Point of Care Coagulation Tests

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UCLPartners
Academic Health Science Partnership

Variability in Transfusion Practice

TRANSFUSION PRACTICE

The ongoing variability in blood transfusion practices in cardiac surgery

*Stephanie A. Snyder-Ramos,† Patrick Möhnle,† Yi-Shin Weng, Bernd W. Böttiger, Alexander Kulier, Jack Levin, and Dennis T. Mangano for the Investigators of the Multicenter Study of Perioperative Ischemia, MCSPI Research Group**

Despite widespread availability of clinical practice guidelines the variability in transfusion practice both within and between institutions is profound and has changed little over the last 20 years.

Do transfusion guidelines influence clinical practice?

bjh Guideline

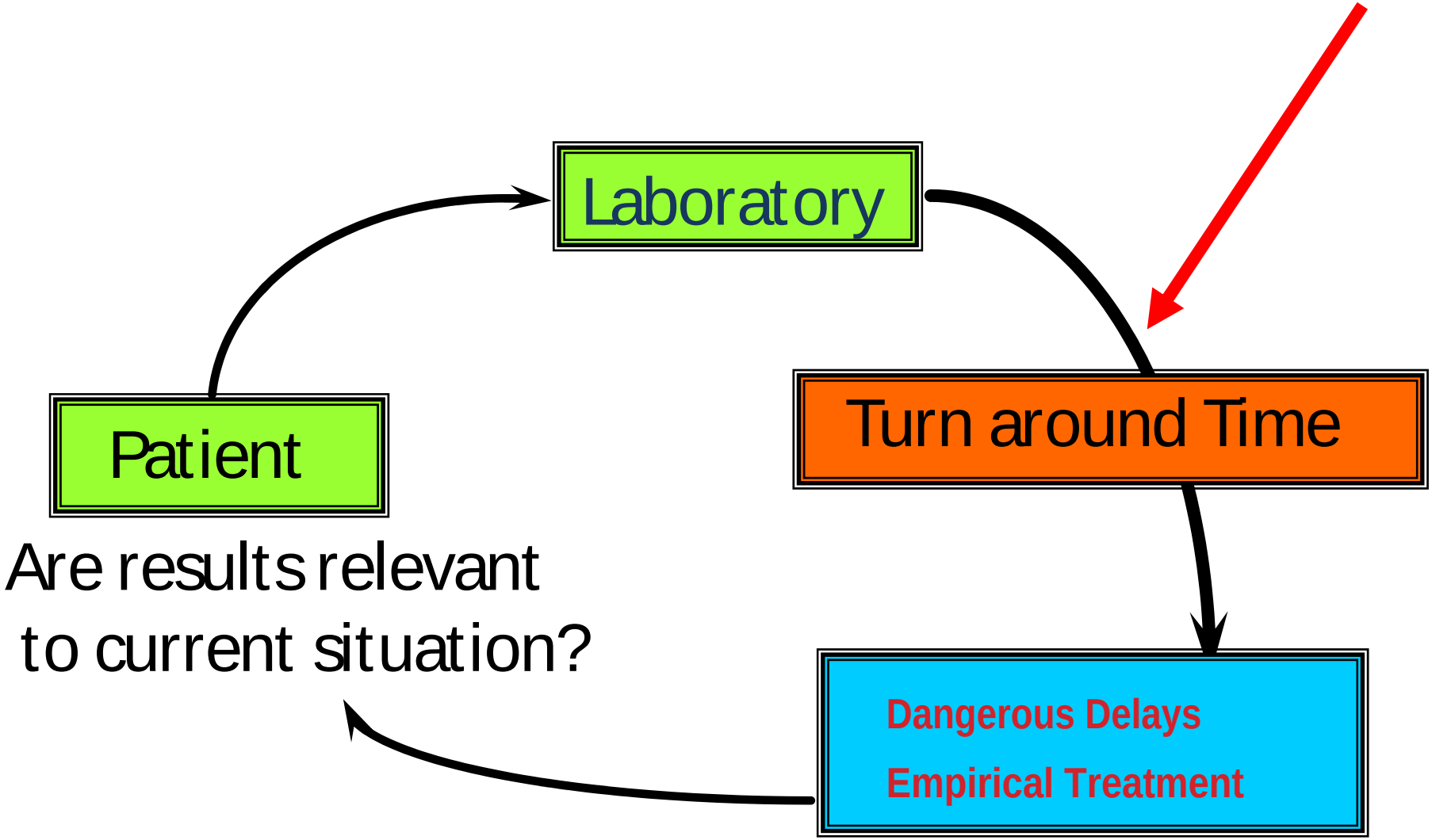
Guidelines on the management of massive blood loss

British Committee for Standards in Haematology: Writing Group: D. Stainsby,[1] S. MacLennan,[1] D. Thomas, [2] J. Isaac[3] and P. J. Hamilton[4]

[1]National Blood Service [2]Morriston Hospital, Swansea [3]University Hospitals, Birmingham [4]Royal Victoria Infirmary, Newcastle upon Tyne, UK

Request laboratory investigations	FBC, PT, APTT, Thrombin time, Fibrinogen (Clauss method); blood bank sample, biochemical profile, blood gases and pulse oximetry Ensure correct sample identification Repeat tests after blood component infusion	Results may be affected by colloid infusion Ensure correct patient identification May need to give components before results available

Laboratory Based Tests: The Bleeding Patient



POC versus central laboratory coagulation testing during haemorrhagic surgery
Toulon.P et al. Thromb Haemostas 2009;101: 394-401

Is Clinical Discretion Okay?

102 elective CABG

POC group

Hepcon
PFA 100
TEG

Lab Group

INR
APPT
Platelet Count

Clinical discretion

102 retrospective controls

Avidan M,S et al 2004 BJA 92 (2); 178-176

Clinical Discretion

Table 3 Blood components received. The table shows the number of patients (%) in each group that received transfusions. LAG=laboratory-guided algorithm; POC=point of care; CD=clinician discretion

Blood component	LAG group (n=51)	POC group (n=51)	CD group (n=108)	P (χ^2 test)
Packed red blood cells	35 (69)	34 (68)	92 (85)	0.01
Fresh frozen plasma	0	2 (4)	16 (15)	0.003
Platelets	1 (2)	2 (4)	14 (13)	0.02

Avidan M,S et al 2004 BJA 92 (2); 178-176

Modern Coagulation Management

"Transfusion of coagulation products should be guided by POC tests that assess haemostatic function in a timely and accurate fashion"

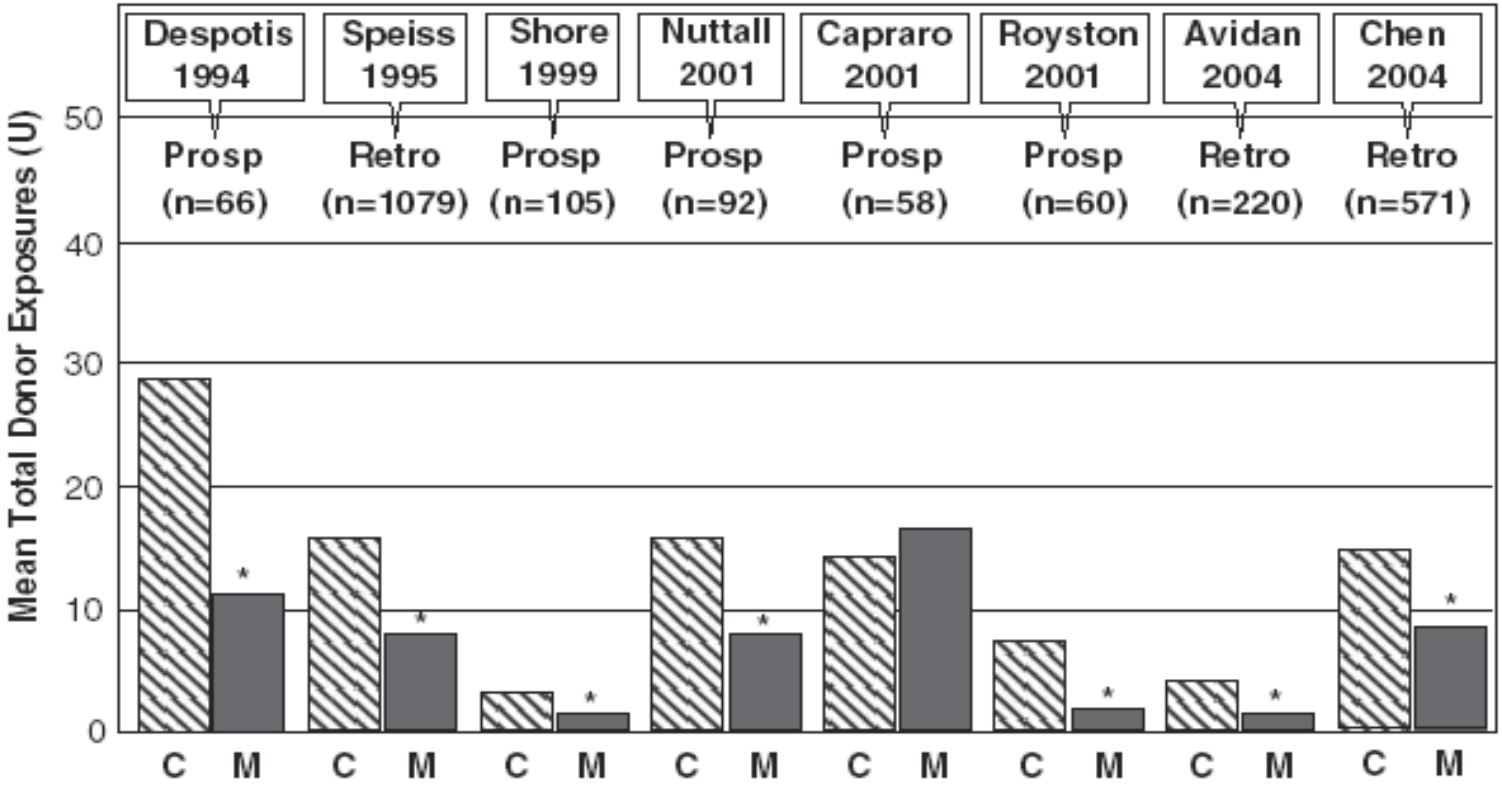
Society of Thoracic Surgeons & Cardiovascular Anesthesiologists.
Ann Thorac Surg 2007,83:S27-86

