What is the Economic Cost of Providing an All Wales Postpartum Haemorrhage Quality Improvement Initiative (OBS Cymru)?
A Cost-Consequences Comparison with Standard Care

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Abstract
Background and Objective A postpartum haemorrhage quality improvement initiative (the Obstetric Bleeding Strategy for Wales [OBS Cymru]), including about 60,000 maternities, was adopted across Wales (2017–2018). We performed a cost-consequences analysis to inform ongoing provision and wider uptake.

Methods Analysis was based on primary data from the All Wales postpartum haemorrhage database, with a UK National Health Services perspective, a time horizon from delivery until hospital discharge and no discounting. Costs were based on UK published sources with viscoelastic haemostatic assay costs provided by the OBS Cymru national team. Mean costs per eligible patient (postpartum haemorrhage > 1000 mL) were calculated for OBS Cymru, using the early implementation period as a comparator. Modelling allowed comparisons of three scenarios (two predefined and one post hoc) and implementation in different sizes of maternity unit.

Results All analyses demonstrated consistent savings in blood products, critical care and haematology time, and also a reduced occurrence of massive postpartum haemorrhage (> 2500 mL). Incremental postnatal length of stay varied between scenarios, substantially impacting on total costs. Mean incremental cost of OBS Cymru, compared with standard care, across Wales was £18.41 per patient (postpartum haemorrhage > 1000 mL) or − £10.66 if the length of stay was excluded. Modelling a maternity unit of 5000 births per annum, OBS Cymru incurred an incremental cost of £9.53 per patient with postpartum haemorrhage > 1000 mL.

Conclusions OBS Cymru reduces the occurrence of massive postpartum haemorrhage, need for transfusions, quantity of blood products and intensive care. In medium-to-large maternity units (>3000 maternities per annum), the OBS Cymru intervention approaches cost neutrality compared to standard care.

Key Points for Decision Makers
The introduction of the Obstetric Bleeding Strategy for Wales (OBS Cymru) resulted in consistent savings in blood product use, critical care utilisation and haematology consultant time.

Length of stay has a strong impact on overall costs, with variations between scenarios.

Costs are dependent on the size of a maternity unit.

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1 Introduction

The Obstetric Bleeding Strategy for Wales (OBS Cymru) is a national quality improvement project aiming to reduce harm associated with postpartum haemorrhage (PPH). The project is based on previous research and reports of quality improvement initiatives [1]. OBS Cymru introduces four pillars of management: universal risk assessment for PPH, early identification of PPH by routine quantification of blood loss, a multidisciplinary team working with escalation at specific blood loss volumes (or clinical concern) and point-of-care testing at 1000-mL blood loss (or clinical concern) to guide fluid and blood product resuscitation. The OBS Cymru project launched in November 2016 and the pillars of management were integrated into clinical care during 2017. The project finished in April 2019 and was subsequently adopted as standard PPH care across Wales [2]. The OBS Cymru design, implementation and outcomes have been published [3–5].

Prior to the introduction of OBS Cymru, laboratory tests were used to identify women with coagulopathy. Because of the time lag from samples being taken to results being available (usually > 60 min), clinicians routinely administered empirical blood products using algorithms derived from research in non-pregnant trauma patients to avoid under-treatment of coagulopathy. Point-of-care testing of coagulation using a viscoelastic haemostatic assay (VHA) identifies coagulation impairment during PPH within 10 min of sampling and can guide clinical treatment [6–8]. The VHA device used was ROTEM Sigma (Werfen, Barcelona), with laboratory testing also continued.

To evaluate the impact of a change in PPH care, it is important to assess both clinical outcomes, reported separately [4] and economic implications. Several publications have investigated the economic impact of specific PPH interventions including different uterotonic, tranexamic acid, hysterectomy and red blood cell (RBC) transfusion [9–14]. A single-centre UK study reported a non-significant reduction in patient costs following integration of a VHA-guided resuscitation algorithm into obstetric practice [15], while a US-based study reported a statistically significant reduction in costs based on 86 patients in a single centre [16]. Current National Institute for Health and Care Excellence guidance (DG13) [6] recommends further research to understand both clinical and health economic aspects of VHA devices in PPH management, whilst the Royal College of Obstetricians and Gynaecologists, Obstetric Anaesthetists Association and British Society of Haematology acknowledge the potential utility of VHA in guiding clinical decision making [17–19].

