



# Adoption support resource – insights from the NHS

Implementation support

Published: 20 August 2014

[www.nice.org.uk](http://www.nice.org.uk)

# Contents

1 Executive summary .....	3
2 Introduction .....	5
3 Current practice .....	7
Standard laboratory tests .....	7
Management of major haemorrhage .....	7
Summary of NICE recommendations .....	9
Tips for adopting viscoelastometric point-of-care testing .....	9
4 Insights from the NHS .....	11
Cardiothoracic surgery case studies .....	11
Trauma case study .....	16
Obstetrics case study .....	17
Other examples of how the technology is used within the NHS .....	18
5 The technologies .....	23
ROTEM .....	23
TEG .....	26
Sonoclot .....	28
6 How to implement NICE's guidance on viscoelastometric point-of-care testing .....	31
Thromboelastography/thromboelastometry toolkit .....	31
Patient blood management .....	32
Quality control .....	32
Overcoming implementation hurdles .....	34
Business case development .....	35
Project management .....	36
7 Additional support and information .....	40
8 Acknowledgements .....	41
9 About this resource .....	44

# 1 Executive summary

This resource has been developed to provide practical information and advice on viscoelastometric point-of-care testing (ROTEM, TEG and Sonoclot systems) ([NICE diagnostics guidance DG13](#)). It is intended for use by both clinical and non-clinical staff who are planning to implement this NICE guidance and start using 1 of these technologies.

NICE's Health Technologies Adoption Programme worked with NHS organisations to collect and share their experiences of using viscoelastometric point-of-care testing with organisations that may want to start using 1 of these technologies in the future. The information included in this resource is intended for the sole purpose of supporting the NHS in adopting or further researching viscoelastometric point-of-care testing. The information has not been assessed by the independent External Assessment Group or considered by the Diagnostics Advisory Committee when making its decision on the use of viscoelastometric point-of-care testing in the NHS.

The benefits of using viscoelastometric point-of-care testing reported by NHS staff involved in the production of this resource include:

- Improved clinical management of patients who are bleeding.
- Reduced risk of transfusion-related complications due a reduced need for blood and blood components.
- Improved management of blood and blood components.
- Cost savings due to reduced use of blood and blood components.

We have produced this information to support organisations in considering the benefits of implementing NICE guidance DG13. This resource explores these benefits in detail and provides practical advice on how NHS trusts can use viscoelastometric point-of-care testing effectively.

The learning gained from existing users of viscoelastometric point-of-care testing is presented as a series of examples of current practice. They are not presented as best practice nor are they necessarily fully in accordance with the guidance. They are presented as real-life examples of how NHS sites have adopted and used these technologies. The examples included in this document that extend beyond the positive

guidance recommendations are presented to assist organisations and clinicians who intend to carry out research.

## 2 Introduction

The causes of haemorrhage are very diverse in nature. Common causes include gastrointestinal bleeding, ruptured aortic aneurysm, traumatic injury and complications associated with surgery or childbirth. In all circumstances, the presence of an underlying or acquired coagulopathy will further complicate the clinical management of the patient and may delay the establishment of haemostasis.

Any surgical procedure carries an inherent risk of bleeding. If surgery is considered to be extensive or involves a particularly vascular part of the body, then the risk of unexpected or severe bleeding is increased. Although some bleeding is inevitable during surgery, the causes of any excess bleeding can be diverse and need to be identified and treated without delay.

Whilst mortality is low for most surgical procedures, ranging from less than 0.1% for most routine surgery to 1–2% for cardiac surgery and 5–8% for elective vascular cases, this may be greatly increased when severe bleeding occurs during the operative procedure.<sup>[1]</sup>

In the UK, obstetric haemorrhage occurs in approximately 3.7 births per 1000.<sup>[2]</sup> The diagnosis and management of obstetric haemorrhage can be challenging and due to the dilution of blood with amniotic fluid, it may be difficult to assess the extent of blood loss. Normal coagulation during pregnancy is also altered and this may complicate subsequent treatment.

Patients who suffer from trauma, such as road traffic accidents, often present with multiple injuries and require immediate medical intervention. Within this population it is recognised that major haemorrhage is the primary cause of death. Furthermore, due to the extent of the injuries sustained, it has been recognised that approximately 25% of these patients arrive in the emergency department with an established coagulopathy, further complicating subsequent treatment.<sup>[3]</sup>

Major blood loss due to any of the above conditions leads to a reduced capacity within the body to deliver oxygen and nutrients to the tissues and organs. This in turn prolongs recovery and increases the risk of further complications. Uncontrolled bleeding can lead to complications such as hypothermia, haemodilution, acidosis and an increased use of clotting factors. This can further exacerbate the bleeding problem and cause a vicious cycle to develop.

The examples above are all potential causes of primary bleeding. However, as part of diagnosis and treatment, it is also important for the clinician to assess the patient for any acquired or underlying coagulopathy. This includes conditions such as disseminated intravascular coagulation, hyperfibrinolysis, thrombocytopenia, inherited or acquired platelet disorders and vitamin K deficiency.

The use of viscoelastometric point-of-care testing enables the clinician to establish whether a coagulopathy is present and if so, to determine the underlying cause. This information guides treatment and determines whether the primary cause of bleeding has been adequately corrected, and if specific blood components need to be administered. The type of coagulopathy identified will help to identify which blood components would be most beneficial to the patient.

---

<sup>[1]</sup> M. Marietta, L. Facchini, P. Pedrazzi, S. Busani, and G. Torelli (2006) Pathophysiology of Bleeding in Surgery. *Transplantation Proceedings*, 38, 812–4.

<sup>[2]</sup> Saving Mothers' Lives: Reviewing maternal deaths to make motherhood safer: 2006–2008. *The Eighth Report of the Confidential Enquiries into Maternal Deaths in the United Kingdom BJOG* March 2011 Volume 118, Issue Supplement s1 Pages 1–203

<sup>[3]</sup> Brohi K, Singh J, Heron M et al. (2003) Acute traumatic coagulopathy. *Journal of Trauma*. 54:1127–30

## 3 Current practice

### Standard laboratory tests

Standard laboratory blood tests for coagulation include prothrombin time, a measure of the extrinsic pathway of coagulation, and activated partial thromboplastin time, which measures the intrinsic pathway of coagulation.

Although these tests can measure coagulation factor function, they are generally unable to assess platelet function, clot strength and fibrinolysis. Depending upon local logistics, results may take between 40 and 90 minutes which can delay subsequent treatment.

Viscoelastometric testing enables clinicians to get a picture of the entire process of blood coagulation using whole blood and so enables them to target therapy appropriately. This reduces the risk associated with unnecessary blood transfusions, helps to manage blood stocks and can help with early identification of patients that require repeat surgery.

### Management of major haemorrhage

The management of major haemorrhage within the NHS is variable. During the development of this resource, NICE has been shown protocols developed by local transfusion committees, in collaboration with clinicians and laboratory staff, which are reported to help improve the consistency of diagnosis and treatment.

Such protocols and algorithms detail a step-by-step approach to the emergency treatment of major haemorrhage and usually include guidance on each element within the process. They are aimed at guiding the following staff:

- the attending doctor or nurse who may be the first person to recognise the need to activate the protocol.
- senior clinical staff called as part of the emergency response or resuscitation team.
- laboratory staff and other supporting services within the hospital, such as porters and managers.