Active, Personalized and Balanced Coagulation Management Saves Lives in Patients with Massive Bleeding

Editorial: Anesthesiology 2010;113:1016-8
Michael Ganter & Donat Spahn

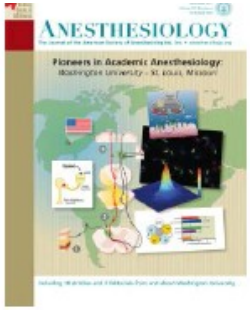
Goal directed, targeted, individualised haemostatic therapy

Impact of POCT on Transfusion



Despotis 2007 European J Anaesthesiology,24: 15 -36

Anesthesiology 2011; 115:1179–91



PERIOPERATIVE MEDICINE

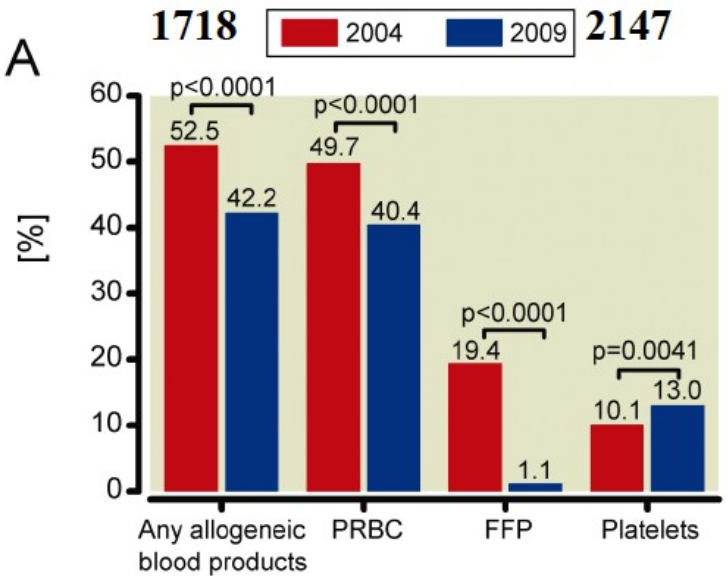
Coagulation Management in Cardiovascular Surgery

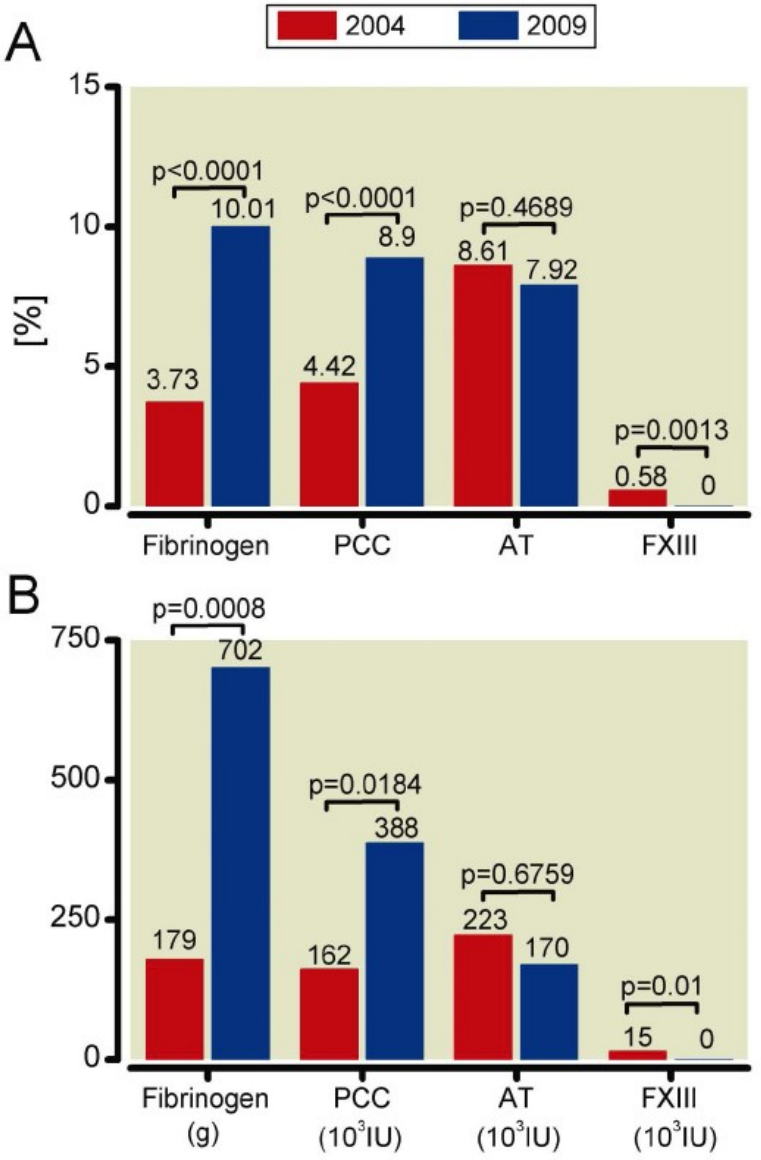
First-line Therapy with Coagulation Factor Concentrates Combined with Point-of-Care Coagulation Testing Is Associated with Decreased Allogeneic Blood Transfusion in Cardiovascular Surgery