No published economic models evaluate all of the OBS Cymru principles in combination.

Economic evaluations of VHA in trauma and cardiac settings have incorporated the costs of blood products, delivery of blood products, testing costs, and costs of procedure-related complications and transfusion-related complications. Although undertaken in different care settings, these assessments inform the creation of an obstetric-specific analysis [20, 21].

2 Methods

A cost-consequences analysis [22] of the OBS Cymru approach was used. The objective was to compare the incremental cost of OBS Cymru against standard PPH care in individual Welsh maternity settings and nationally, and contribute to the available evidence on the use of VHA in obstetrics for wider uptake. Reporting was informed by the Consolidated Health Economic Evaluations Reporting Standards (CHEERS) checklist [23].

2.1 Clinical Data

A PPH quality improvement initiative (OBS Cymru) was introduced across Wales between 2017 and 2018 [3, 4]. All 12 obstetric units were included in the programme (31,000 births per annum); comprising three large, four medium and five small units (defined as > 3000; 2–3000 and < 2000 maternities per year). The Welsh Maternity Indicators Dataset (National Health Service [NHS] Wales Informatics Service) provided data regarding the number of births across Wales. An All Wales OBS Cymru database was established by Improvement Cymru and data were collected for 2017 and 2018. Women experiencing PPH > 1000 mL (or in whom there was concern about abnormal bleeding) were defined as having a PPH episode and had data collected including: length of stay (from delivery until discharge), blood products transfused, hysterectomy, critical care admission (high-dependency care off the maternity unit [Level 2] or intensive care [Level 3] [24]) and VHA use. Analysis was based on primary individual-level data from all maternity units, unless otherwise stated.

2.2 Analysis Scenario Development

As a single-arm quality improvement project, the comparator was standard care prior to OBS Cymru. Because of a lack of standardised reliable data prior to OBS Cymru, data for the comparator arm were taken from the early stages of the project (2017), prior to full adoption of OBS Cymru, as an approximation to previous standard care.

Prior to the start of data analysis, time periods for intervention and comparator data were identified, following consultation with the clinical team, as summarised in Table 1.
The base case (scenario 1) was chosen to utilise the large quantity of real-world data collected, whilst reflecting the change in practice that occurred following OBS Cymru adoption. One maternity unit was excluded because it had already introduced all of the OBS Cymru principles by 2017 [1]. As part of the deterministic sensitivity analysis, scenario 2 used the same time periods but included all maternity units. For both scenarios 1 and 2, standard care data were taken from the first 8 months of 2017, with the same months in 2018 used for comparison (minimising any difference due to seasonal variation).

During analysis, it was apparent that two maternity units were early VHA adopters, with minimal changes recorded in their use of VHA between the two time periods in scenarios 1 and 2. In addition, two units did not fully record their VHA use in the last 6 months of 2018. A post-hoc analysis (scenario 3) was developed, comparing the percentage of women with recorded VHA tests in the first 3 months of 2017 and the last 3 months of 2018 for each unit, to indicate OBS Cymru adoption. Only units that reported a difference of at least 30% in women with VHA tests recorded (8/12 units) were included in scenario 3. The 30% decision point was informed by the patterns of recorded VHA use but was set prior to an additional analysis of any other clinical data or the calculation of associated cost comparisons. Scenario 3 was intended to identify the units with the greatest uptake of the OBS Cymru intervention to explore the impact of implementation.

### 2.3 Statistical Analysis

Clinical data and costs were analysed using Stata MP15 (Version 15; StataCorp, College Station, TX, USA). Records with missing data for red blood cells were excluded, with a mean imputation for any remaining missing data (n = 10 records). Hours of care in Level 2 critical care were not analysed because of a high proportion of missing data. Bootstrapping was used to obtain confidence intervals for means and incremental costs. Additional analysis in clinical papers [3–5] includes changes in clinical outcomes using linear regression [4] and interrupted time series for massive PPH [4]. The cost model was completed using Microsoft Excel (2013).