The current treatment of massive haemorrhage usually includes the transfusion of large volumes of blood and blood components based upon a protocol-driven approach. However, the [North West Regional Blood Transfusion Committee](#) has highlighted some potential concerns relating to this approach, as detailed below.

<b>Pros and cons of formula-driven massive transfusion protocols</b>	
<p><b>Pros</b></p> <p>May reduce mortality from bleeding.</p> <p>May improve speed of delivery of blood components.</p> <p>Reduced communications back and forth between clinical area and lab.</p> <p>May target and prevent onset of coagulopathy.</p> <p>Reduce dependency on lab testing in acute resuscitation phase.</p>	<p><b>Cons</b></p> <p>Based on level III and IV evidence mainly in major trauma.<sup>[a]</sup></p> <p>Exposure to additional units of fresh frozen plasma and platelets will increase risk of complications such as transfusion-related acute lung injury, organ failure, thrombosis and sepsis<sup>[b]</sup>.</p> <p>Inappropriate triggering of formula-driven care in non-massive transfusion patients.</p> <p>Increased wastage of fresh frozen plasma and platelets.</p> <p>Depletion of platelet and plasma stocks.</p>
<p><sup>[a]</sup> Callum JL, Nascimento B, Tien H, Rizoli S Editorial: "Formula-Driven" Versus "Lab-Driven" Massive Transfusion Protocols: At a State of Clinical Equipoise Transfusion medicine Reviews 2009 23 247-254</p> <p><sup>[b]</sup> Inaba K, Branco BC, Rhee P, Blackbourne LH, Holcomb JB, Teixeira PG, Shulman I, Nelson J, Demetriades D. Impact of plasma transfusion in trauma patients who do not require massive transfusion. J Am Coll Surg. 2010 Jun;210(6):957-65</p>	

As can be seen in the [Insights from the NHS](#) section, by including the use of viscoelastometric point-of-care testing as part of major haemorrhage protocols, clinicians may be able to address some of the issues listed above. The administration of blood components can be guided by the early results, the risks reduced, wastage minimised and the management of blood stocks improved.

The North West Regional Blood Transfusion Committee has carried out work to produce a massive haemorrhage toolkit for hospital transfusion teams and committees. The toolkit



includes flow charts outlining the management of massive haemorrhage in adults and children and a 7-step guide to coordinating the response. The [flow charts and guide](#) can be downloaded from the website and adapted by NHS trusts to meet their individual requirements and local needs.

## Summary of NICE recommendations

[Diagnostics Guidance 13](#): evaluated 3 viscoelastometric point-of-care testing devices (ROTEM, TEG and Sonoclot systems) used to help detect, manage and monitor haemostasis. The guidance states:

1.1 The ROTEM system and the TEG system are recommended to help detect, manage and monitor haemostasis during and after cardiac surgery. Healthcare professionals using these systems surgery should have appropriate training and experience with these devices.

1.2 The Sonoclot system is only recommended for use in research to help detect, manage and monitor haemostasis during and after cardiac surgery. Research is recommended into the clinical benefits and cost effectiveness of using the Sonoclot system during and after cardiac surgery.

1.4 There is currently insufficient evidence to recommend the routine adoption of viscoelastometric point-of-care testing (ROTEM, TEG and Sonoclot systems) in the NHS to help detect, manage and monitor haemostasis in the emergency control of bleeding after trauma and during postpartum haemorrhage. Research is recommended into the clinical benefits and cost effectiveness of using viscoelastometric point-of-care testing to help in the emergency control of bleeding after trauma or during postpartum haemorrhage.

## Tips for adopting viscoelastometric point-of-care testing

Tips for NHS trusts thinking about adopting or carrying out research into viscoelastometric point-of-care testing:

- Consider the implementation of viscoelastometric point-of-care testing as part of a wider [patient blood management](#) approach. See [North Manchester General Hospital case study](#) for more details.

- Include the use of viscoelastometric point-of-care testing as part of a [major haemorrhage protocol](#). Specific protocols may need to be developed depending upon whether viscoelastometric testing is or is not available.
- Develop local protocols that include the use of viscoelastometric testing within the chosen patient pathways, such as cardiothoracic surgery. See [The Royal Brompton case study](#) for more details.
- Plan where the device will be situated to ensure that this is both convenient and that the environment is suitable (equipment can be sensitive and care needs to be taken regarding its location).
- Have a number of named people as champions for the technology who can be designated as 'super-users'. They will act as the main points of contact for the manufacturer and will be responsible for day-to-day management and problem solving.
- Ensure that the number of staff selected to perform tests will allow them to maintain their skills and knowledge regarding the equipment and the procedure. Carrying out these tests requires basic laboratory skills such as pipetting and the use of reagents. Although these skills can be taught in a relatively short period, staff will need to maintain their skills through regular use of the technology. See [Education](#) for further details.
- Ensure that clinicians are fully educated in the interpretation of results and in their application to practice. Interpretation can depend on the test used and the population being tested. It is important for clinicians to use these skills on a regular basis to maintain quality. See [North Manchester General Hospital case study](#) for more details.
- Ensure that trust laboratories and the point-of-care committee are included in all decisions regarding purchase of equipment, maintenance and quality control schemes. See [Quality control](#) for more information.
- In order to demonstrate continued cost savings, conduct regular audits of blood component usage. See [Golden Jubilee National Hospital](#) or [North Manchester General Hospital](#) for examples.

For more information refer to [Insights from the NHS](#) for the experiences of NHS trusts currently using viscoelastometric point-of-care testing.

## 4 Insights from the NHS

During the development of this resource, NICE worked with the manufacturers to identify NHS trusts using viscoelastometric point-of-care testing technologies. These organisations agreed to provide structured feedback on their experiences of using the technology as detailed in this section.

The information gained from these NHS organisations during the development of this resource is intended for the sole purpose of supporting the NHS in adopting or undertaking research into viscoelastometric point-of-care testing devices. This information has not been assessed by the independent External Assessment Group and was not considered by the Diagnostics Advisory Committee when making its decision on the use of these technologies in the NHS.

The examples given are not presented as best practice nor are they necessarily fully in accordance with the guidance. Rather they are presented as interesting, real-life examples of how NHS sites have adopted and used these technologies. The examples included in this document that extend beyond the positive guidance recommendations are presented to assist organisations and clinicians who intend to carry out research.

### Cardiothoracic surgery case studies

#### Golden Jubilee National Hospital

Golden Jubilee National Hospital is located in Clydebank, Scotland. It is described as a national resource for NHS Scotland and is managed by the National Waiting Times Centre Board.

The hospital has over 200 beds and 1400 staff, and specialises in orthopaedics, heart conditions and lung disease. It has 4 cardiac catheterisation labs, 16 theatres, and is home to regional and national heart and lung services.

Clinicians have used viscoelastometric testing within cardiothoracic surgery since 2002, initially at the Western Infirmary and latterly at the Golden Jubilee. They currently use the TEG system across all their clinical sites, and have a total of 32 TEG channels allowing them to run 32 individual tests at any time. They also have 3 ROTEM systems (12

channels) used alongside the TEG systems. All viscoelastometric testing at the Golden Jubilee is carried out at point of care in theatres or intensive therapy unit, with the support of the local point-of-care testing committee.

Anaesthetists carry out all tests, maintenance activities and quality control procedures at the Golden Jubilee. All educational requirements are done in-house by anaesthetic consultants who pass on their knowledge and skills to junior doctors during their rotation through the hospital.