A Retrospective, Single-center Cohort Study

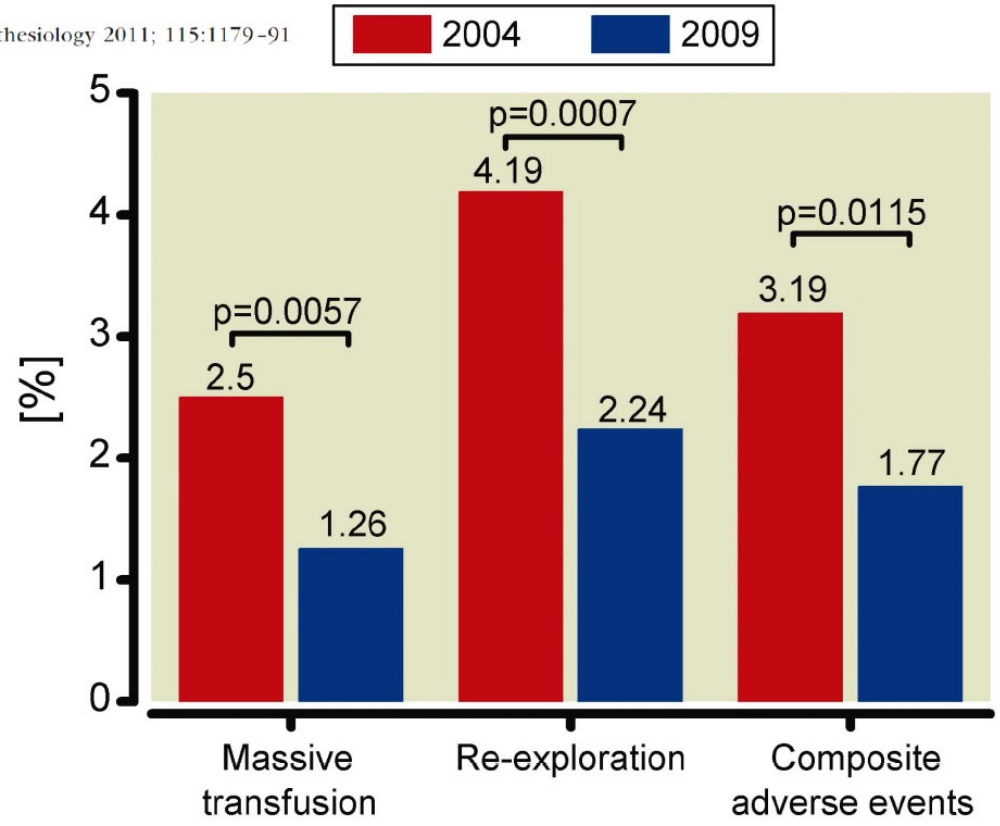
Klaus Görlinger, Dr. med,* Daniel Dirkmann, Dr. med,† Alexander A. Hanke, Dr. med,† Markus Kamler, PD Dr. med,‡ Eva Kottenberg, PD Dr. med,* Matthias Thielmann, PD Dr. med,‡ Heinz Jakob, Prof. Dr. med,§ Jürgen Peters, Prof. Dr. med‖

Methods: In a retrospective cohort study including 3,865 patients, we analyzed the incidence of intraoperative allogeneic blood transfusions (primary endpoints) before and after algorithm implementation.


A
1718
2004
2009
2147
[%]
p<0.0001
52.5
42.2
p<0.0001
49.7
40.4
p<0.0001
19.4
1.1
p=0.0041
10.1
13.0
Any allogeneic blood products
PRBC
FFP
Platelets
B
[Units per year]
p<0.0001
3276
2959
p<0.0001
1986
102
p=0.085
336
581
PRBC
FFP
Platelets


A
2004
2009
[%]
p<0.0001
3.73
10.01
p<0.0001
4.42
8.9
p=0.4689
8.61
7.92
p=0.0013
0.58
0
Fibrinogen
PCC
AT
FXIII
B
p=0.0008
179
702
p=0.0184
162
388
p=0.6759
223
170
p=0.01
15
0
Fibrinogen (g)
PCC (10^3IU)
AT (10^3IU)
FXIII (10^3IU)

Anesthesiology 2011; 115:1179–91



Point-of-Care Testing

A Prospective, Randomized Clinical Trial of Efficacy in Coagulopathic Cardiac Surgery Patients

Christian Friedrich Weber, Dr. med.,* Klaus Görlinger, Dr. med.,† Dirk Meininger, P.D. Dr. med.,‡ Eva Herrmann, Prof. Dr. rer. nat.,§ Tobias Bingold, Dr. med.,‡ Anton Moritz, Prof. Dr. med.,‖ Lawrence H. Cohn, M.D., Ph.D.,# Kai Zacharowski, Prof. Dr. med., Ph.D., F.R.C.A.**

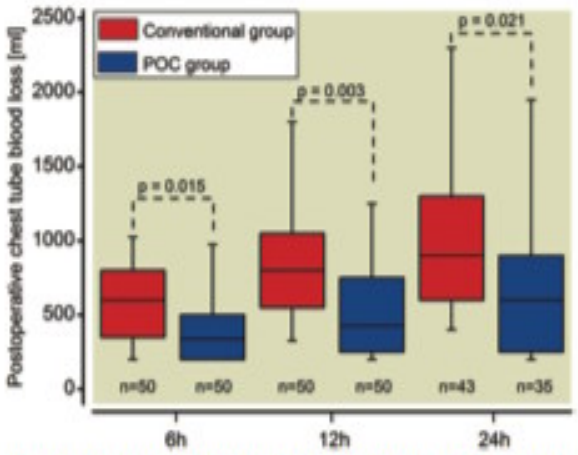


Fig. 3. Postoperative chest tube blood loss. POC = point-of-care.

Table 6. Cumulative Costs of Transfused Allogenic Blood Products, Hemostatic Therapy (Including Coagulation Factor Concentrates), and Costs of Performed POC Analyses

	Conventional Group	POC Group
Allogenic blood products	—	—
Packed erythrocytes [72 €/U]	18,648	13,176
FFP [0.162 €/g]	13,530	4,665
PC [231 €/U]	28,755	15,123
Other hemostatic therapy	—	—
Desmopressin [3.3 €/μg]	3,128	3,412
Fibrinogen [233 €/g]	35,882	27,727
PCC [114 €/600 IU]	10,944	6,726
rVIIa [2,784 €/240 kIU]	44,544	5,568
Total blood products and hemostatic therapy	155,431	76,397
Expendable materials	—	—
POC Diagnostics		
ROTEM®	—	4,093
Multiplate®	—	2,427
Cumulative [€]	[illegible]	[illegible]
Mean costs per patient [€]	3,109	1,658

Weber C F et al. Anesthesiology 2012;117:S31-47

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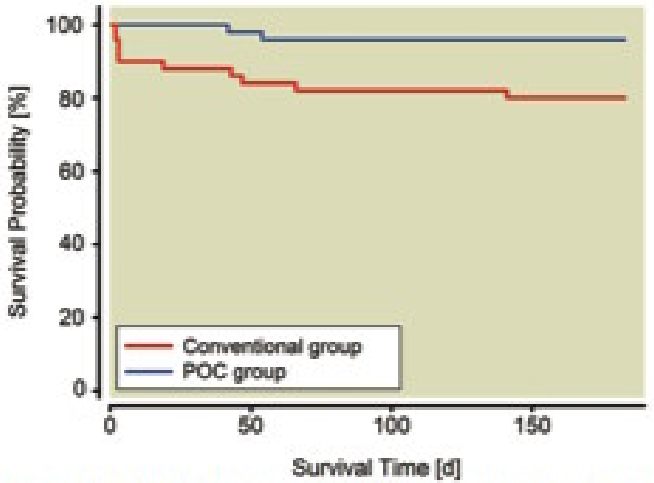

Fig. 4. Kaplan–Meier curve demonstrating survival by type of performed coagulation management during the 6-month follow-up period. POC = point-of-care.

Weber C F et al. Anesthesiology 2012;117:S31-47

NICE National Institute for Health and Care Excellence

Detecting, managing and monitoring haemostasis: viscoelastometric point-of-care testing (ROTEM, TEG and Sonoclot systems)

Issued: August 2014

NICE diagnostics guidance 13

www.nice.org.uk/dg13

NICE has accredited the process used by the Centre for Health Technology Evaluation at NICE to produce diagnostics guidance. Accreditation is valid from October 2011 to September 2017, and applies to guidance produced using the processes described in NICE's 'Diagnostics Assessment Programme manual' (published December 2011). More information on accreditation can be viewed at www.nice.org.uk/accreditation

NICE accredited

www.nice.org.uk/accreditation

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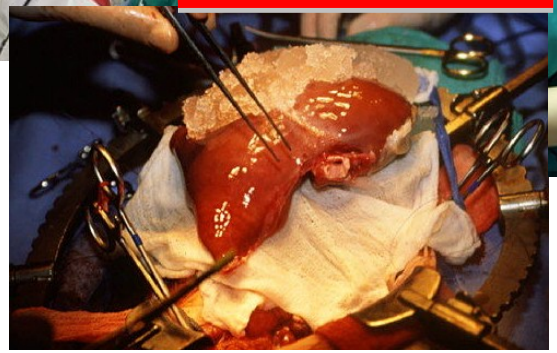
Massive Transfusion