#### 2.4 Costing Approach

OBS Cymru costs (excluding VHA) comprised a paperwork proforma to guide PPH management for every maternity patient (£0.09 per patient), purchase and maintenance of weighing scales for quantitative blood loss measurement (£58 per annum per maternity unit) and ongoing training (£50 per year for materials per maternity unit, with time integrated into routine training). Following consultation with clinicians, the time to perform a risk assessment and measure blood loss was assumed equivalent to existing roles in standard care and have not been included in the costing.

Development costs for the OBS Cymru approach (including the PPH proforma) were not included. Midwife champions (0.1 full-time equivalent per maternity unit) were employed to collect data and supervise local training during the project implementation. These roles were then integrated into existing provision for ongoing training, and these initial costs were not included.

Changes in staff workload resulting from OBS Cymru were not recorded in the OBS Cymru database. Midwives, obstetricians and anaesthetists were asked to estimate the time spent on tasks before and after OBS Cymru introduction, but found this very challenging to specify. Consultant haematologists were able to report this information as they were sited remotely, receiving phone calls for advice that were easier to quantify.

A major change in both practice and expense was the introduction of point-of-care testing of coagulation, VHA (ROTEM, Werfen, Barcelona). Devices are currently not purchased, but annual costs included a rental and maintenance contract (£1950, excluding VAT) and quality control (total of £1404 including £54 per month for consumables and support from the point-of-care testing team [£500 per annum]). A consultant superuser and cascade training were included at £926.50 per annum. The total annual cost
of £4280.50 was independent of the number of tests, and required for each maternity unit. Each patient test required a cartridge (£30 excluding VAT) and time to perform the test (5 minutes, band 5, cost £3.17 [25]). Costs applied were those negotiated by the OBS Cymru project.

Costs for any provision of OBS Cymru (including VHA) in the comparator arm data were not included, as the standard care being modelled would not include these components. This conservative assumption is likely to underestimate the economic impact of OBS Cymru.

Blood product transfusion costs were from the NHS England price list [26], with an additional cost to include the full cost of delivering the transfusion to the patient [27]), inflated to 2018/19. The authors calculated costs for delivering each type of blood product, with a slightly higher cost for the first transfusion, reflecting additional preparation time and consumables. The majority of women in the OBS Cymru database who had any type of blood coagulation product transfusion also received at least one unit of RBC. Therefore, the higher initial set-up costs for the first unit of blood product transfused is applied only to the first RBC unit delivered. Subsequent RBC and all units for other products used the lower cost of additional units (Table 2).

**Assumptions** Across Wales, a national OBS Cymru PPH guideline standardised uterotonic practice and surgical intervention (in line with Royal College of Obstetricians and Gynaecologists published guidance [32]). We therefore assumed that there was no change in the use of these resources, and also assumed that the costs related to delivery and postpartum care were unchanged. No changes in staff time were included other than haematology consultants and the time required to carry out VHA tests. It is unclear how the initiative may have impacted on staff time, although staffing levels remained constant.

### 2.5 Patient-Level Analysis

Incremental costs and clinical outcomes were calculated from primary data using the base-case scenario, and bootstrapping. The comparator arm was assumed to approximate standard care prior to the introduction of OBS Cymru, and no costs were included for OBS Cymru or VHA in this arm. Total VHA costs for rental and maintenance were averaged across all 12 units in Wales.

### 2.6 Cost Model Description

The cost-consequences analysis compared OBS Cymru and an approximation of standard care, from a NHS perspective. The time horizon was from delivery until discharge from hospital, and no discounting was required for this time period. Resource use was based on the OBS Cymru database, with additional information from consultation with clinicians. Costs were taken from published sources where available (Table 2), and the resource information from clinical data (Table 3). All costs were for 2018–19 and inflated using Personal Social Services Research Unit indices [25] where necessary. Clinical data were taken from the quality improvement register; however, the modelling element allowed the findings to be applied to different-sized maternity units, the use of scenarios and a sensitivity analysis.

