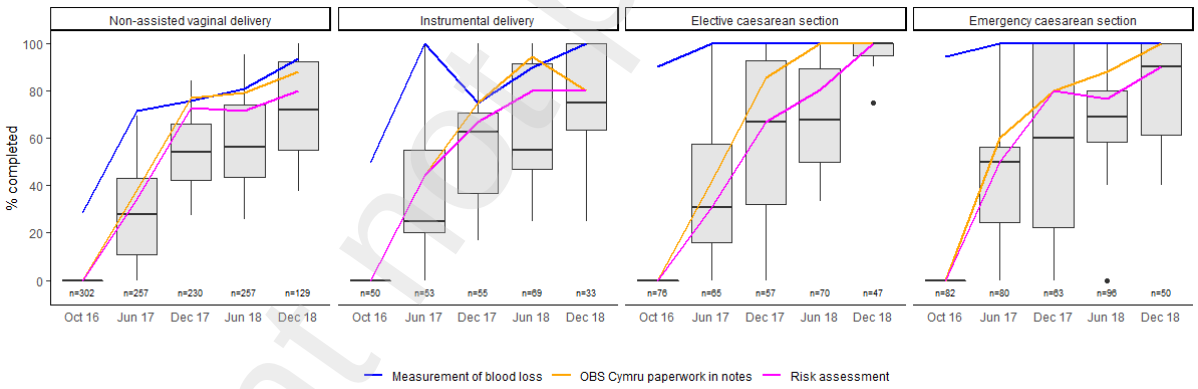
	Date and Time	Hb (g/L)	Platelets ($x10^9$/L)
1. Pre Delivery			
2. Test with first ROTEM			
3. On Discharge from Hospital			

Thank you for filling out this form, it helps with the data collection tremendously.

Please contact one of your local champions if you would like to become more involved.

Thank you for your ongoing support of OBS Cymru

Figure 3. Uptake of OBS Cymru interventions dependent on mode of delivery



The proportion of women who had quantitatively measured blood loss (blue), paperwork proforma in the notes (orange) and risk assessment completed (pink) is shown for each of five audits dependent on mode of delivery. The box plots show median, interquartile range and range for completion of all three components.

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Change in blood loss of 2500 mL of more at individual sites

Four obstetric units had a massive PPH (≥2500mL) rate below 4 per 1000 maternities in the first month of 2017, all of whom observed an increase in the rate in the last 6 months of 2018. In 2 of these sites the rate remained below 4 per 1000 maternities, whilst 1 unit saw an increase to 6.0 per 1000 maternities. The smallest obstetric unit in Wales reported a substantial increase in PPH rate, this was due to two events in the final 6 months compared to one event in the first 6 months and so may not be representative. This unit also reported very low use of ROTEM in cases of PPH ≥ 1.5L PPH in comparison to the other sites. The 8 obstetric units with rates above 5 per 1000 maternities in the first 6 months of 2017 observed a reduction in massive PPH rate. In these obstetric units, completion of the paperwork in cases of PPH was the least adopted intervention, whilst risk assessment, measurement of blood loss and use of ROTEM were widely adopted.

Size of obstetric unit (no. maternities July-Dec 2018)	≥2500 mL PPH rate per 1000 maternities Jan- June 2017	Change in ≥2500 mL PPH rate per 1000 maternities rate between Jan- June 2017 to July-Dec 2018	% of women who had a risk assessment	% of women who had the paperwork completed	% of women who had quantitative measurement of blood loss	% of women who experienced a PPH ≥1500mL and had a ROTEM test performed
1418	2.6	+1.0	94.4	66.4	100	84.2
2799	2.9	+1.0	na	Na	97.6	86.2
978	3.0	+3.0	97.3	96.4	99.1	95.7
206	3.5	+6.2	68.0	52.0	100	18.2
972	5.3	-4.2	97.0	95.5	98.5	na
1947	6.0	-0.2	97.6	97.6	99.0	na
939	7.2	-1.8	63.4	42.7	100	96.9
1710	7.4	-3.8	60.0	32.8	99.5	69.7
864	9.2	-6.2	88.3	53.2	97.4	88.9
1302	10.7	-4.4	86.2	74.8	98.7	81.1
1048	11.6	-4.0	68.4	62.4	97.4	73.3
967	12.0	-3.7	99.1	10.1	99.1	91.2