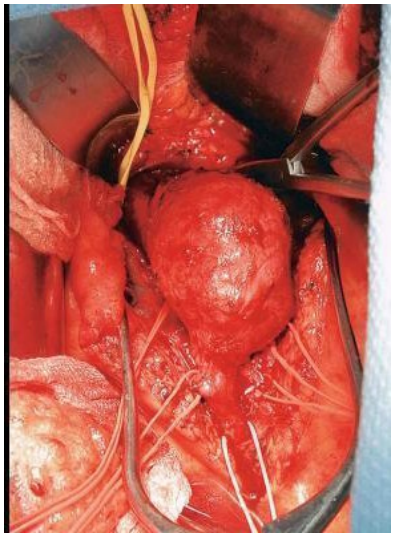
Trauma

Different circumstances have different problems

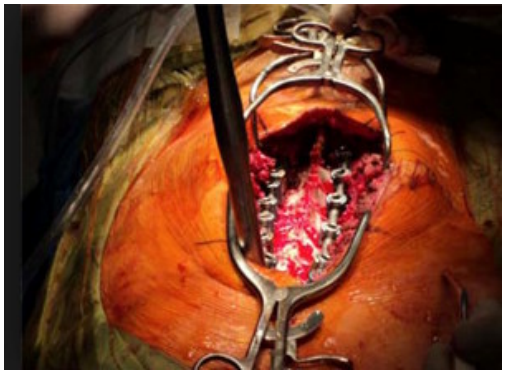
Obstetrics



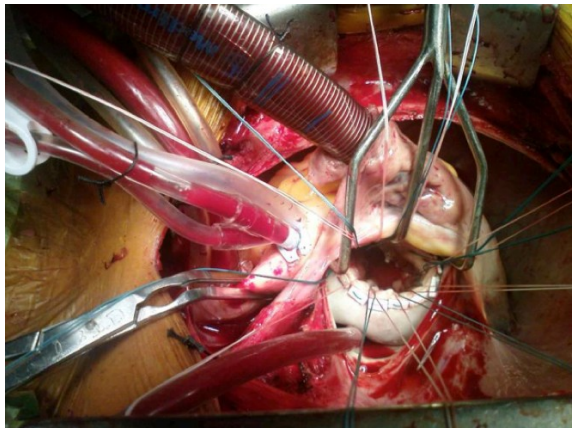
Liver Transplantation



Vascular Surgery



Spinal Surgery



Cardiac surgery

The Bleeding Patient

Adequate Thrombin Generation

Coagulation factors > 30%
Platelets > 50,000

Adequate Fibrinogen

Critical level: >1.0 g/dl
Recent work suggest > 1.5 or 2g
Obstetric haemorrhage > 2g

Adequate clot formation

Stop excessive clot dissolution

Inhibit excessive fibrinolysis

Tranexamic Acid

Hypothermia, Acidosis

TRANSFUSION

REVIEW

Fibrinogen as a therapeutic target for bleeding: a review of critical levels and replacement therapy

Jerrold H. Levy[1,*], Ian Welsby[1] and Lawrence T. Goodnough[2]

Article first published online: 9 OCT 2013

DOI: 10.1111/trf.12431

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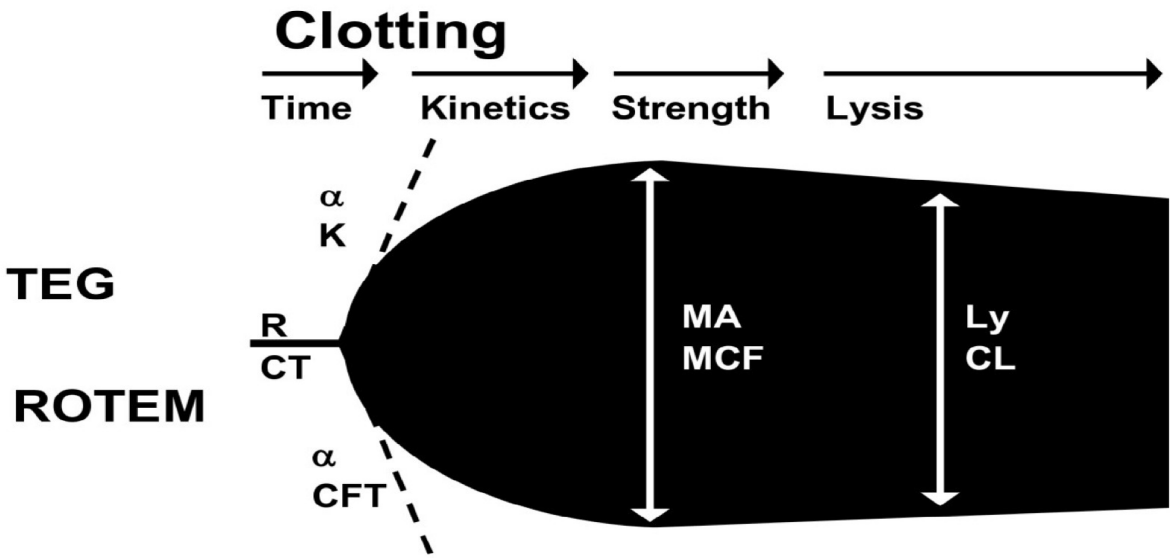
Issue

Transfusion

Volume 54, Issue 5, pages 1389–1405, May 2014

Viscoelastic POC tests of Coagulation

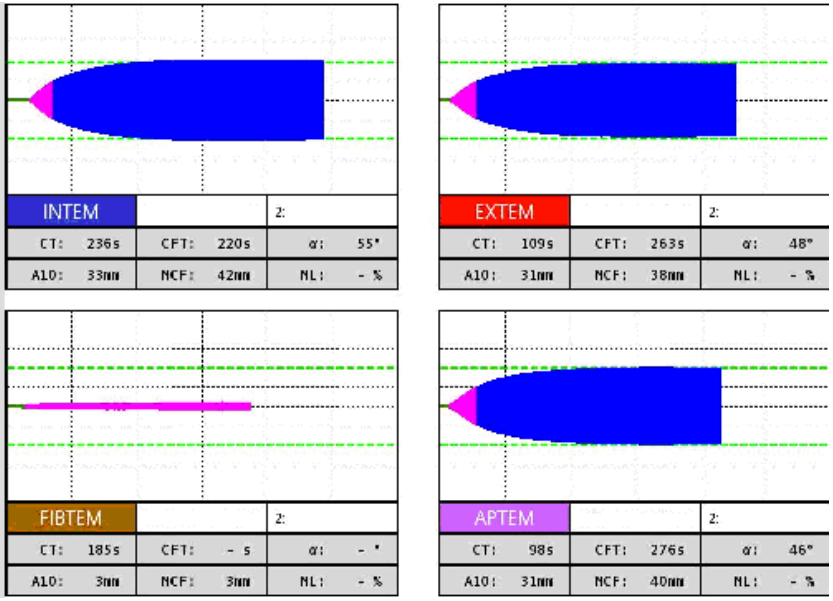
Schematic of TEG/ ROTEM parameters



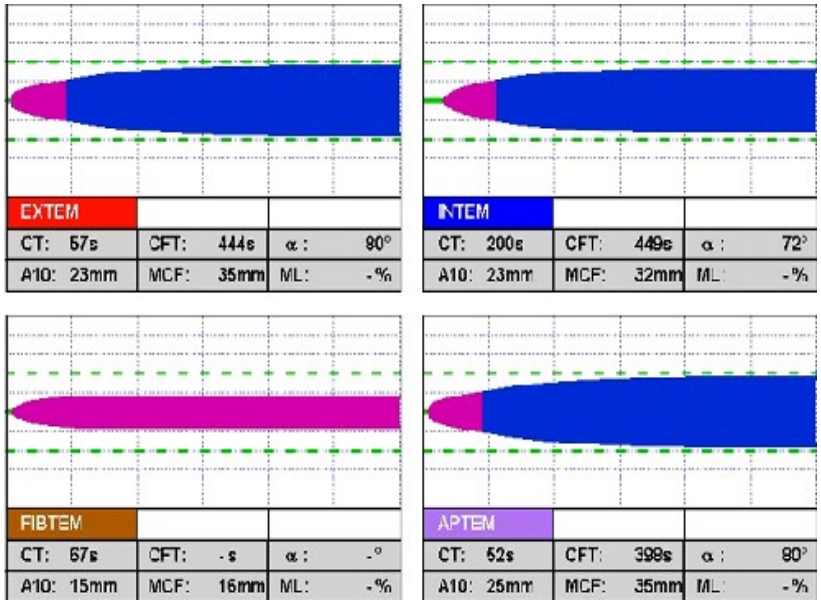
What information do we need ?