### 3 Results

#### 3.1 Clinical Results (Scenario 1)

The pre-defined primary outcome was the base case, (scenario 1), comparing 8 months of data in 2017 to the same period in 2018 for all units in Wales, excluding one unit that had implemented OBS Cymru previously. Detailed clinical outcomes (occurrence of massive PPH and blood transfusion

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**Table 2** Costs included in the analysis

| Resource                        | Cost per unit                                      |
|---------------------------------|----------------------------------------------------|
| **Blood products**              |                                                    |
| Red blood cells                 | £190.23 for first unit, £167.68 subsequent units [26, 27] |
| Fresh frozen plasma             | £64.01 per unit [26, 27]                           |
| Platelets                       | £229.03 per pool [26, 27]                          |
| Cryoprecipitate                 | £219.01 per pool [26, 27]                          |
| Fibrinogen concentrate          | £400 per 1 g [28]                                  |
| **Other resources**             |                                                    |
| Hysterectomy                    | £3837 non-elective hysterectomy (MA08B) [29]       |
| Critical care (Level 3)         | £90.41, per hour [30] inflated to 2019             |
| Length of stay                  | £337, per day [31] non-elective excess bed days across all HRGs, inflated to 2019 |

**HRGs**

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data) and resource use are reported for scenario 1 (in the text and Table 3), and for scenarios 2 and 3 in the Electronic Supplementary Material (ESM).

Standard care arm: a total of 15,937 women gave birth at the included maternity units and 1651 episodes (103.6/1000 maternities) were recorded in the OBS Cymru database (due to PPH > 1000 mL or clinical concern of abnormal bleeding). There were 123 (7.72/1000 maternities) episodes of blood loss > 2500 mL recorded, and 429 ROTEM tests performed; however, test costs are not included as they do not represent standard care prior to OBS Cymru.

OBS Cymru arm: a total of 15,570 women gave birth at the included maternity units, and 1680 episodes (107.9/1000 maternities) were recorded in the OBS Cymru database. There were 84 (5.39/1000 maternities) episodes of blood loss > 2500 mL recorded, and 934 ROTEM tests performed.

### Table 3 Resource use, percentage of women in database (scenario 1) receiving each intervention

| Resource               | Percentage of women in OBS Cymru database receiving intervention | Mean resource use per woman receiving the resource |
|------------------------|---------------------------------------------------------------|--------------------------------------------------|
|                        | Comparator, n (%) OBS Cymru n (%)                              | Comparator Mean ± SD OBS Cymru Mean ± SD          |
| Total number of women recorded in OBS Cymru database | 1651 1680                                                    |                                                  |
| Total number of records for analysis                      | 1518 1517                                                    |                                                  |
| Number of women receiving VHA testing                      | 310/1518 (20.42%) 760/1517 (50.10%)                           | 1.32 ± 0.80 tests 1.16 ± 0.50 tests              |

**Blood product use**

- Red blood cells: 401/1518 (26.42%) 302/1517 (19.91%) 2.43 ± 1.23 units 2.32 ± 1.18 units
- Fresh frozen plasma: 31/1518 (2.04%) 23/1517 (1.52%) 3.61 ± 1.91 units 3.39 ± 1.23 units
- Platelet: 13/1517 (0.86%) 5/1516 (0.33%) 1.54 ± 0.66 pool 1.4 ± 0.55 pool
- Cryoprecipitate: 7/1517 (0.46%) 4/1516 (0.26%) 2.57 ± 1.40 pool 2 ± 0 pool
- Fibrinogen: 22/1518 (1.45%) 21/1515 (1.39%) 4.41 ± 2.50 g 4.76 ± 2.17 g

