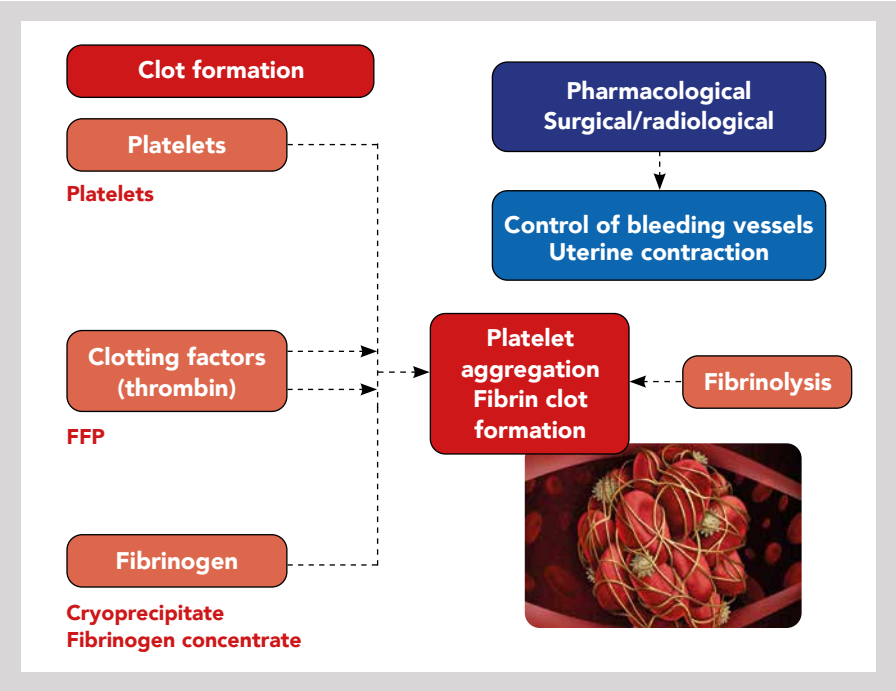
Viscoelastic POC testing helps to stem post-partum haemorrhage

Point-of-care testing has found application across the breadth of healthcare, a recent prime example being the role of viscoelastic POC testing in post-partum bleeding management in obstetrics.

The value of point-of-care (POC) coagulation testing using viscoelastic technology to address obstetric bleeding is leading to a new approach in managing post-partum haemorrhage (PPH), which is still the main cause of maternal death.[1]

It is recognised that PPH can be exacerbated by coagulopathy, with a decline in fibrinogen levels known to be the first indicator of the condition. However, the clinical utility of laboratory fibrinogen testing to predict progression of PPH has always been limited because 'time to results' can be 60–90 minutes. Faced with PPH, this can be too long to wait. The bleed will either have stopped or results are retrospective, with the clinician having relied on empirical transfusion ratios.

The ability to monitor fibrinogen and other parameters at the point of care within 10–15 minutes would enable surgeons to deliver early, targeted fibrinogen replacement that might stem the progression of PPH. It is equally important to be able to monitor and interpret other coagulation parameters at the same time, as research shows that replacing fibrinogen will not improve outcomes if these levels are normal.[2]



Steps to halt obstetric bleeding.

Quantra POCT delivers laboratory comparable results

The specific role of viscoelastic testing (VET) at the point of care to carry out this measurement has come to the fore with clinicians now reviewing a role for this technology in PPH bleeding management.

Quantra, Stago's point-of-care VET solution, delivers laboratory comparable results within 15 minutes and is already being used by cardiac surgeons at New Cross Hospital.[3,4]

Pathology in Practice had previously highlighted, from the IBMS Congress in 2019, the original study carried out by the hospital's core laboratory as part of its ISO15189 accreditation and to approve its use in surgery.

This is in line with the latest guidelines from the Institute of Biomedical Science, which makes it clear that point-of-care testing (POCT) should be operated within "the framework of a clearly defined policy that recognises the essential role of laboratory trained personnel".