1: Is clot forming & how rapidly? Clotting factor levels & anticoagulants: R/CT
2: How strong is the clot? Platelets & Fibrinogen: MA/MCF
3: Is it stable? Fibrinolysis : CLI

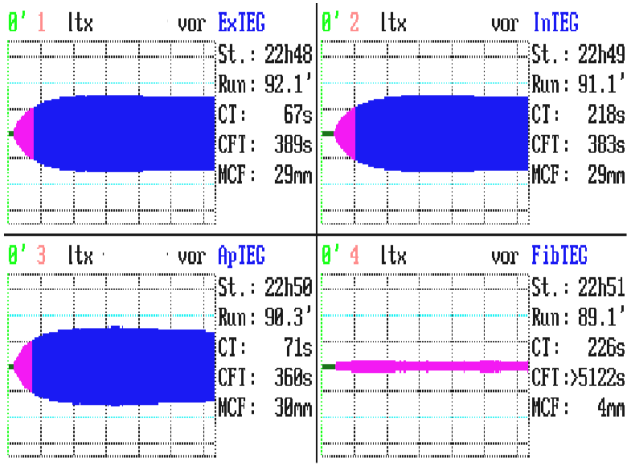
Reduced MA/MCF
Low fibrinogen



Reduced MA/MCF
Thrombocytopenia

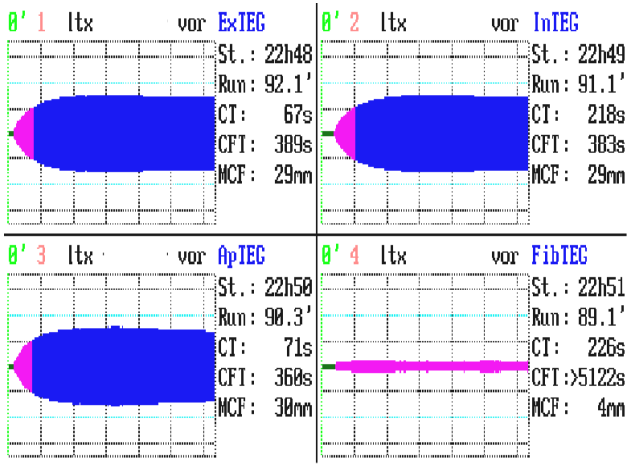


Monitoring the efficacy of treatment intervention

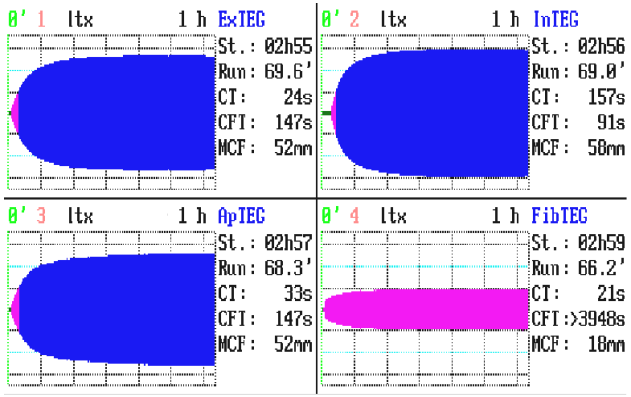


A: Low fibrinogen
Reduced MCF and FibTEM

Monitoring the efficacy of treatment intervention



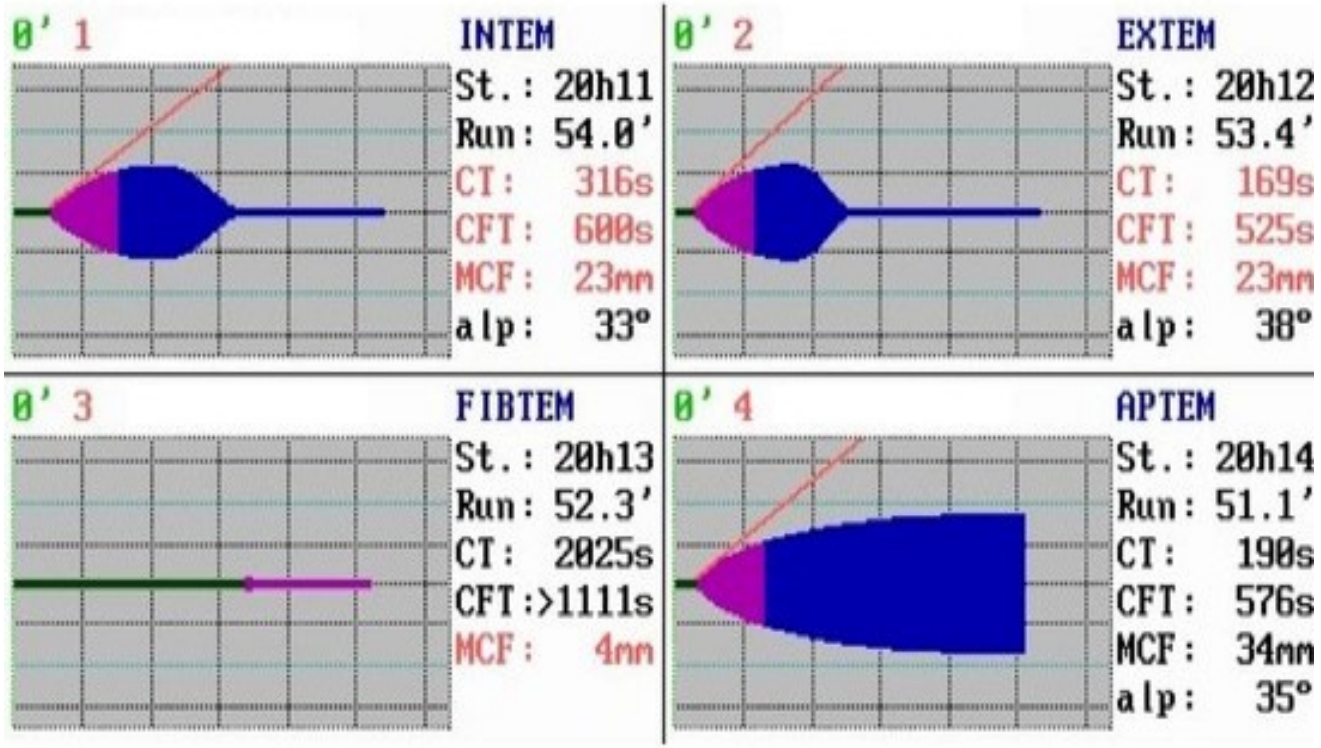
A: Low fibrinogen
Reduced MCF and FibTEM



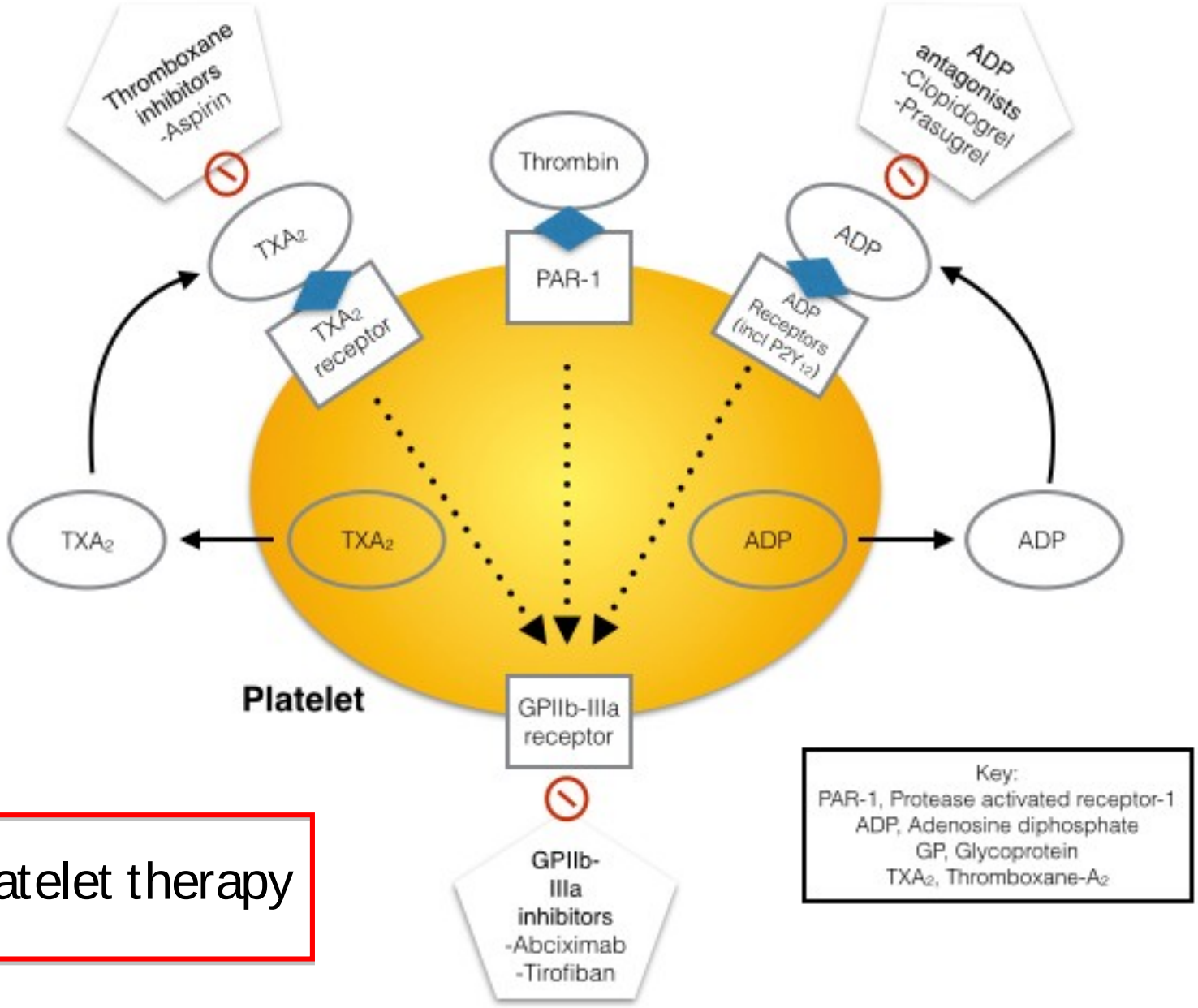
B: After treatment with
fibrinogen concentrate
Normal MCF & Normal FibTEM