Dr Lynne Anderson carried out an audit published in 2006 to assess the impact of using viscoelastometric testing within cardiothoracic surgery. The audit looked at the demographic data and transfusion requirements of 990 patients covering 6 months prior to the introduction of the ROTEM systems (488 patients) and 6 months after (502 patients). The table below summarises the changes in blood use observed.

	Percentage of patients requiring blood and blood components		Total number of units transfused	
	6 months prior to introduction of the ROTEM system	6 months following introduction of the ROTEM system	6 months prior to introduction of the ROTEM system	6 months following introduction of the ROTEM system
Red blood cells	60%	53%	1094	931
Fresh frozen plasma	17%	12%	343	271
Platelets	16%	11%	96	75

This audit confirmed the clinical impression that both the number of patients requiring blood components and the number of units transfused were significantly reduced following the introduction of the ROTEM system. During the audit, tests were performed post-operatively in almost all bleeding patients and did not influence intra-operative management of the patients. Results of the audit therefore reflect post-operative transfusion requirements. Admission and discharge haemoglobin levels were not significantly different during the 2 time periods.

Although the NHS in Scotland does not currently pay the Scottish National Blood Transfusion Service for blood and blood components, the estimated costs and six-month savings available at the time of the audit are represented in the table below.

	Units saved	Total cost saving (£)
Red blood cells (£150 per unit)	163	24,450
Fresh frozen plasma (£54 per unit; usually 4 administered)	72	3,888
Platelets (£256 per unit)	21	5,376
Total		33,714

Although the cost benefits noted within this audit are important, from a clinical perspective the reduced short- and long-term clinical risks associated with blood transfusion were also considered to be of major benefit to patients.

Subsequent analysis following the audit has demonstrated that reductions in blood and blood component use have been maintained.

Further detailed information regarding this audit can be found in:

Anderson L et al. (2006) An audit of red cell and blood component use after the institution of thromboelastometry in a cardiac intensive care unit. *Transfusion Medicine* 16, 31–9.

## John Radcliffe Hospital, Oxford

The [John Radcliffe Hospital](#) is part of the Oxford University Hospitals NHS Trust and is Oxfordshire's main accident and emergency site. The John Radcliffe is the largest of the trust's hospitals, covering around 66 acres. It provides acute medical and surgical services including trauma, intensive care and cardiothoracic services. It is situated in Headington, about 3 miles east of Oxford city centre.

Clinicians at the John Radcliffe have used viscoelastometric testing since 2001. There are currently 18 point-of-care TEG systems in use (36 channels). There are 4 within cardiac surgery, 2 in cardio-thoracic critical care, 4 in general surgery and 4 in general intensive care. There are a further 2 TEG systems used in vascular services and 2 in the transplant

laboratories.

Tests are carried out by dedicated clinical haemostasis practitioners, who are also responsible for the operation of cell salvage devices, and operating department practitioners and nurses within critical care. These staff are also responsible for maintenance and quality control of the equipment. Results from tests are considered essential for the assessment of blood component requirements, especially prior to the administration of fresh frozen plasma, cryoprecipitate or platelets.

The initial procurement of the TEG system at the John Radcliffe was supported by the Trust blood bank and the point-of-care service. Since the introduction into cardiac surgery, cardiothoracic critical care and adult intensive care units, benefits have been observed in 3 different areas of blood management.

Firstly, exposure of patients to transfusion of blood and blood components has been reduced. For example, within adult intensive care, red cell transfusions have been reduced by 31%, fresh frozen plasma transfusions by 43% and platelet transfusions by 35%. This benefits patients due to the inherent risks associated with blood transfusion.

Secondly, the use of the TEG has enabled the trust to reduce the number of blood transfusions administered outside of agreed guidelines. This puts the trust in a better position at times of national blood shortage and minimises disruption to clinical activity.

Thirdly, reducing blood transfusions has reduced costs. The adult intensive care unit spent £198,756 on blood and blood components in the financial year April 2003 to March 2004. Based on audit results, it is estimated that £98,053 of this was spent on unnecessary transfusions. By using the TEG system to enable clinicians to make more informed decisions regarding transfusion, the estimated financial saving in blood use in the adult intensive care unit is £65,488 per year.

In summary, the trust found that the TEG system has had a positive impact on blood management. The technology has helped clinicians to make informed decisions regarding individualised treatment of bleeding at the time of need and at point of care.

## **The Royal Brompton**

The [Royal Brompton Hospital](#) is part of the Royal Brompton and Harefield NHS Foundation Trust and is situated in Chelsea, London. The hospital is a specialist centre for the

treatment of heart conditions and lung disease. It has 295 beds, more than 1600 staff, 6 operating theatres and 4 catheter laboratories.

The Royal Brompton has 5 TEG systems (10 channels) within its theatre complex which specialises in cardio-thoracic surgery. These are routinely used for the assessment of clotting for all patients. The devices are located centrally within the theatre where they are operated and maintained by clinical perfusion scientists. There are plans at the Royal Brompton to build a new point-of-care testing room, centrally within the main theatre suite. This will enable all testing equipment to have a central location for more convenient maintenance and quality control.

Clinical perfusionists have been trained to carry out the tests, maintain the equipment on a daily basis and perform the required quality controls. Any problems with the equipment that cannot be addressed locally can be escalated to the trust 'point-of-care' committee as required. All education is carried out by the 'point-of-care' manager in conjunction with the manufacturer.

Anaesthetists, perfusionists and haematologists have also assessed the utility of the ROTEM and Sonoclot systems. They have preliminary data that suggests the Sonoclot system is helpful in the assessment of platelet function and the ROTEM system for the assessment of fibrinogen. TEG is also a useful adjunct when exploring the haemostasis defects incurred via extra corporeal membrane oxygenation, a technique used to provide cardiac and respiratory support for patients whose heart and lungs are not working sufficiently. Patients having this procedure are particularly susceptible to coagulopathies and often require the transfusion of blood components to stabilise and maintain haemostasis.

Intensivists and anaesthetists at the Royal Brompton have developed a treatment algorithm using laboratory parameters and TEG to guide the management of bleeding after cardiac surgery. This provides a step-by-step approach to the identification and management of bleeding and demonstrates how this technology can help clinicians to identify the most appropriate blood components to administer for a given scenario. The algorithm is available for [download here](#).

Clinicians at the Royal Brompton have specifically found the technology useful for establishing a pre-operative clotting baseline, for the monitoring of haemostasis during surgery and in the post-operative period, and to guide transfusion decisions.



# Trauma case study

## British Army

The British Army currently uses viscoelastometric point-of-care testing as part of the emergency trauma services provided for the armed services at Camp Bastion in Afghanistan and at the Queen Elizabeth Hospital in Birmingham where injured troops are cared for when repatriated to the UK.

Camp Bastion Field Hospital is the major military trauma centre for Helmand Province, Afghanistan. The multidisciplinary medical team is British-led and commanded and staffed by both the regular and Territorial Army, as well as international staff from allied nations.

In order for this technology to be effectively adopted into routine use, it was recognised that staff need to have a good level of knowledge and understanding of the system and to be familiar with its use. For this reason, prior to being deployed to Afghanistan, military medical staff carry out an intensive pre-deployment training course which includes education on the theory, practice and interpretation of viscoelastometric results. This is provided by a cohort of consultant doctors who are experts in the field. The course includes theoretical understanding of the technology, practical experience, maintenance, quality control and troubleshooting. This is followed by a 1 week series of practical exercises.