**Other additional care**

- Hysterectomy: 5/1518 (0.33%) 7/1517 (0.46%) na na
- Critical care (Level 3): 16/1513 (1.06%) 11/1517 (0.65%) 27.14 ± 39.01 hours 19.82 ± 6.24 hours
- Length of stay (delivery to discharge): 100% 100% 2.58 ± 1.89 days 2.67 ± 1.87 days

*na, OBS Cymru Obstetric Bleeding Strategy for Wales, SD standard deviation, VHA viscoelastic haemostatic assay

\(^a\)Costs for ROTEM were not included in the standard care arm

### 3.3 Study Data: Cost Consequences

The analysis calculates the cost per patient with PPH > 1000 mL and uses an average VHA device cost across all units in Wales (Table 4). The OBS Cymru arm showed a reduced cost for blood products (− £35.67), and critical care [Level 3] (− £13.18) compared with standard care. There were fewer blood transfusions and fewer women escalated to a massive PPH (PPH > 2500 mL). The mean incremental cost of OBS Cymru compared to standard care, across Wales, was £18.41 per person with PPH > 1000 mL if the length of stay was included, and − £10.66 if omitted.

#### 3.3.1 Modelled Incremental Costs (Base Case)

The incremental cost of using OBS Cymru (and each component), for a maternity unit with 5000 maternities per annum was £18.41 per person with PPH > 1000 mL if the length of stay data was included (Table 5). A unit of this size was calculated to experience approximately 540 incidents of PPH > 1000 mL per annum based on the national OBS Cymru data.

#### 3.3.2 One-Way Sensitivity Analysis (Scenario 1)

A one-way sensitivity analysis confirmed that length of stay had the biggest impact on the incremental cost. Sensitivity parameters utilised 95% confidence intervals for clinical data, and 20% variation for all other variables [19].

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except where the clinical team were able to give estimations of plausible values (ESM). A 20% variation for unit costs reflected potential price changes. Variation in the mean length of stay for the OBS Cymru arm was 2.57–2.76 days (4.5 hours difference), leading to an incremental cost of £22.68 or £41.74. Parameters and results for sensitivity analysis are included in the ESM.

### 3.4 Results for Additional Scenarios

The second scenario (including data from all units), resulted in an incremental cost of £3.32 per patient with PPH > 1000 mL in a maternity unit with 5000 deliveries per annum. The difference in incremental cost between the two scenarios was largely owing to a variation in the length of stay in the different cohorts.

The scenario 3 post-hoc analysis resulted in an incremental cost of −£94.39 per patient with PPH > 1000 mL in a maternity unit with 5000 deliveries per annum. The incremental costs savings comprised £45 for a reduced length of stay, and greater reductions in blood product use, critical care admission, staff time and hysterectomies. The results were summarised in Table 6, with full results available in the ESM. In all scenarios, there was an increase

### Table 4 Costs and consequences for patient-level data analysis, base case

| Comparator (£) Mean (95% CI) | OBS Cymru (£) Mean (95% CI) | Incremental cost (£) Mean (95% CI) |
|-----------------------------|-----------------------------|-----------------------------------|
| ROTEM and OBS Cymru device fixed costs<sup>a</sup> | 17.76 | 17.76 |
| ROTEM consumables | 0 | 17.64 (16.59, 18.69) | 17.64 (16.59, 18.69) |
| Blood products | 149.56 (126.94, 172.17) | 113.89 (93.77, 134.01) | −35.67 (−4.68, −66.65) |
| Hysterectomy | 12.90 (1.47, 24.33) | 18.07 (4.80, 31.35) | 5.15 (−12.01, 22.36) |
| Critical care, Level 3<sup>b</sup> | 26.48 (2.75, 50.21) | 13.30 (5.31, 21.29) | −13.18 (−34.99, 8.63) |
| Staff time<sup>c</sup> | 5.03 | 2.64 (2.53, 2.75) | −2.39 (−2.29, −2.49) |
| Total costs excluding length of stay | 193.96 (155.10, 232.84) | 183.30 (153.49, 213.11) | −10.66 (−61.02, 39.69) |
| Length of stay | 891.23 (858.91, 923.54) | 920.30 (888.17, 952.43) | 29.07 (−17.78, 75.93) |
| Total costs, including length of stay | 1085.196 (1032.17, 1138.22) | 1103.60 (1051.09, 1156.20) | 18.41 (−57.97, 94.77) |
| Clinical outcomes | | | |
| PPH >2500 mL | 0.081 (0.068, 0.094) | 0.055 (0.044, 0.067) | −0.026 (−0.042, −0.009) |
| RBC transfusion | 0.264 (0.242, 0.286) | 0.199 (0.178, 0.220) | −0.065 (−0.096, −0.034) |