Severe Trauma

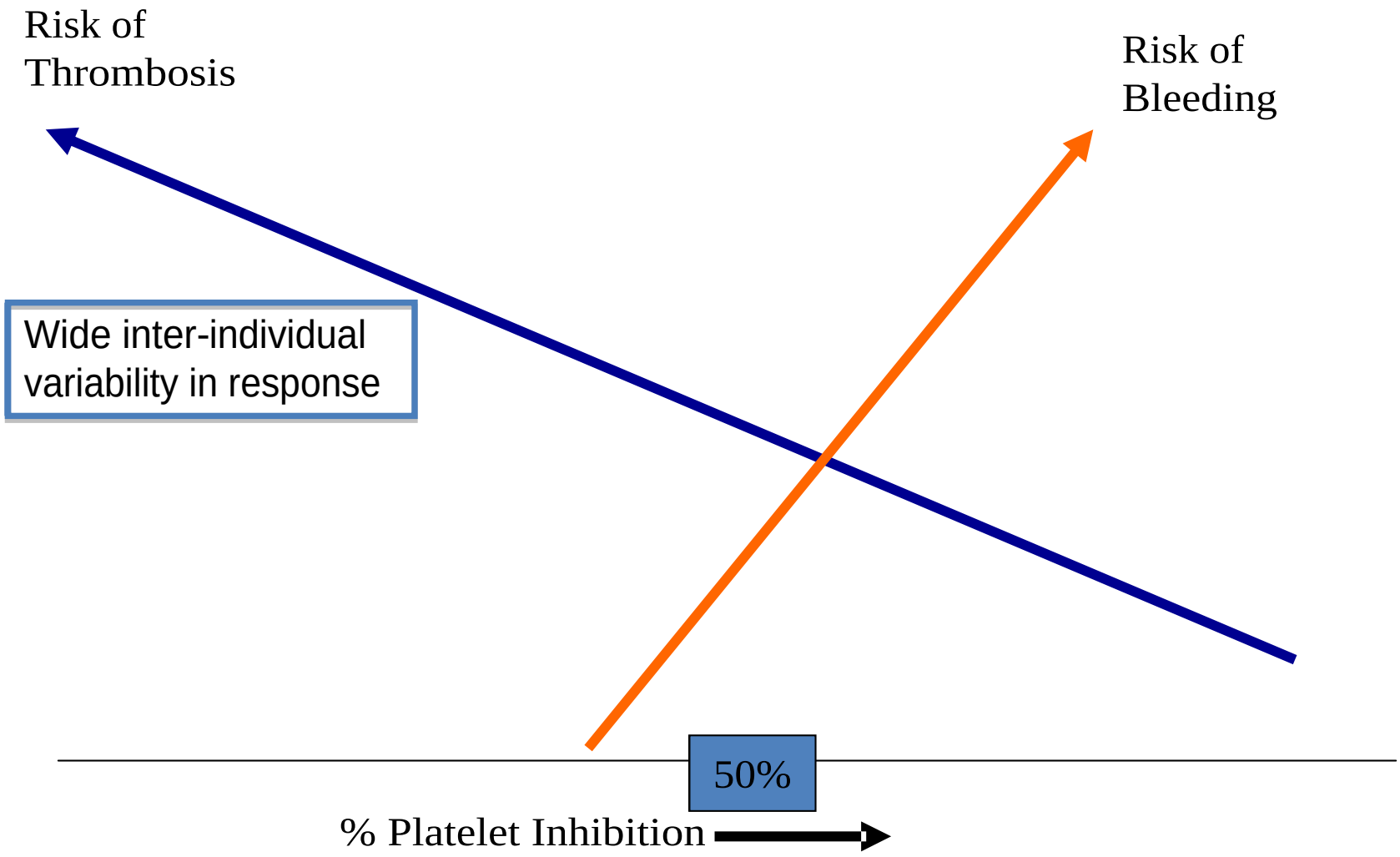
Hypofibrinolysis & Hypofibrinoginaemia



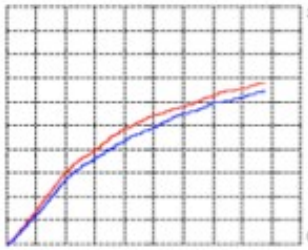
Anti-platelet therapy



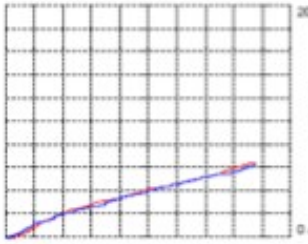
Anti-platelet therapy



Multiple electrode platelet aggregometry: Multiplate®



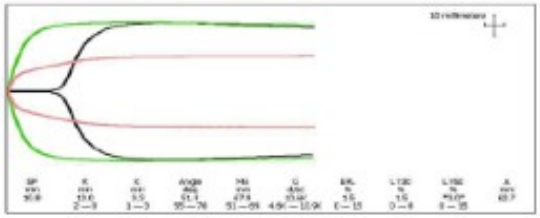
A: Normal response to agonist:
no platelet inhibition



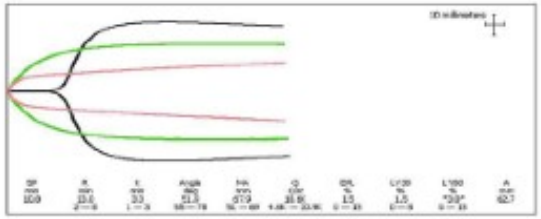
B: Reduced response to agonist:
significant platelet inhibition

Key
AU, Aggregation Units

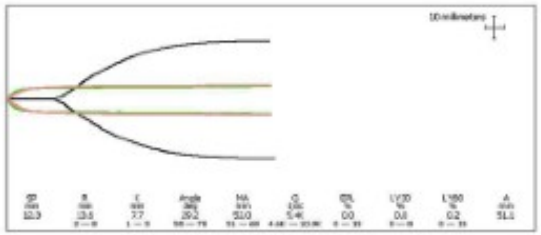
Thromboelastography® Platelet Mapping



A: No platelet inhibition
Maximum Amplitude (MA) on Adenosine Diphosphate (ADP) stimulation (green trace) the same as MA on Kaolin (black trace)



B: Partial platelet inhibition (40%)
ADP MA (green) less than kaolin MA (black)

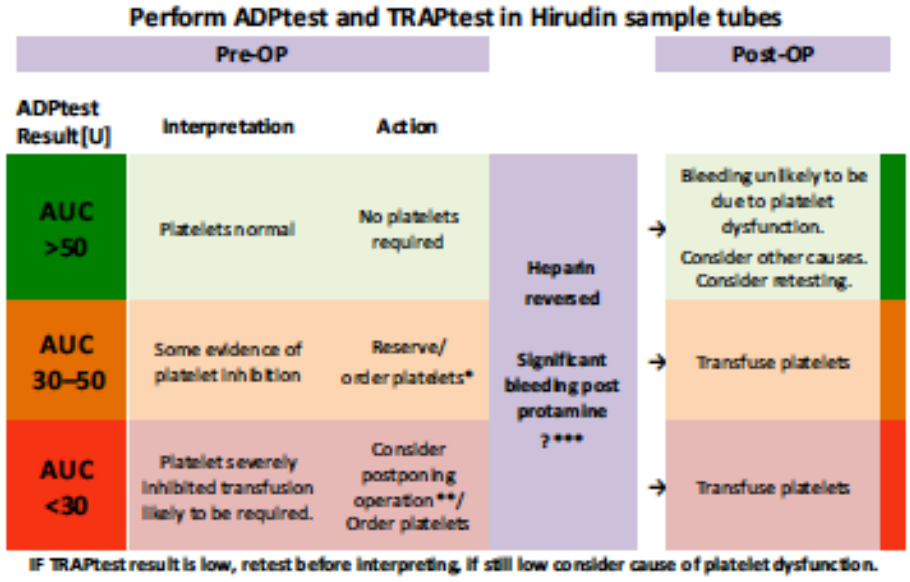


C: Complete platelet inhibition
ADP MA (green) the same as Fibrin (pink trace) and no demonstrable platelet activation with ADP