It was also recognised that viscoelastometric testing should always be available as required. There are 3 ROTEM systems at Camp Bastion, 2 located in theatre and 1 which is used for research purposes. This allows for increased capacity and helps to maintain availability of the test during maintenance activities or repairs. A further 2 ROTEM systems are used in the Queen Elizabeth Hospital, in theatre and in the Trauma Critical Care unit.

Soldiers who sustain traumatic injuries often require massive blood transfusions and their management can be further complicated due to their location and access to blood and blood components.

The British Army has found the use of viscoelastometric testing in this situation very helpful. The benefits noted are:

- Targeted use of blood and blood components, especially those which are in limited supply.



- Identification of those patients who are bleeding due to trauma or surgery rather than due to a coagulopathy.
- Ability to identify and appropriately manage those patients who, despite a normal clotting profile and surgical control, continue to bleed.

Within Camp Bastion, trauma patients are resuscitated and transfused as part of a seamless approach from arrival, through the emergency department and into theatre. Viscoelastometric testing is carried out as soon as possible upon arrival at Camp Bastion, as coagulopathies are common in this patient population. Although results may not be available prior to initial treatment (which may include blood transfusion), as soon as early results become available, treatment options and transfusion protocols can be adjusted as required.

Casualties are often repatriated within 36 hours of their initial trauma and are flown direct from Camp Bastion to the UK. During this time, the patient's clinical condition continues to evolve and change. For this reason, on arrival at the Queen Elizabeth Hospital in Birmingham, ROTEM analysis is performed as part of the admission protocol and is used to guide ongoing haemostatic resuscitation. Further surgery usually occurs within 2–4 hours of admission and during this time, clinicians use ROTEM results to help target transfusion therapy and manage any coagulopathy.

## Obstetrics case study

### Liverpool Women's NHS Foundation Trust

Liverpool Women's NHS Foundation Trust is 1 of only 2 specialist Foundation Trusts in the UK dedicated to the healthcare of women, babies and their families. It has a staff of 1410 and provides clinical and patient services in maternity, gynaecology, neonatal care, fertility and clinical genetics. Each year the trust delivers approximately 8000 babies.

Liverpool Women's Hospital uses the ROTEM system for all obstetric bleeding scenarios. Currently, 1 ROTEM system is used clinically and 1 is on loan and used for research purposes. The trust mainly uses the fib-tem and ex-tem assays to guide decision-making. In order to be most responsive to the needs of the patient, the system is located centrally within the obstetric operating theatre complex.

During adoption of this technology, it was recognised that in order for results to be

reliable, the quality and consistency of testing would need to be maintained. For this reason, the 11 consultant anaesthetists who carry out the tests provide education to the junior doctors who rotate within the region on a 3-monthly basis. All staff are assessed for competency prior to being able to run a test or interpret results. The trust [training and competency assessment form](#) is available for download as an example.

Liverpool Women's Hospital has been using the ROTEM system since April 2011. From April 2011 to March 2012 it used the technology in conjunction with conventional transfusion of blood and blood components. A second phase then ran from July 2012 to June 2013 when a dose of 3 g fibrinogen concentrate was included in the algorithm, with further doses titrated according to the patient's response to treatment. When comparing the 2 periods, clinicians discovered that there were statistically significant reductions in the volume of fresh frozen plasma, cryoprecipitate, fibrinogen and platelets transfused for those patients who had received fibrinogen concentrate. There were also significantly fewer patients who needed 6 or more units of red cells in the latter group.

They also noted that since incorporating use of the ROTEM system to guide the use of fibrinogen concentrate in the treatment algorithm, no patients have suffered the negative effects of receiving too much fluid. This in turn has reduced the number of admissions to intensive care. This is their current algorithm and analysis of a further year's data is due to begin soon as part of their ongoing audit. For additional information please contact: Dr Shuba Mallaiah at [shuba.mallaiah@nhs.net](mailto:shuba.mallaiah@nhs.net)

As the normal clotting values for people who are pregnant are not clearly defined, Liverpool Women's Hospital is also currently carrying out a research study designed to establish normal values within each of the trimesters of pregnancy. The findings of this study are expected to be published in late 2014.

## **Other examples of how the technology is used within the NHS**

### **North Manchester General Hospital**

[North Manchester General Hospital](#) is the largest hospital within the Pennine Acute Hospitals NHS Trust and is located in Crumpsall, 3.5 miles north of Manchester City Centre.

The hospital has 580 beds and offers hepatobiliary, orthopaedic, gynaecology and general surgery services. It is also the base for the regional specialist infectious diseases unit.

Consultant anaesthetist Dr Patrick Waits carried out a trial using the TEG system, with the aim of determining whether it would reduce blood component usage and expenditure, and if it would be a useful tool as part of a patient blood management approach.

The TEG 5000 system was trialled from July 2012 to March 2013. During the adoption of this technology, it was recognised that in order to maintain quality during the trial period, use would be limited to a core group of anaesthetists, theatre staff and staff within critical care. Training in the use and operation of the equipment, interpretation of results and quality assurance was provided. However, ensuring staff were available for training was difficult and caused a number of operational problems.

During the trial period, it was also agreed that due to clinician's limited experience of using the technology and interpreting results, they would be free to combine clinical parameters and other laboratory results with TEG results in order to guide decision-making.

In order to ensure the adoption of this technology was systematic and well planned, a small group supported the project including anaesthetists, the trust point-of-care team, the blood bank manager, the manufacturer and the directorate manager. The trust point of care committee was particularly helpful in providing guidance with quality assurance and writing a standard operating procedure and training competency checklist for the technology.

During the trial period, 24 surgical patients were enrolled. In 46% of cases (11/24), use of the TEG system led to a reduction in blood component administration, with an associated saving of 30 units of fresh frozen plasma and 4 therapeutic doses of platelets.

In a further 29% of cases (7/24), the TEG results indicated that fewer blood components were required but the clinicians decided, based upon clinical judgement, to administer the components. If these blood components had not been administered, this would have accounted for a further saving of 10 units of fresh frozen plasma.

In all cases, clinical opinion was that the technology improved management of bleeding.

The following table summarises the savings of blood components and the associated cost savings achieved during the trial.

	Actual saving (units)	Actual saving (£)	Additional potential saving (units)	Additional potential saving (£)
Platelets	4	832	0	0
Fresh frozen plasma	30	839	10	290

The results of the trial demonstrated that the use of this technology helped clinicians to manage patients who are bleeding as part of an overall patient blood management approach.

It is anticipated that with further experience and training, greater savings would be achieved. Following the trial, Dr Waits carried out an audit over 3 months, which found 150 surgical patients who required 4 units of blood with or without blood components. It is estimated that use of the technology within this larger group of patients would save approximately £48,000 per year in blood components (£13,774 net savings in year 1). The following table provides an estimation of costs and potential savings if all capital costs paid in year 1.

	Year 1 (£)	Year 2 (£)
<b>Capital costs</b>		
2 x 2-channel TEG systems	20,000	0
Training/service costs	0	6000
Reagents £20–30 (mean £25) x 600 patients	15,000	15,000
Total costs (A)	35,000	21,000
<b>Savings based upon findings of audit</b>		
£81 per patient x 600 patients (B)	48,774	48,774
<b>Overall total savings (B-A)</b>	13,774	27,774

If the capital cost was spread over the expected 5 year lifespan of the equipment, the saving could be calculated as follows:

	Year 1 (£)	Year 2-5 (£)

<b>Capital costs</b>		
2 x 2-channel TEG systems	4000	4000
Training/service costs	0	6000
Reagents £20–30 (mean £25) x 600 patients	15,000	15,000
Total costs (A)	19,000	25,000
<b>Savings based upon findings of audit</b>		
£81 per patient x 600 patients (B)	48,774	48,774
<b>Overall total savings (B-A)</b>	29,774	23,774

## Addenbrooke's Hospital

Addenbrooke's Hospital is a university teaching hospital and part of the Cambridge University Hospitals NHS Foundation Trust. It provides emergency, surgical and medical services for people living in the Cambridge area. It also provides regional specialist services including organ transplantation, cancer, neurosciences, paediatrics and genetics.