<sup>a</sup>Ci confidence interval, HDU high-dependency unit, OBS Cymru Obstetric Bleeding Strategy for Wales, PPH postpartum haemorrhage, RBC red blood cell, VHA viscoelastic haemostatic assay
<sup>b</sup>Costs for ROTEM were not included in standard care arm
<sup>c</sup>Not including HDU, Level 2
<sup>d</sup>Staff included were consultant haematologists and band 5 performing the VHA test

### Table 5 Summary table of the incremental cost per women with postpartum haemorrhage in a maternity unit delivering 5000 births per annum for the base case

| | Standard care | OBS Cymru | Incremental cost incurred by OBS Cymru |
|-----------------------------|-----------------------------|-----------------------------|-----------------------------------|
| OBS Cymru programme | £0 | £1 | £1 |
| ROTEM costs<sup>a</sup> | £0 | £26 | £26 |
| Blood product costs | £150 | £114 | −£36 |
| Hysterectomy costs | £13 | £18 | £5 |
| Critical care, Level 3 costs | £26 | £13 | −£13 |
| Included staff<sup>b</sup> costs | £5 | £3 | −£2 |
| Length of stay costs | £891 | £920 | £29 |
| Total | £1085 | £1095 | £9.53 |

<sup>a</sup>Costs for ROTEM were not included in standard care arm
<sup>b</sup>Staff included were consultant haematologists and band 5 performing the VHA test

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in the number of PPH > 1000 mL or of clinical concern recorded, owing to an increased measurement of blood loss and staff awareness.

### 3.5 Impact of Maternity Unit size

Further analysis explored the impact of maternity unit size on the cost of providing OBS Cymru. The fixed costs associated with VHA use mean that the overall cost implications for a small unit are higher, with costs rising steeply below 2000 maternities per annum, as shown in Fig. 1.

### 3.6 Impact of Individual Components on Costs of Delivering OBS Cymru

The impact of individual components on incremental costs in all three scenarios is shown in Fig. 2. Direction of incremental costs is consistent for most inputs, with OBS Cymru programme resources and ROTEM resulting in additional costs and changes in blood products, including staff, and critical care admission resulting in cost reductions across all three scenarios. Hysterectomies and length of stay are shown in Fig. 2, with an incremental cost that changes in direction for scenario 3. Figures 2 and 3 show the impact on the overall incremental cost of OBS Cymru, which was cost incurring for scenarios 1 and 2, but cost saving for scenario 3. The length of stay was not normally distributed. A Mann–Whitney U test for the primary scenario revealed a statistical difference ($p = 0.0118$), but this is not clinically significant and the mean comparison for cost calculations performed using a t-test (based on the central limit theorem) also showed no difference ($p = 0.1842$). Length of stay had a substantial impact on the model results, but differences observed may have been due to random variation or to multifactorial influences outside of the scope of the OBS Cymru programme, and not associated with the PPH directly. Therefore, the impact of removing the length of stay on the total cost of delivering OBS Cymru for varying maternity unit sizes, in each of the three scenarios, is shown in Fig. 4.