International Journal of Laboratory Hematology
The Official journal of the International Society for Laboratory Hematology
REVIEW INTERNATIONAL JOURNAL OF LABORATORY HEMATOLOGY

Consensus recommendations for using the Multiplate® for platelet function monitoring before cardiac surgery

R. KONG*, A. TRIMMINGS*, N. HUTCHINSON*, R. GILL†, S. AGARWAL‡, S. DAVIDSON§, M. ARCARI¶



BJS

Original article

Risk of bleeding and adverse outcomes predicted by thromboelastography platelet mapping in patients taking clopidogrel within 7 days of non-cardiac surgery

R. Kasivisvanathan[1,*], N. Abbassi-Ghadi[2], S. Kumar[2], H. Mackenzie[2], K. Thompson[1], K. James[1] and S. V. Mallett[1]

Article first published online: 4 AUG 2014

DOI: 10.1002/bjs.9592

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Issue

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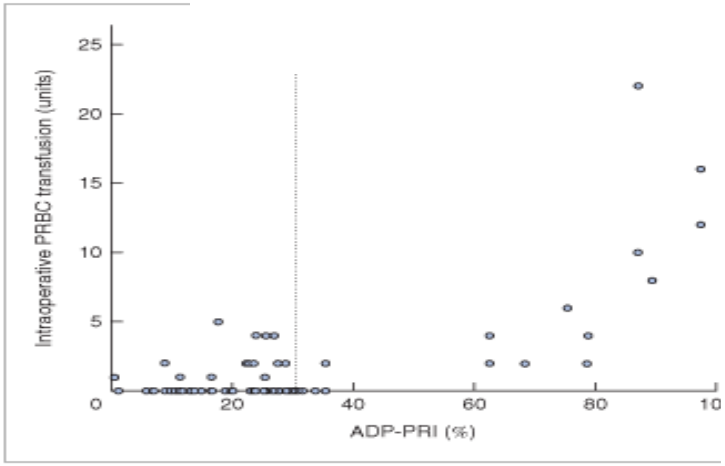

	ADP-PRI < 30% (*n* = 112)	Control (*n* = 112)	*P*†	ADP-PRI ≥ 30% (*n* = 19)	Control (*n* = 19)	*P*†
Intraoperative transfusion*						
PRBCs (units)	0·3(0·9); 0	0·3(1·0); 0	0·851‡	5·3(6·0); 4 (2–8)	0·6(1·1); 0 (0–1)	< 0·001‡
FFP (units)	0·1(0·3); 0	0·1(0·3); 0	0·537‡	2·6(2·8); 2 (0–3)	0; 0	< 0·001‡
Platelets (pools)	0·1(0·3); 0	0·1(0·4); 0	0·702‡	1·4(2·1); 0 (0–2)	0·1(0·5); 0	0·046‡

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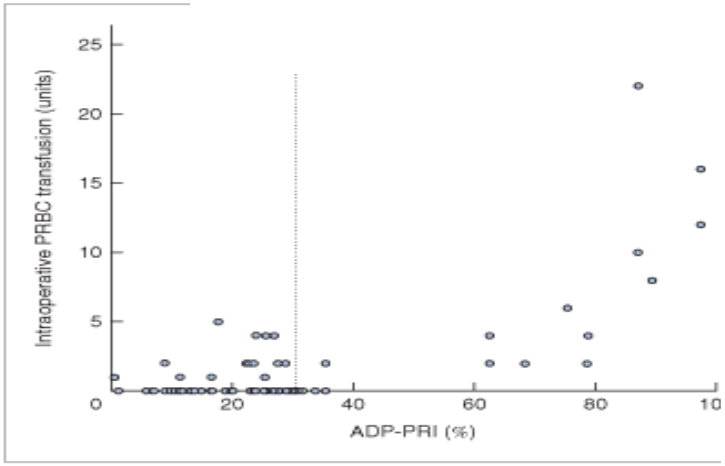

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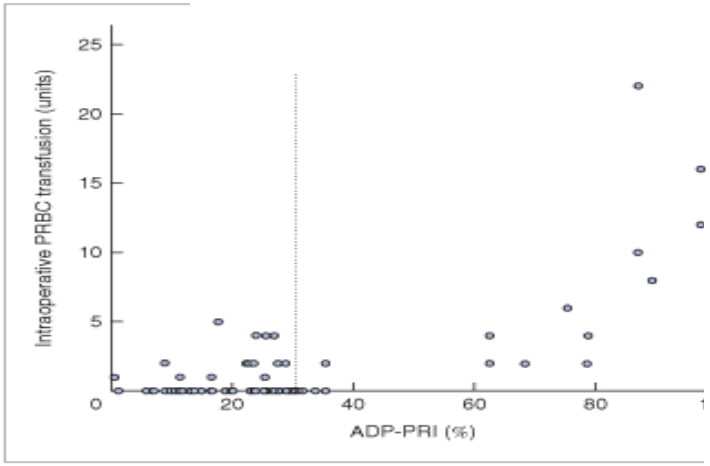

	ADP-PRI < 30% (*n* = 112)	Control (*n* = 112)	*P*†	ADP-PRI ≥ 30% (*n* = 19)	Control (*n* = 19)	*P*†
Intraoperative transfusion*						
PRBCs (units)	0·3(0·9); 0	0·3(1·0); 0	0·851‡	5·3(6·0); 4 (2–8)	0·6(1·1); 0 (0–1)	< 0·001‡
FFP (units)	0·1(0·3); 0	0·1(0·3); 0	0·537‡	2·6(2·8); 2 (0–3)	0; 0	< 0·001‡
Platelets (pools)	0·1(0·3); 0	0·1(0·4); 0	0·702‡	1·4(2·1); 0 (0–2)	0·1(0·5); 0	0·046‡

BJS

Original article

Risk of bleeding and adverse outcomes predicted by thromboelastography platelet mapping in patients taking clopidogrel within 7 days of non-cardiac surgery

R. Kasivisvanathan[1,*], N. Abbassi-Ghadi[2], S. Kumar[2], H. Mackenzie[2], K. Thompson[1], K. James[1] and S. V. Mallett[1]

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Issue

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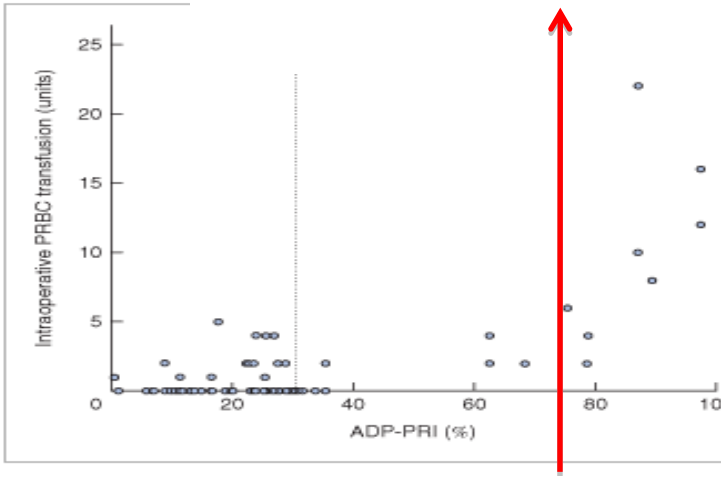