Laboratory evaluation study

The New Cross laboratory compared the precision of critical parameters (including fibrinogen) between the laboratory and point of care. The positive outcomes of

the study enabled the laboratory to demonstrate to clinical colleagues the good correlation between POC and accredited laboratory results.

This supported the introduction of the Quantra POC solution into surgical protocols, significantly reducing their reliance on blood products. The laboratory noted that there was no point in risking patient safety by giving unnecessary blood products if they could provide data that better informed medical decision-making when a critical bleed occurred.

Three years on, consultant anaesthetist Dr Mario Ferrante at New Cross relies on Quantra to support him when faced with acute perioperative situations. Talking about his recent experiences he explained: "…within five minutes we know exactly how to treat the patients. Without the Quantra results it is likely that they would have (been) given more products."

Left: The Quantra POC analyser.

Above: Easy-to-read dials display QStat parameters.

Reducing use of blood products

The UK's Royal College of Obstetricians and Gynaecologists (RCOG) defines PPH as blood loss of ≥500 mL within 24 hours of vaginal delivery, or ≥1000 mL after Caesarean delivery. Blood loss that is severe (>2000 mL) or massive (>2500 mL) is defined, irrespective of the means of delivery.

Observational findings from a 10-year study across Wales showed that a fibrinogen level of 1.0–1.5 g/L is likely to be too low for adequate haemostasis during ongoing PPH.[5] Fibrinogen below 3 g/L and especially below 2 g/L is associated with progression of bleeding, increased RBC and blood component requirements, and the need for invasive procedures.[6]

Data also showed it was possible to achieve a 60% reduction in bleeding of more than 2500 mL and a fall in hysterectomies and intensive care unit admissions. From the laboratory perspective, there was a 30% reduction in the use of blood products.[7]

The study's overall aim was to find ways to improve maternal outcomes[8] by assessing the value of POCT and to investigate the role of fibrinogen as a marker for increasing PPH. Its findings have already led to new risk assessment strategies.[9] These start with the need to make an early, formal risk assessment of every patient, and they recommend that multidisciplinary clinical care is available at the point of care when blood loss reaches 1000 mL.

Confidence in POC algorithm

In terms of decision-making, it emphasised that having information provided by the cumulative measurement of blood loss was essential. It further advised that this could be facilitated by having access to POCT-guided blood-product decisions using a robust, clinical-based algorithm.[10]

Willingness to switch to a POCT protocol as recommended by the Welsh study relies on having confidence in the device. Independent evidence from both a NEQAS evaluation and one carried out in the USA both confirm the precision of the Quantra, again putting it firmly in line with laboratory accreditation standards.

The NEQAS report shows that the Quantra cartridge consistently demonstrated robustness and good precision, with a 5% coefficient of variation (CV) and an overall CV range of 2.6% to 6.9%. NEQAS further confirmed that the results would be suitable benchmarks for EQA compliance.

> It is recognised that PPH can be exacerbated by coagulopathy, with a decline in fibrinogen levels known to be the first indicator of the condition

The 2020 US quality assurance study[11] also confirmed the Quantra's precision with data demonstrating that the system was "able to generate results with high precision, while operating at the POC". It showed that the CV for total imprecision was 3.6% to 8.0% for all measured parameters.

Technological excellence

The internal design of Quantra enables opportunities for internal quality control (QC) that are made possible by the ultrasound-based technology within the device. It uses ultrasound to directly measure clot elasticity rather than amplitude. The result is increased sensitivity to early clot formation and also to soft clots, often linked to clinical bleeding.

With this approach, every time an ultrasound pulse is transmitted, and echoes are received, the system effectively obtains a 'line' image through the sample. This offers unique capabilities to perform more advanced quality checks that are not currently available with other VET devices, especially during the preanalytical and analytical phases of testing.

