

What is the economic cost of providing an all Wales postpartum haemorrhage quality improvement initiative (OBS Cymru)? A cost-consequences comparison with standard care

Megan Dale, Sarah Bell, Susan O'Connell, Cerys Scarr, Kathryn James, Miriam John, Rachel Collis, Peter Collins, Grace Carolan-Rees

Megan.dale@wales.nhs.uk

Cedar, Cardiff and Vale University Health Board

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Supplementary materials 1: Consideration of ethical requirements

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OBS Cymru was funded by an Efficiency Through Technology grant from the Welsh Government. It was supported by Improvement Cymru (the national improvement body for NHS Wales) and the Wales Deanery through Clinical Leadership Fellows.

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.

The funders 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.

Declaration 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

Consideration of ethical requirements

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 Cymru 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 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