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Operator Variability

Skilled Laboratory
Scientist

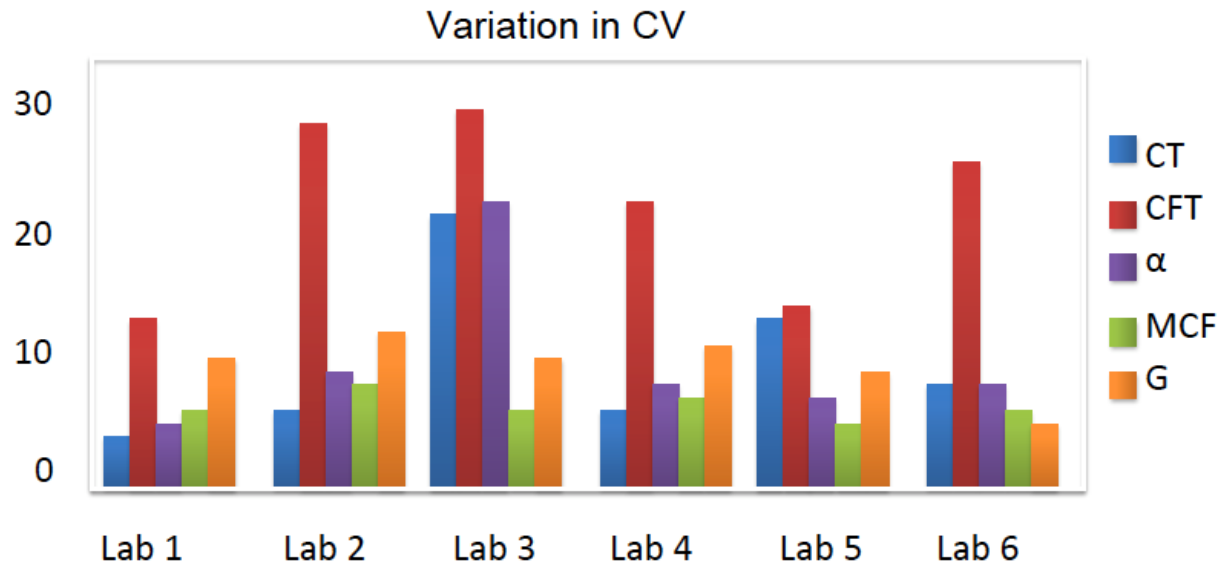
Operator Variability

Skilled Laboratory Scientist

Skilled Anaesthetist

Point of Care Equipment must have
Quality Assurance & SOP
Trained & competent operatives

International TEG-ROTEM working group



Chitlur M. *Haemophilia* 2011;17:532-7

Journal of Cardiothoracic and Vascular Anesthesia

Volume 28, Issue 6, December 2014, Pages 1550–1557

Original Articles

Interoperator and Intraoperator Variability of Whole Blood Coagulation Assays: A Comparison of Thromboelastography and Rotational Thromboelastometry

Lynne Anderson, FRCA[*], Isma Quasim, FFARCSI[*], Mark Steven, FRCA[*], Stephen F. Moise, FRCA[*], Ben Shelley, FRCA[*,†], Stefan Schraag, MD, PhD[*], Andrew Sinclair, FRCA[*]

Unrivalled performance with TEG® 6S

- **Builds on current strengths**
  - Proven value in coagulation
  - Strong KOL network
  - Emerging literature on TEG® value
- **True Point-of-Care system**
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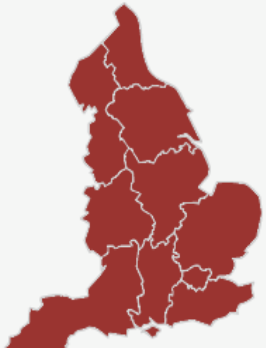
  - Vibration resistant
  - Easier lab management
  - Internet connected
- **Global product planning**
  - Two recent FDA filings
  - Planned registration in EU, Japan and Asia

Welcome
Audits
Calendar
Contacts
Education
Policies
- Massive haemorrhage toolkit
- **TE Toolkit**

RTC Business



Thromboelastography/Thromboelastometry (TE)

Getting Started

Business Case Guidance (Word doc 316KB)
This generic business case framework can be used to form the basis of your organisation's funding bid to introduce TE. The text may be adapted to suit local requirements.

TE contacts (pdf 32KB)
Email addresses of manufacturers and those involved in TE in the North West region and nationally.

Literature review (pdf 28KB)

The manufacturing companies for TEG® and ROTEM® have provided technical specifications, key features and details of the services they provide. The manufacturers are responsible for this information and it is correct as of the date of publication.

TEG® 5000 Hemostasis Analyser System supported by Haemonetics (pdf 400KB)
Further information: http://www.haemonetics.com/ email: info@haemonetics.com

ROTEM® system description supported by TEM UK Ltd (pdf 72KB)
ROTEM® service packages (Word 20KB)
Further information: http://www.rotem.de/ email: jim.leith@tem-internatioal.co.uk

Framework for the provision of Thromboelastography/Thromboelastometry (Word 316KB)
This policy has been written to support the implementation of TE in a Trust and may be adapted to meet local needs.

Education and Training

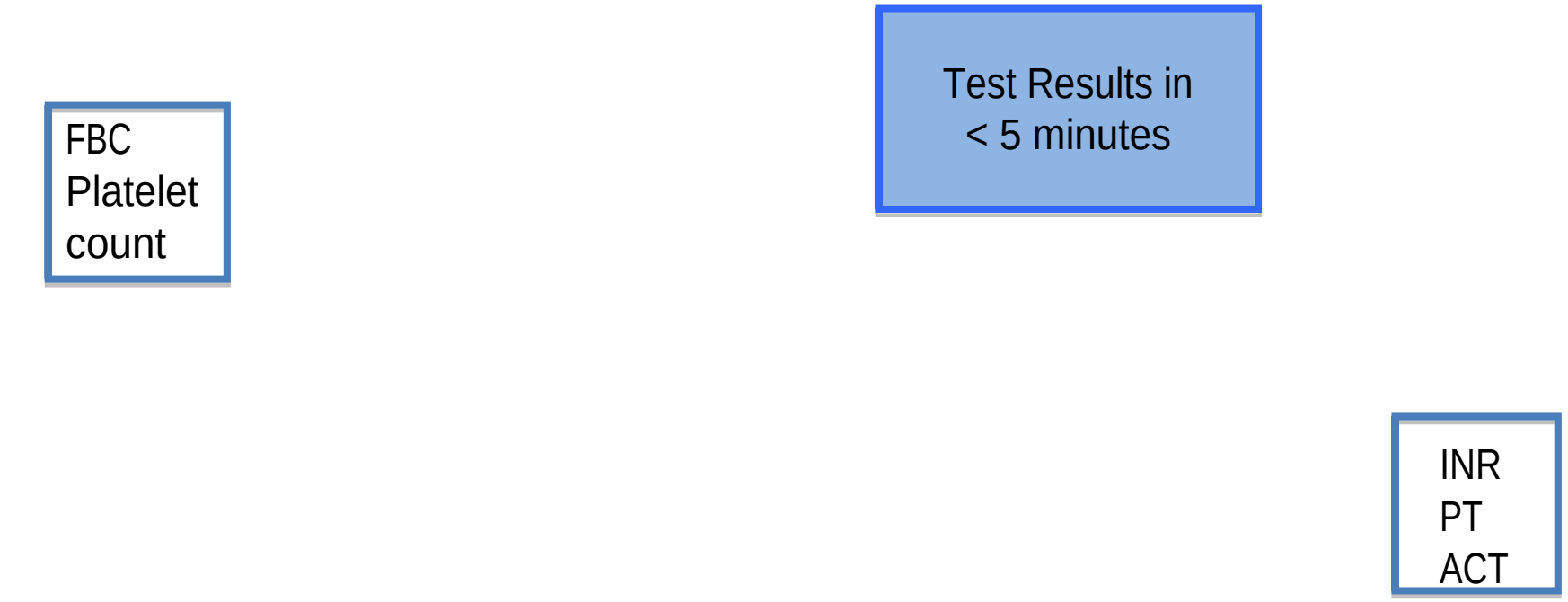
Factsheet 1: Sample collection (pdf 132KB)
Factsheet 2: Operating procedure (pdf 248KB)
Factsheet 3: Interpretation (pdf 344KB)

Algorithms based on simple POCT improve transfusion decision making

- ACT, INR, Platelet count
- Patients receive fewer transfusions of FFP & platelets
- Use of algorithms result in greater use of specific types of blood components
- More directed therapy may correct haemostatic defect more effectively with decreased bleeding on ITU

Nuttall G et al. Anesthesiology 2002,94:773-82
Avidan M,S et al BJA 2004 92 (2); 178-176
Samama & Ozier. Vox Sang 2003;84, 251-255
Despotis GJ et al. Anesthesiology 1994;84:338-351

Point of Care Coagulation Monitoring



1: Reduces unnecessary & inappropriate transfusions
2: Improves compliance with transfusion guidelines

Conclusion: POC Coagulation testing

Requires education programmes and competency training of all staff using the equipment
Quality assurance and maintenance
Forms part of permanent patient record

Integral part of PBM

Facilitates rapid assessment & optimisation of coagulopathy
Focused delivery of appropriate products
Reduces transfusion requirements
Improves patient outcomes
Reduces hospital costs