| Scenario 1 | Scenario 2 | Scenario 3 |
|------------|------------|------------|
| Standard Care | OBS Cymru | Standard Care | OBS Cymru | Standard Care | OBS Cymru |
| Total maternities ($n$) | 15,937 | 15,570 | 19,623 | 19,145 | 4369 | 4226 |
| PPH >1000 mL or clinical concern ($n$) (per 1000 maternities) | 1651 | 1680 | 2009 | 2074 | 409 | 428 |
| ROTEM tests ($n$) (per 1000 maternities) | 103.6 | 107.9 | 102.4 | 108.3 | 93.6 | 101.3 |
| Data available for analysis | 429 | 934 | 721 | 1258 | 5 | 294 |
| Incremental cost per woman PPH >1000 mL | £9.53 | £3.32 | −£94.39 |

Fig. 1 Incremental cost of Obstetric Bleeding Strategy for Wales [OBS Cymru] (per woman with postpartum haemorrhage [PPH]) for obstetric units between 500 and 6000 maternities per annum.
Fig. 2 Incremental cost attributed to each cost component for the three scenarios. OBS Cymru Obstetric Bleeding Strategy for Wales, PPH postpartum haemorrhage.

Fig. 3 Illustration of the impact of the length of stay on the results. PPH postpartum haemorrhage.

Fig. 4 Incremental results for each scenario when the length of stay is excluded. OBS Cymru Obstetric Bleeding Strategy for Wales, PPH postpartum haemorrhage.
illustrates how the length of stay was driving much of the difference between scenarios.

### 4 Discussion

This is the first cost analysis of the effect of introducing a complex PPH care bundle. The key strength of this analysis is the use of real data for large numbers of patients, in a real-world setting across many different healthcare providers and geographical areas in Wales. The modelling suggests that in larger maternity units with greater than 3000 maternities per annum, OBS Cymru has minimal cost implications whilst potentially improving patient outcomes. Costs increased as unit sizes fell because of the fixed costs of VHAs. Clinical outcomes included a reduction in the proportion of women who progress to massive PPH (> 2500 mL) and who receive blood transfusions.

The lack of true comparator data, either prior to implementation or from a comparator arm, is a limitation, and likely to lead to an underestimation of any incremental cost savings. This is because implementation was partially included in the comparators for scenarios 1 and 2. In addition, multiple factors such as uterotonic use and surgical interventions were neither measured nor controlled for, although all PPH care was informed by the same All Wales PPH Guideline. No data were available to inform changes in staff activity (other than performing the test and haematology consultation) and unmeasured factors (e.g. changes in the induction of labour pathways) that may have influenced the length of stay following delivery. Costs for the provision of OBS Cymru (including VHA costs) delivered in the standard care arm data were not included because the standard care being modelled would not normally have included these components. This is a conservative assumption that is likely to have underestimated the economic impact of OBS Cymru.

Economic modelling of VHA in cardiac surgery and or trauma have taken longer time horizons, with the inclusion of quality-of-life measures and the avoidance of costs associated with transfusion-related complications [21]. No data regarding complications due to transfusion, psychological effects on women giving birth and the level of support required by parents and babies after going home were included in this analysis; however, their inclusion would be expected to increase any cost saving due to OBS Cymru, based on the improvements in maternal outcomes observed.

When comparing the results for different scenarios, there is a clear and consistent reduced incremental cost for blood product use, critical care admission and haematologist time. For a medium or large maternity unit (more than 3000 births per annum), the costs of delivering OBS Cymru are largely offset by these savings. The reduction in blood product use is also consistent with the findings reported by Malliaiah et al. [15] who reported a reduction in the cost of blood products per woman following the introduction of a ROTEM-guided fibrinogen administration for PPH, and Snegovskikh et al. [16] who also reported reduced critical care stay and length of stay. The OBS Cymru model adds information to the costs of providing ROTEM, as part of a managed approach to PPH, with modelling allowing insights into the impact on different sizes of maternity unit.

The size of the maternity unit has a substantial impact on the cost implications of OBS Cymru, owing to the fixed costs of managing the VHA device. This analysis suggests that smaller maternity units (below around 2000 maternities per year) would either need to share device use with other clinical areas (e.g. a trauma or emergency unit) or VHA costs would need to reduce to justify the expense of providing VHA testing in these settings. Across all maternity units in Wales, the direct cost of providing the service (OBS Cymru and ROTEM equipment, training, consumables and time for tests) is £113,313 per annum. Reductions in blood products, critical care and haematology time result in an incremental cost for OBS Cymru compared with a standard care of −£33,163 (cost saving). If the length of stay is included in the analysis, the incremental cost is £57,274 (cost incurring), but this may be due to random variation in the length of stay data.