TEG systems are used within the liver theatre. A ROTEM and a Sonoclot system are also used within the Haemophilia & Thrombophilia Centre, which uses these technologies for its own patients as well as offering an 'office hours' service to patients accessing A&E and general theatre.

Dr Roger Luddington, principal clinical scientist at the Cambridge Haemophilia & Thrombophilia Centre, wrote the following description of the use of the technologies within this setting: "Despite seeing the majority of patients within the centre we choose to use citrate anticoagulated blood samples rather than native blood. This gives a longer window for sample analysis (increasing from 30mins to 2 hours) which is crucial during busy periods in clinic when there is limited machine availability.

We carry out pre-operative screening of patients where hyper-coagulation is a concern, such as pre-pancreas transplantation, but the main application of the technology in our centre is in the investigation of hypo-coagulation.

Viscoelastic measurement is used for a number of applications within the Haemophilia Centre. Initially it is used in the laboratory investigation of an unexplained bleeding

diathesis. This is 1 of the only whole blood measurements of haemostatic potential at our disposal.

Each of the technologies has its own unique features to add to the diagnostic picture. The ROTEM system gives measures of clot formation and breakdown (fibrinolysis) and the Sonoclot dissects out a measure of fibrin formation kinetics and platelet involvement. Neither test is used in isolation. They are used as part of a comprehensive panel of analysis. This panel includes assessment of thrombin generation using principally platelet poor plasma, but where indicated platelet rich plasma, whole blood aggregometry, platelet nucleotide measurement and coagulation factor assessment.

The ROTEM system is also used in the assessment of the efficacy of coagulation factor treatment. This is particularly useful in the treatment of haemophiliacs with specific factor inhibitors treated with some form of bypassing agent such as recombinant VIIa or FEIBA. In the absence of specific assays for the effects of these products, the improvement in the viscoelastometric trace gives reassurance to clinicians following therapy. In the laboratory we can add these bypassing agents to patient sample ahead of treatment and perform viscoelastometry as a guide to the likely response.

The assessment of fibrinolysis is a challenging area of haemostasis. The use of both the ROTEM and Sonoclot systems allows some measure of both hypo- and hyper- fibrinolysis.

In gross abnormalities these changes can be seen in the unmodified tests. However the addition of tissue plasminogen activator to the reaction mixture is used to increase the sensitivity."

## 5 The technologies

### ROTEM

[www.rottem.de](http://www.rottem.de)

The ROTEM system, manufactured by Tem International, is a point-of-care analyser used to assist with the detection, management and monitoring of haemostasis. The device uses thromboelastometry, a method for testing haemostasis. This includes measurements relating to the initiation of clotting, platelet and fibrinogen function and hyperfibrinolysis.

The ROTEM system uses 5 assays to examine the clotting characteristics of a whole blood sample. These are available as liquid reagents or single-use reagents. The following table details the information provided by each.

Reagent	Information provided
in-tem	Assessment of clot formation, fibrin polymerisation and fibrinolysis via the intrinsic pathway
ex-tem	Assessment of clot formation, fibrin polymerisation and fibrinolysis via the extrinsic pathway
hep-tem	Analysis without heparin influence: specific detection of heparin (compared to in-tem), assessment of clot formation in heparinised patients
fib-tem	Analysis without platelets: qualitative assessment of fibrinogen status
ap-tem	In-vitro fibrinolysis inhibition: detection of lysis when compared to ex-tem

The ROTEM analysis is generally performed with citrated whole blood, at point of care, during surgery or post-operatively. The system can run 4 tests concurrently and provides step-by-step instructions and automated pipetting of blood and reagents to simplify the test procedure.

The results of the test are calculated and presented on a touch-sensitive computer screen in the form of a graph of the coagulation process over time. The results of up to 4 tests can be viewed alongside each other and example curves can also be viewed to aid

interpretation. The initial test result is available within 5 minutes, followed by full results within 20 minutes.

Results can also be incorporated into patient data management systems utilising hospital information system and laboratory information system connectivity.

An example of the ROTEM result can be seen on the [manufacturer's website](#) and educational resources are available at <http://learning.rottem.de>.

## Cost and procurement

At the time of publication (August 2014), the current UK pricing and other procurement options available are as follows:

- Capital purchase: £24,950 plus VAT. Cost of assays vary; please contact the company for more information.
- Rental options: a rent-to-buy scheme agreed over 1–3 years with final payment securing ownership of the device. This price varies depending on duration of agreement but is generally between £450 and £900 per month.
- Leasing agreement: no capital outlay. The costs of the device and servicing can be spread over the cost of the reagents and consumables. This varies in price depending on the agreed duration of contract and test volume.
- Consignment agreement: the device is placed and remains the property of TEM. Agreement is made on test volume at the beginning of the contract, with a minimum of 800 tests required per year. Usage is audited every 6 months to ensure consistency. If the agreed volume is reached, the contract continues; if not, the device may be purchased, rented or removed. Consumable costs are slightly higher and depend on whether servicing is included as part of the agreement.

Consumables:

Description	Cost	Number of tests
in-tem	£116.30	10x10
t ap-tem	£111.00	10x5
r ex-tem	£125.00	10x10



fib-tem	£116.00	10x5
hep-tem	£174.30	10x7
star-tem	£65.60	10x20
in-tem S	£128.10	20
ex-tem S	£128.10	20
ap-tem S	£202.00	20
fib-tem S	£202.00	20
hep-tem S	£211.10	20
ROTROL N Level I	£60.50	5x4
ROTROL P Level II	£60.50	5x4
Cup & pin pro	£645.80	200
Tip Tray eLine	£46.10	10x96

For further details and up-to-date costs of equipment, reagents and consumables please contact the company.

## Contact details

TEM UK Ltd, 2 Rivergreen Business Centre, Queen's Meadow, Hartlepool, TS25 2DL

National Sales Manager – UK & ROI, Jim Leith, [jim.leith@tem-international.co.uk](mailto:jim.leith@tem-international.co.uk) 07824 361091.

Area Sales Manager – UK Midlands, Jon Hollinshead, [jon.hollinshead@tem-international.co.uk](mailto:jon.hollinshead@tem-international.co.uk) 07823 328545.

Area Sales Manager – UK South, Adam Knight, [adam.knight@tem-international.co.uk](mailto:adam.knight@tem-international.co.uk) 07824 361096.

Area Sales Manager – Ireland, Declan Brennan, [Declan@dsbmedical.ie](mailto:Declan@dsbmedical.ie) 00353 87 222 1770.

Office Manager – Hartlepool, Julie Bolton, [julie.bolton@tem-uk.com](mailto:julie.bolton@tem-uk.com) 01429 871517, Fax 01429 871258.

ROTEM Hotline – Service & Support, 01429 528419.