Legend. Table illustrating the individual obstetric unit level change in massive PPH rate and the uptake of the OBS Cymru complex intervention. NA is not available. Data source: OBS Cymru database

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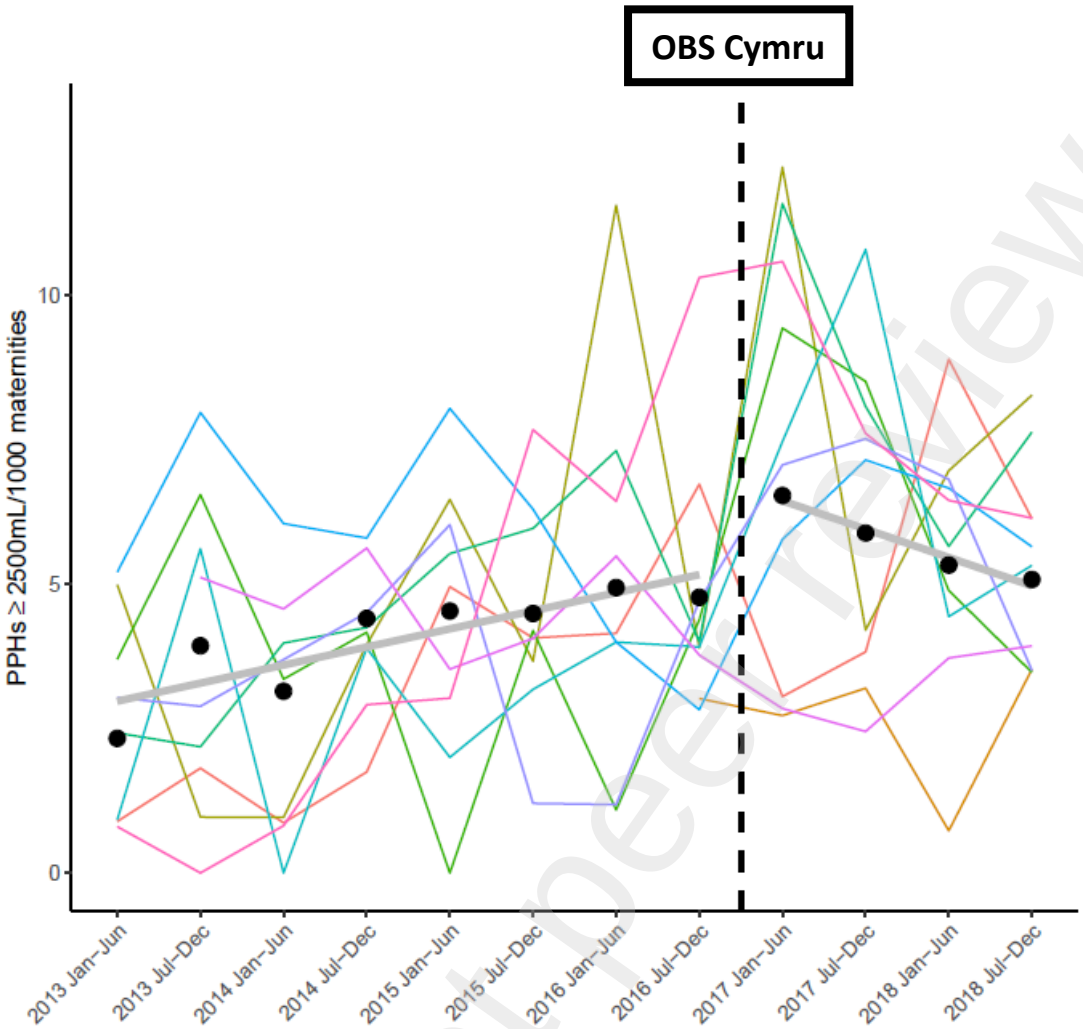
Figure 4 Interrupted time series analysis of massive postpartum haemorrhage



The trend in the incidence of bleeds ≥2500 mL before and after OBS Cymru is shown. The data between 2013 and 2016 were obtained retrospectively from obstetric units by the OBS Cymru team. There was insufficient data from two obstetric units and these were not included. An interrupted time series analysis showed an upward trend for bleeds ≥2500 mL before OBS Cymru and a downwards trend during the project. Coloured lines are for individual obstetric units and the grey line is a segmented linear mixed-effects model fitted to aggregate unit-level data with random effects for obstetric units (thus weighted by number of maternities per unit at each time point).