All scenarios showed an incremental cost reduction in maternity unit >3000 births per annum when the length of stay was not included. The length of stay was inconsistent in both magnitude and direction between the different scenarios, and strongly influenced the overall cost outcomes. The change in the length of stay observed in scenario 1 was small (2 h) and not clinically relevant to an individual patient. The length of stay will also have been affected by multiple influences outside of the scope of PPH care (e.g. neonatal complications, breastfeeding), which were not described within the OBS Cymru data and may be purely due to random variation. It is however apparent in a large dataset and warrants further research to investigate this unexpected finding. Other economic analyses have also included the length of stay, Prick et al. report similar durations (means of 2.6 and 2.4 days) for women with anaemia after PPH in the UK [13]. Snegovskikh et al. report a statistically significant ($p < 0.001$) reduction in the median length of stay from 5 to 4 days based on a study of 86 patients [16]. The US healthcare setting may make this less relevant to the UK length of stay.

Scenario 3 demonstrated a greater incremental cost reduction associated with the use of OBS Cymru, compared with the pre-specified scenarios 1 and 2. This result must be treated cautiously, as it is a post-hoc analysis, with the intention of exploring the impact of implementation in units with comprehensive adoption of OBS Cymru. In addition, the 3-month data periods for each arm were at different
seasonal timepoints. Despite these cautions, this scenario indicates that a full cost evaluation of the implementation of OBS Cymru principles, using a true comparator arm, might show an incremental cost reduction per woman with PPH in small-sized to medium-sized maternity units (>1000 deliveries per annum), in addition to improved clinical outcomes. Figures 2, 3, 4 demonstrate that for key parameters other than the length of stay, the reduction in resource use is greater in Scenario 3, as this reflects the maternity units and time periods that experienced the greatest change in practice.

5 Future Research

Future research into clinical outcomes would support improvements in economic evaluations if improved comparator data were available and the impact on staff time was considered more fully. Since completion of the quality improvement project, alternative point-of-care testing devices are starting to be adopted, and this may change future findings, as may other changes in unit costs for blood products and NHS services. Collection of quality-of-life measures would enable the completion of a full cost-effectiveness model, which should include a probabilistic sensitivity analysis, and the inclusion of longer term outcomes for complications from blood transfusion and additional support requirements. This would give a more complete picture of the full impact on patients, both in terms of cost and quality of life.

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Declarations

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Conflicts of Interest RE Collis has received research support from CSL Behring, Werfen and Haemonetics. PW Collins has received honoraria from CSL Behring and Werfen and research support from CSL Behring, Werfen and Haemonetics. He has received support to attend a conference from CSL Behring. All other authors have no conflicts of interest to declare.

Ethics Approval In the UK, the need for submission to an ethics committee is governed by the Health Research Authority. The data published in this paper comply 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 [33]. 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. E-mail confirmation of this decision is included in the supplementary materials.

Consent to Participate Not applicable.

Consent for Publication Not applicable.

Availability of Data and Material Patient-level data cannot be made available; however, the STATA code and Excel model may be made available on request.

Code Availability Not applicable.

Authors’ Contributions RC and PC led the research under-pinning OBS Cymru, SB and RC obtained funding. SB, CS, KJ, MJ and RC designed OBS Cymru. SB and RC led the quality project. CS, KJ, MJ and PC managed the quality project. CS, KJ and MJ collected the clinical data. MD was responsible for health economic methodology, with contributions from SOC and GCR. SB, CS, KJ, RC and PC provided clinical expertise for health economic inputs. SOC and GCR critically reviewed the health economic analysis. MD, SB and SOC wrote the initial drafts of the manuscript. All authors contributed to revisions of the manuscript and all authors read and approved the final version.

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