## TEG

<http://www.haemonetics.com>

The TEG 5000 Haemostasis Analyser system is a diagnostic device that provides whole blood haemostasis testing, can help assess bleeding and thrombotic risks, and monitor antithrombotic therapies.

TEG is based on the viscoelastometric method but the mechanical systems are slightly different to the ROTEM system. The TEG 5000 Haemostasis System utilises different assays to provide the following information via 2 independent channels.

Reagent	Information provided
Kaolin – activated test	Assessment of clot formation, fibrin polymerisation and fibrinolysis
Kaolin with heparinase	Assessment of clot formation in heparinised patients
Platelet mapping	Assessment of platelet function and monitoring of antiplatelet therapy
Rapid TEG	A more rapid measurement of the clot strength than a standard kaolin assay with the addition of a correlated ACT value and is used mainly in emergency situations such as trauma
Functional fibrinogen assay	Assessment of the impact of fibrinogen on clot strength and stability (made possible by the suppression of the platelet contribution factor)

The TEG system can use platelet mapping to produce a picture of a patient's potential response to antiplatelet therapy relative to their overall haemostasis.

Graphical and numerical results are relayed through a computer interface where real-time analysis is displayed. They can also be viewed remotely in real time, via an appropriate hospital network. Results include the time until initial fibrin formation, the kinetics of fibrin

formation and clot development, the ultimate strength and stability of the fibrin clot and clot lysis. An [example TEG result](#) and [educational resources](#) are available from the manufacturer's website.

## Cost and procurement

- Capital purchase option: a 2-channel TEG analyser with PC, printer and installation costs £10,000. If 4 channels are needed, the cost is £20,000. This cost includes all software, including training and support. Maintenance is included for the 1-year full warranty period. Following this, the customer can then take out a maintenance contract. This costs up to £2500 per analyser but a discount may be given for sites with multiple devices.
- Use plan: under this scheme, the customer buys the reagents and the manufacturer loans the TEG systems. Volume levels are agreed, as is the length of the agreement (usually 3 years). Maintenance is included within this plan as Haemonetics still have ownership of the devices.

Consumables:

Description	Cost	Number of tests
Kaolin Activator Vials (for standard testing)	£2.72	1 (for 2 channels)
Functional Fibrinogen test	£8.75	1
Platelet Mapping Complete Kit for Kaolin/ADP/AA/Activator and 4 cups and pins	£25.00	4
Rapid TEG Activator Vial (Tissue factor/Kaolin combination) Fast test	£10.50	1
Biological QC Level I	£7.21	1 (for 2 channels)

Biological QC Level II	£7.21	1 (for 2 channels)
Plain Cup & Pin	£5.45	1
Heparinase Cup & Pin (cup surface lyophilised)	£8.75	1

For further details and up-to-date costs of equipment, reagents and consumables please contact the company.

## Contact details

United Kingdom Sales Office

Haemonetics Ltd., Business Innovation Centre, Harry Weston Road, Coventry CV3 2TX

Contact Customer Support: 0808 234 4817 / 0808 234 4845

Email: [Info.uk@haemonetics.com](mailto:Info.uk@haemonetics.com)

Haemonetics (UK) Ltd, 5 Ashley Drive, Bothwell, Glasgow G71 8BS

## Sonoclot

As discussed, NICE only recommends the Sonoclot system for use in research. The following information is provided for organisations which may wish to purchase the Sonoclot system for this purpose.

Current web address for UK distributor, Linc Medical Systems: [www.linc-medical.co.uk](http://www.linc-medical.co.uk)

Current web address for manufacturer, Sienco Inc: [www.sienco.com/sonoclot-worldwide/](http://www.sienco.com/sonoclot-worldwide/)

The Sonoclot Coagulation and Platelet Function Analyser is a viscoelastic monitor used for measuring coagulation and platelet function in whole blood or plasma. It provides information on the haemostasis process including coagulation, fibrin gel formation, clot retraction and fibrinolysis. The Sonoclot utilizes the following assays.

Reagent	Information provided
kACT	Assessment of large-dose heparin management with or without aprotinin
aiACT	Assessment of large-dose heparin management with aprotinin
gbACT+	Assessment of overall coagulation and assesses platelet function in non-heparinised patients
H-gbACT+	Assessment of overall coagulation and assesses platelet function in heparinised patients
gbACT	Assessment of overall coagulation in non-heparinised patients (without platelet function)

The Sonoclot Analyser generates both a qualitative graph, known as the Sonoclot signature, and quantitative results on the clot formation time and the rate of fibrin polymerization. This helps to identify numerous coagulopathies including platelet dysfunction, factor deficiencies, anticoagulant effects, hypercoagulable tendencies and hyperfibrinolysis.

The results are automatically calculated. They appear on the LED display and are printed on the hard copy graphic output.

An [example Sonoclot result](#) and [educational resources](#) can be seen on the manufacturer's website.

## Cost and procurement

Capital costs are as follows:

- Single-channel device, gives ACT and CR: £2500.
- Single-channel device, gives ACT, CR, PF and signature: £3950.
- Double channel, gives ACT, CR, PF and signature: £7950.
- 4 channel, gives ACT, CR, PF and signature: £14,950.

Consumables:

Description	Cost	Number of tests
C1/gbACT	£52.80	24
C1/gbACT	£200.00	100
C3/kACT	£52.80	24
C3/kACT	£200.00	100
C4/non activated test box	£52.80	24
C4/non activated test box	£200.00	100
C5/aiACT	£66.00	24
C5/aiACT	£250.00	100
H1/gbACT	£132.00	24
H1/gbACT	£500.00	100
P1/H-gbACT	£165.00	20
P1/H-gbACT	£375.00	50
Oil QC (for daily use)	£120.00	24
Plasma QC (for use with new reagent batches)	£37.50	1

For further details and up-to-date costs of equipment, reagents and consumables please contact the company.

## Contact details

LINC Medical Systems, The Green Lane Workshop, Green Lane, Countesthorpe, Leicestershire, LE8 5QQ

Email:

[sales@linc-medical.co.uk](mailto:sales@linc-medical.co.uk) – General enquiries

[joebailey@linc-medical.co.uk](mailto:joebailey@linc-medical.co.uk) – Product specialist for Sonoclot

## 6 How to implement NICE's guidance on viscoelastometric point-of-care testing

The experiences of NHS trusts have been used to develop practical suggestions for how to implement NICE guidance on viscoelastometric point-of-care testing.

### Thromboelastography/thromboelastometry toolkit

A toolkit to support the implementation of thromboelastography and thromboelastometry in NHS trusts has been developed by a working group of the [North West Regional Transfusion Committee](#).

The [toolkit](#) includes a variety of documents, educational resources, templates for funding bids, a literature review, manufacturers' technical specifications, contact details, factsheets and audit and competency documentation. All the resources are free to download and can be adapted to suit local requirements.

#### Education

The successful adoption of this technology is reliant upon the knowledge and skills of those staff maintaining and quality controlling the device, undertaking the tests and interpreting the results.

All manufacturers of viscoelastometric point-of-care testing devices offer comprehensive training packages which include online resources, face-to-face theoretical education and hands-on sessions. Initial training is usually included in the cost of the equipment with further training sessions either free or at an additional cost.

The following educational resources are available as part of the [toolkit](#).