The increase in incidence prior to the start of OBS Cymru (p=0.005) is likely to be due to the introduction of quantitative measurement of blood loss leading to improved recognition of massive haemorrhage. The retrospective data from the obstetric units and the prospective data from the OBS Cymru database cannot be directly compared because they have been collected using different methods. The comparison, however, supports the conclusion that there was a change in the trend of massive haemorrhage associated with the introduction of OBS Cymru (p=0.004).

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Opinion from the lead research and development office confirming that the OBS Cymru project is a service evaluation and not research

Professor Fegan was the head of the Research and Development office at the time the projected was initiated.

From: Christopher Fegan (Cardiff and Vale UHB - Haematology)
Sent: 13 September 2016 16:30
To: Peter Collins (Cardiff and Vale UHB - Haematology); Lee Hathaway (Cardiff and Vale UHB - Research & Development)
Cc: Sarah Bell (Cardiff and Vale UHB - Anaesthetics); Peter Collins; Adam Watkins (Public Health Wales - No. 2 Capital Quarter); 'Thomas Kitchen'; Miriam John
Subject: RE: Request for review of quality improvement project

Dear Peter,

Both myself and Lee have reviewed this and independently come to the same conclusion that this is not research and hence does not require REC and/or R and D approval as all the parameters being collected are standard of care. I think this comes better under service evaluation/improvement. As such the permission to undertake this project resides with the individual directorates.

Thanks for sharing this with us and the best of luck.

Chris F

From: Peter Collins (Cardiff and Vale UHB - Haematology)
Sent: 05 September 2016 11:02
To: Lee Hathaway (Cardiff and Vale UHB - Research & Development); Christopher Fegan (Cardiff and Vale UHB - Haematology)
Cc: Sarah Bell (Cardiff and Vale UHB - Anaesthetics); Peter Collins; Adam Watkins (Public Health Wales - 1000 Lives Improvement Unit); 'Thomas Kitchen'; Miriam John
Subject: Request for review of quality improvement project

Dear Chris

Following our previous conversation I am attaching details of the Obstetric Bleeding Strategy for Wales (OBS Cymru). Our national management team does not think that this should be classified as a research project but we would like this to be formally considered by R&D. Please can you review this initiative and let us know whether you consider this to be a research study requiring ethics and R&D approval. The project has been registered in each Health Board as a Quality Improvement Project.

OBS Cyrmu is a quality improvement exercise that aims to improve the management of postpartum haemorrhage throughout Wales. The initiative involves introducing a 4 stage response to postpartum haemorrhage in each of the 12 consultant-led maternity units and all midwifery-led units in Wales (see OBS Cymru 4 stage management check list). Key elements of the 4 stage response are early recognition of bleeds, measurement of blood loss, involvement of senior staff at appropriate times and point of care (Rotem and blood gas) guided blood product replacement.

The introduction of the strategy will be facilitated in the units by 3 Welsh Clinical Leadership Fellows (WCLFs), a champion midwife at each unit and a lead clinician at each unit. In

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addition, a national midwifery project lead (22.5 hrs a week) has been funded by 1000 Lives. The project is led by a national co-ordinating team (see OBS Cymru project outline) and is supported by 1000 Lives.

The project is funded by a Welsh Government grant with matched funding from TEM International (the suppliers of the Rotem machines), 1000 Lives and Welsh Deanery/Health Boards (for the WCLFs).

Data will be collected on all women who have a postpartum haemorrhage >1000 mL, receive blood or blood products, have a rotem test performed, require a hysterectomy, are admitted to ITU or die.

The data will be collected in an identifiable form in each maternity unit and women given a unique number. The data will be collated centrally at C&V with women identified by the unique number only. All data are routinely collected for women with postpartum haemorrhage (attached dataset). Data will be collected for 6 months before the introduction of the new management processes and for 2 ½ years after. We will look for changes in key outcomes such as ITU admission, hysterectomy, need for invasive procedures and blood product usage. There will be feedback of the results to each unit at least every 3 months to facilitate change and quality improvement.

We will be interested in analysing trends across time and differences between units to identify drivers and barriers to change and quality improvement.

The aggregate results will be collated, presented to stakeholders, presented at national and international meetings and submitted for publication in peer reviewed journals. Data are likely to be held at C&V for at least 2 years after completion of the project for analysis.

Please let us know whether you need any further information and we would be happy to meet with you to discuss further.

Best regards

Peter Collins
Sarah Bell
Rachel Collis

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