Other innovations focus on the ease of use and interpretation of results in a fast-moving environment like the operating theatre. The dials on the Quantra display the readings of each of the parameters as numbers (although this can easily be changed to review as curves if desired). The data can also be shared remotely with the laboratory or blood bank through the Remote Desk Viewer, with real-time or historical results assessed from any networked Quantra instrument in the hospital.

The Quantra QStat cartridge has a role to play in PPH due to its ability to measure fibrinolysis. QStat parameters include clot time (CT), clot stability to lysis (CSL), clot stiffness (CS), platelet contribution to clot stiffness (PCS) and fibrinogen contribution to clot stiffness (FCS).

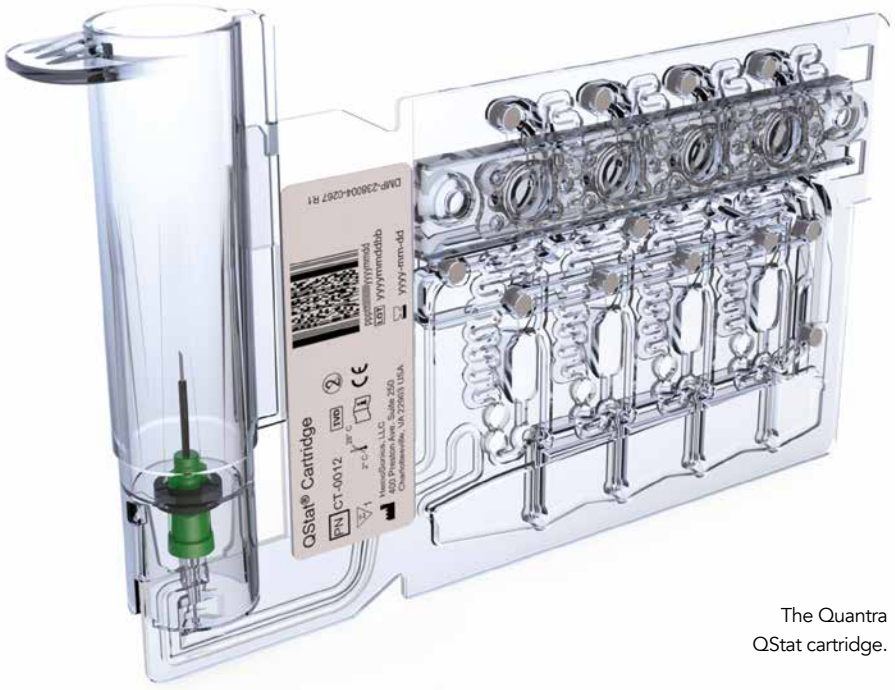
The second Quantra cartridge, the QPlus, offers clot times with and without heparinase (CT and CTH), CS and FCS. From these, two unique parameters are automatically calculated: the clot time ratio (CTR) and platelet contribution to clot stiffness (PCS). The PCS accounts for the platelet count and platelets' ability to aggregate, contract and contribute to clot strengthening.[12]

Improving bleeding management

Point-of-care VET testing has a potentially life-saving role to play when PPH blood loss reaches 1000 mL – indicating if early intervention with fibrinogen replacement would be of value, while also providing data on the patient's coagulation status.

Greater awareness of the role of fibrinogen parameters can support actual measurement of blood loss rather than relying on estimated loss while waiting for laboratory tests to be processed. This in turn can reduce clinical anxiety[13] when faced with increasing PPH, with previously little choice but to administer blood products.

Acute perioperative situations demand fast action on whether or not to transfuse critically bleeding patients. Confidence in the Quantra algorithm and the precision of its parameters enables informed clinical decision-making based on laboratory comparable results with a turnaround time for urgent results of under 15 minutes.



The Quantra QStat cartridge.

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The ability to monitor fibrinogen and other parameters at the point of care within 10–15 minutes would enable surgeons to deliver early, targeted fibrinogen replacement

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