Factsheets	<a href="#">Factsheet 1: Sample collection</a> <a href="#">Factsheet 2: Operating procedure</a> <a href="#">Factsheet 3: Interpretation</a>
------------	---

TEG learning module	<a href="http://www.transfusionguidelines.org.uk/uk-transfusion-committees/regional-transfusion-committees/north-west/policies/thromboelastography-thromboelastometry-toolkit">www.transfusionguidelines.org.uk/uk-transfusion-committees/regional-transfusion-committees/north-west/policies/thromboelastography-thromboelastometry-toolkit</a>
TEM learning module	<a href="http://learning.rottem.de">http://learning.rottem.de</a>
Examples training and competency records which can be used to inform the development of local documentation	<a href="#">Liverpool Women's NHS Foundation Trust Competency Statement</a> <a href="#">East Lancashire Hospitals NHS Trust Competency Assessment</a> <a href="#">Central Manchester University Hospitals NHS Foundation Trust Training Record</a>

## Patient blood management

According to the [National Blood Transfusion Committee](#), patient blood management is defined as "a multidisciplinary, evidence-based approach to optimising the care of patients who might need blood transfusion."

NHS Blood and Transplant is working with the Department of Health and the National Blood Transfusion Committee to support NHS trusts in effective blood use management, and to ensure that inappropriate use of blood and blood components is minimised.

Viscoelastometric point-of-care testing can be used as an element of a patient blood management approach. Other elements include the use of blood-tracking, automated dispensing and peri-operative cell salvage devices.

[Patient Blood Management recommendations](#) prepared by the National Blood Transfusion Committee and supported by NHS England and NHS Blood and Transplant were published in June 2014.

A further table of national drivers for change is included in the [Business Case Development](#) section.

## Quality control

Tests performed in a point-of-care setting need quality control procedures to be in place in



just the same way as tests carried out in a laboratory setting.

The aim of quality assurance is to ensure reliable, accurate results when testing patient samples. It is also important that quality assurance records are well documented and records retained so they may be consulted should any queries arise.

The process of quality control requires a combination of internal quality control and external quality assessment.

IQC is a process controlled by the test user and is a way of checking the day-to-day precision (reproducibility) of the method. Test material for internal quality control is usually purchased from the manufacturer of the test device. The test sample will have a pre-assigned acceptable range and the operator should have a procedure in place should the results fall outside this range.

In contrast, external quality assessment is provided by an external organisation and is a spot check which occurs at a number of set times in the year. The basis of external quality assessment testing is that centres testing the same sample in the same way should all get a similar result. If a centre records a result outside of the acceptable or target range (as determined by analysis of the results submitted by the group of testers using the same method), there may be a problem with that centre's test systems. In practice, for each external quality assessment exercise, the provider sends aliquots of the same sample to centres performing the same test. External quality assessment samples do not have a pre-assigned target value or range and only after all centres have tested the sample and the results analysed is a target range calculated.

Both internal quality control and external quality assessment processes are required to ensure that a system of testing is working reliably.

The United Kingdom National External Quality Assessment Service (UK NEQAS) has a formal external quality assessment programme for both TEG and Rotem systems which consists of 3 surveys per year, with 1 sample per survey.

Registration with the programme is made by contacting UK NEQAS Blood Coagulation by phone: 0114 267 3300, Fax: +44(0)114 267 3309 or email: [neqas@coageqa.org.uk](mailto:neqas@coageqa.org.uk)

## Overcoming implementation hurdles

NHS sites currently using viscoelastometric point-of-care testing reported a number of implementation hurdles, as set out in the table below.

Implementation hurdle	Solution
Capital and ongoing revenue costs	Preparation of business case. Selection of appropriate metrics to demonstrate cost benefit. Investigate alternative purchase options.
Educational requirements of staff	Ensure all staff are available for training sessions. Ensure staff chosen to carry out tests and interpret results do so often enough to maintain knowledge and skills. Keep accurate training records. Ensure only trained staff use equipment.
Consistency of interpretation of results	Try to gain consensus from clinicians regarding interpretation of results and how they influence transfusion protocols. Ensure the use of the technology is included as part of all relevant care pathways and transfusion protocols.
Finding a suitable location for the device	Ensure the location is free from undue interference. Ensure there is adequate space available to store (refrigerated) and prepare reagents and to conduct tests.
Need to maintain high standards of quality and governance	Ensure that quality control regimes are adhered to. Include the local blood transfusion committee and laboratories/ point-of-care committee in the adoption of the technology.
Connectivity with laboratory reporting systems	Discuss connectivity with the manufacturer and local network manager prior to procurement of technology. Remote viewing of tests as they develop may be required by, for example, laboratory staff.

## Business case development

### Cost savings

Some NHS trusts reported that using viscoelastometric point-of-care testing reduced their use of blood and blood components and saved money. Further details of these examples can be found within the [Insights from the NHS](#) section.

Expert clinical opinion is that both the ROTEM and TEG tests are already widely used in cardiac centres, therefore we do not expect there to be a significant cost impact to the NHS following the publication of the guidance 'Detecting, managing and monitoring haemostasis: viscoelastometric point-of-care testing (ROTEM, TEG and Sonoclot systems)'. Costing information for these tests has been included throughout this document and can be used to advise cardiac centres which do not currently use ROTEM or TEG but are considering using them in the future.

### Business case

The implementation team should treat the development of a robust business case as an early priority in the life of the implementation project.

A fully worked example of a business case for the adoption of viscoelastometric point-of-care testing is available as part of the North West Regional Blood Transfusion Committee thromboelastography/ thromboelastometry [toolkit](#) and includes information that you can copy and paste into your own business case documentation.

Local arrangements for developing and approving business plans will vary from trust to trust, and each organisation is likely to have its own template and process in place.

### National drivers

When developing a business case, NHS trusts may find it useful to refer to the following national drivers for implementing viscoelastometric point-of-care testing.

Driver	Significance or measure
--------	-------------------------

<p><u>NHS outcomes framework 2014 to 2015</u></p>	<p>Domain 3 – improving outcomes from planned treatments and from injuries and trauma.</p> <p>Domain 4 – ensuring that people have a positive experience of care.</p> <p>Domain 5 – treating and caring for people in a safe environment and protecting them from avoidable harm/reducing the incidence of avoidable harm.</p>
<p><u>European Society of Anaesthesiology</u></p>	<p><u>Management of bleeding and coagulopathy following major trauma: an updated European guideline (2013)</u> recommends that viscoelastic methods also be performed to assist in characterising the coagulopathy and in guiding haemostatic therapy.</p>
<p><u>The Royal College of Anaesthetists</u></p>	<p><u>Cardiac and thoracic anaesthesia services (2013)</u>.</p> <p>In cardiac surgery, there should be satellite or point-of-care laboratory facilities in or near the operating room for the measurement of blood gases, electrolytes, haemoglobin and anticoagulation (including thromboelastography or thromboelastometry).</p>
<p><u>The Association of Anaesthetists of Great Britain and Ireland</u></p>	<p><u>Blood transfusion and the anaesthetist: management of massive haemorrhage (2010)</u>.</p> <p>Immediate actions in dealing with a patient with massive haemorrhage; if available, carry out near-patient testing such as through thromboelastography (TEG) or thromboelastometry (ROTEM).</p> <p><u>Guidelines for Obstetric Anaesthetic Services (2013)</u>.</p> <p>It is strongly recommended that there should be equipment to enable bedside estimation of coagulation such as thromboelastography (TEG) or thromboelastometry (ROTEM).</p>

## Project management

It is the experience of the Health Technologies Adoption Programme that in order to gain maximum benefit, the adoption of this technology should be carried out using a project management approach.

## Project team

A systematic and collaborative approach will support the successful adoption of viscoelastometric point-of-care testing in line with NICE guidance.

The first step in this approach is to form a local project team who will work together to implement the technology and manage any changes in practice. Individual NHS organisations will determine the membership of this team and how long the project will last.

In order to implement this guidance in an effective and sustainable way, consider the following membership of the team:

- **Clinical champion(s):** this person could be an anaesthetist with an interest in this area, a clinical scientist or another suitably qualified and experienced individual. They should have the relevant knowledge and understanding to be able to drive the project, answer any clinical queries and champion the project at a senior level.
- **Point-of-care committee representative:** this person will be a vital link to the laboratories and will be able to provide advice and guidance on maintenance, quality control, educational issues and standard operating procedures.
- **Blood transfusion representative:** this will help to establish baseline metrics, ensure that use of the technology is integrated into blood transfusion protocols, and help to monitor the ongoing use of blood and blood components.
- **Management sponsor:** this person will be able to help assess the financial viability of the project, drive the formulation of a business case and help to demonstrate the cost savings achieved.
- **Project manager:** this person could be someone in a clinical or managerial role and will be responsible for the day-to-day running of the project, coordinating the project team and ensuring the project is running as planned.
- **Clinical audit facilitator:** to help set up mechanisms to collect and analyse local data related to the project metrics.
- **Other staff:** theatre nurses, operating department practitioners, and clinical perfusion staff and nurses may also be valuable members of the implementation team.

Early questions that the implementation team may wish to consider are as follows:

- Which technology will be selected and why?
- How will the project be funded?
- How to best measure both financial impact and clinical outcomes of implementing this technology?
- How will local metrics be identified and measured?
- Who will be responsible for collecting clinical data?
- How will the required education be provided?
- Are there any obvious challenges and how can these be overcome?
- How can effective communication with all involved be ensured?

## **Communication and collaborative working**

Experience shared by NHS sites has indicated that when implementing viscoelastometric testing, it is important that there is good communication between all stakeholders. This will include surgeons, anaesthetists, clinical perfusion staff, laboratory staff/point-of-care committee, blood bank/transfusion committee, managers and procurement staff.

In order to achieve the desired aims of the project, clear written and verbal communication between staff should include:

- keeping staff updated on the project aims, project plans and updates
- highlighting implementation hurdles and proposed solutions to staff
- listening to staff so that team members are able to report problems or issues, share success and useful experiences.

## **Measuring success**

In order to demonstrate the benefits of adopting viscoelastometric point-of-care testing it is important to take measurements before, during and after implementation. This will enable the benefits and impact achieved at a local level to be measured and built upon.

When implementing viscoelastometric point-of-care testing, the following metrics are

suggested:

- Use of blood and blood components, specifically red blood cells, fresh frozen plasma, cryoprecipitate and platelets.
- Costs associated with the use of blood and blood components.
- Re-operation rates.
- Length of stay in intensive care.
- Staff experience and satisfaction.

## 7 Additional support and information

- [TEM International](#)
- [Haemonetics](#)
- [Sienco Inc](#)
- [Linc Medical](#)
- [NHS Blood and Transplant](#)
- [Joint United Kingdom \(UK\) Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee](#)
- [United Kingdom National External Quality Assessment Service](#)



## 8 Acknowledgements

NICE would like to acknowledge and thank the following people and organisations for their valuable contribution to this resource.

**Jayne Addison**

Patient Blood Management Practitioner, NHS Blood and Transplant, Liverpool

**Dr Lynne Anderson**

Consultant Anaesthetist, Golden Jubilee National Hospital

**Dr Seema Agarwal**

Consultant Cardiothoracic Anaesthetist, Liverpool Heart and Chest NHS Foundation Trust

**Joe Bailey**

Linc Medical Ltd

**Dr Simon Davidson**

The Royal Brompton Hospital, Royal Brompton and Harefield NHS Foundation Trust

**Dr Sarah Haynes**

Autologous Blood Transfusion Practitioner, University Hospitals of South Manchester NHS Foundation Trust

**Emma James**

Point of Care Testing Manager, Central Manchester University Hospitals NHS Foundation Trust

**Major Damian Keene**

Specialist Trainee, Department of Military Anaesthesia and Critical Care, Royal Centre for Defence Medicine, Birmingham

**Dianne Kitchen**

Specialist Scientific Lead for Point of Care Programmes, United Kingdom National External Quality Assurance Service Blood Coagulation

**Jim Leith**

TEM UK Ltd

**Dr Roger Luddington**

Addenbrooke's Hospital, Cambridge University Hospitals NHS Foundation Trust

**Dr Shuba Mallaiah**

Consultant Obstetric Anaesthetist, Liverpool Women's NHS Foundation Trust

**Lynne Mannion**

Transfusion Practitioner, East Lancashire Hospitals NHS Trust

**Lt Col Jackie McLennan**

Consultant in Emergency Medicine, Central Manchester University Hospitals NHS Foundation Trust/ British Army

**Rachel Parker**

The John Radcliffe Hospital, Oxford University Hospitals NHS Trust

**Dr Kate Pendry**

Consultant Haematologist, NHS Blood and Transplant, Manchester and Central Manchester University Hospitals NHS Foundation Trust

**Mark Powell**

Haemonetics Ltd

**Dr Jecko Thachil**

Consultant Haematologist, Central Manchester University Hospitals NHS Foundation Trust

**Stephen Von-Kier**

The John Radcliffe Hospital, Oxford University Hospitals NHS Trust

**Dr Patrick Waits**

Consultant Anaesthetist, Pennine Acute Hospitals NHS Trust

**Jackie Whitehurst**

Point of Care Manager, Pennine Acute Hospitals NHS Trust

**Dr Paul Wood**

Consultant Anaesthetist, University Hospitals Birmingham NHS Foundation Trust

**Lt Col Tom Woolley**

Consultant Anaesthetist, Plymouth Hospitals NHS Trust

## 9 About this resource

The NICE Health Technologies Adoption Programme produces practical advice on adopting health technologies in the NHS in England.

NICE's Health Technologies Adoption Programme surveyed and worked with NHS organisations to help share their experiences of using viscoelastometric point-of-care testing with organisations that may want to use them in the future. The information gained from these NHS organisations and included in this resource is intended for the sole purpose of supporting the NHS in adopting or researching viscoelastometric point-of-care testing. The information was not assessed by the independent External Assessment Group or considered by the Diagnostics Advisory Committee when making its decision on the use of viscoelastometric point-of-care testing devices in the NHS.

This resource accompanies the diagnostics guidance: Detecting, managing and monitoring haemostasis: viscoelastometric point-of-care testing (ROTEM, TEG and Sonoclot systems). It was developed using the NICE Health Technologies Adoption Programme process.

This resource should be read in conjunction with NICE guidance on [viscoelastometric point-of-care testing DG13](#). It is an implementation tool and discusses and summarises the experiences reported by NHS sites who have previously adopted this technology and shares the learning that took place.

Implementation of the guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity and foster good relations. Nothing in this document should be interpreted in a way that would be inconsistent with compliance with those duties.

[Click here for more information about the Health Technology Adoption Programme](#)

### Copyright

© National Institute for Health and Care Excellence 2014. All rights reserved. NICE copyright material can be downloaded for private research and study, and may be reproduced for educational and not-for-profit purposes. No reproduction by or for

commercial organisations, or for commercial purposes, is allowed without the written permission of NICE.

ISBN: 978-1-4731-0707-6