Auditing The Preanalytical Phase: Lessons from 40+ Audits

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Laboratory Analysis

Preanalytical

Sample Tube & Device Manufacturers

Analytical

Diagnostic Instrument & Reagent Manufacturers

Post-Analytical

Laboratory Information Systems (LIS) Suppliers

Preanalytical (PA) Phase is defined as
the time from when the test is ordered by the physician until sample is ready for analysis.

The Preanalytical Phase

- Receive test order
- Complete order form
- Deploy staff for collection
- Note urgency level
- Collect supplies

- Locate patient
- Identify patient
- Prep patient
- Draw sample
  - Location (bedside, home, doctor's office, draw station)
  - Phlebotomy technique (catheter draws, tourniquet time, order of draw, mixing of tubes)
- Label
- Disposal of supplies

- Prioritise sample for transport
- Send sample to lab
  - Pneumatic tube
  - Robot
  - Hand carry
  - courier

- Accession
- Apply/verify sample label
- Barcode for testing
- Identify STAT tests
- Rack Sample

- Centrifuge
- Aliquot
- Pre-treat
- Re-rack

- Send sample to appropriate lab section
  - Main lab
  - Reference lab
- Re-rack

PA Phase outside the laboratory

PA Phase outside the laboratory

Literature Reviews of Errors in Laboratory Analysis

Processing Phases

Preanalytical | Analytical | Post Analytical

Reference	Time
Goldschmidt and Lent Whole laboratory: total 133 errors	6y
Nutting et. al. Primary care: 160,714 patients: error 0.11% of [illegible]nts	6m
Ple[illegible] and C[illegible]ra[illegible] STAT l[illegible]to[illegible] 40,[illegible] te[illegible] error[illegible] of [illegible] results	3[illegible]
Sta[illegible] al. Whole laboratory: 676,564 tests; error 0.61% of test results	3y
Hofgartner and Tait Molecular genetic tests: 88,394 patients; error 0.33% of test results	1y

26% have significant effects on patient outcome

Errors in laboratory medicine;

Pierangelo Bonini, Mario Plebani, Ferruccio Ceriotti, Francesca Rubboli

Clin Chem. 2002; 48:5:691-698

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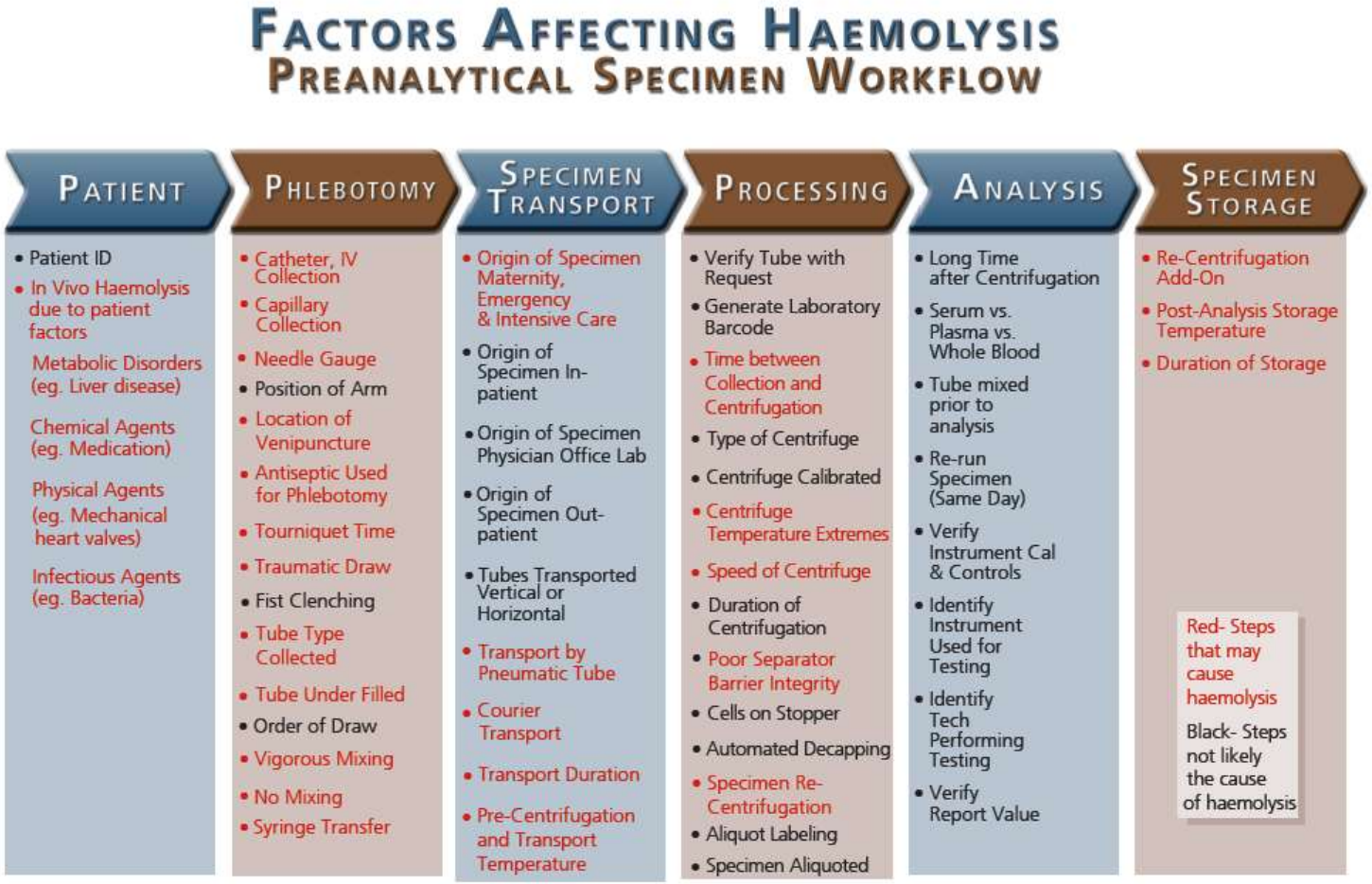
Factors Effecting the Preanalytical Phase



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23 September 2011 Last updated at 01:06

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Call for more training to improve blood tests in A&E

By Adam Brimelow
Health Correspondent, BBC News

Scientists say doctors need better training to avoid mistakes in blood samples taken in hospital A&E departments.

The warning from the Association for Clinical Biochemistry follows an audit at Birmingham City Hospital.

The trust has put in place extra training, but the ACB says this is a problem across the

Can doctors take a blood sample?

- 50 ER Samples
- Collection with incorrect equipment
- Potential for sample contamination

Call for more training to improve blood tests in A&E, BBC News, 23 September 2011, http://www.bbc.co.uk/news/health-15025970, last accessed 22nd July 2013.

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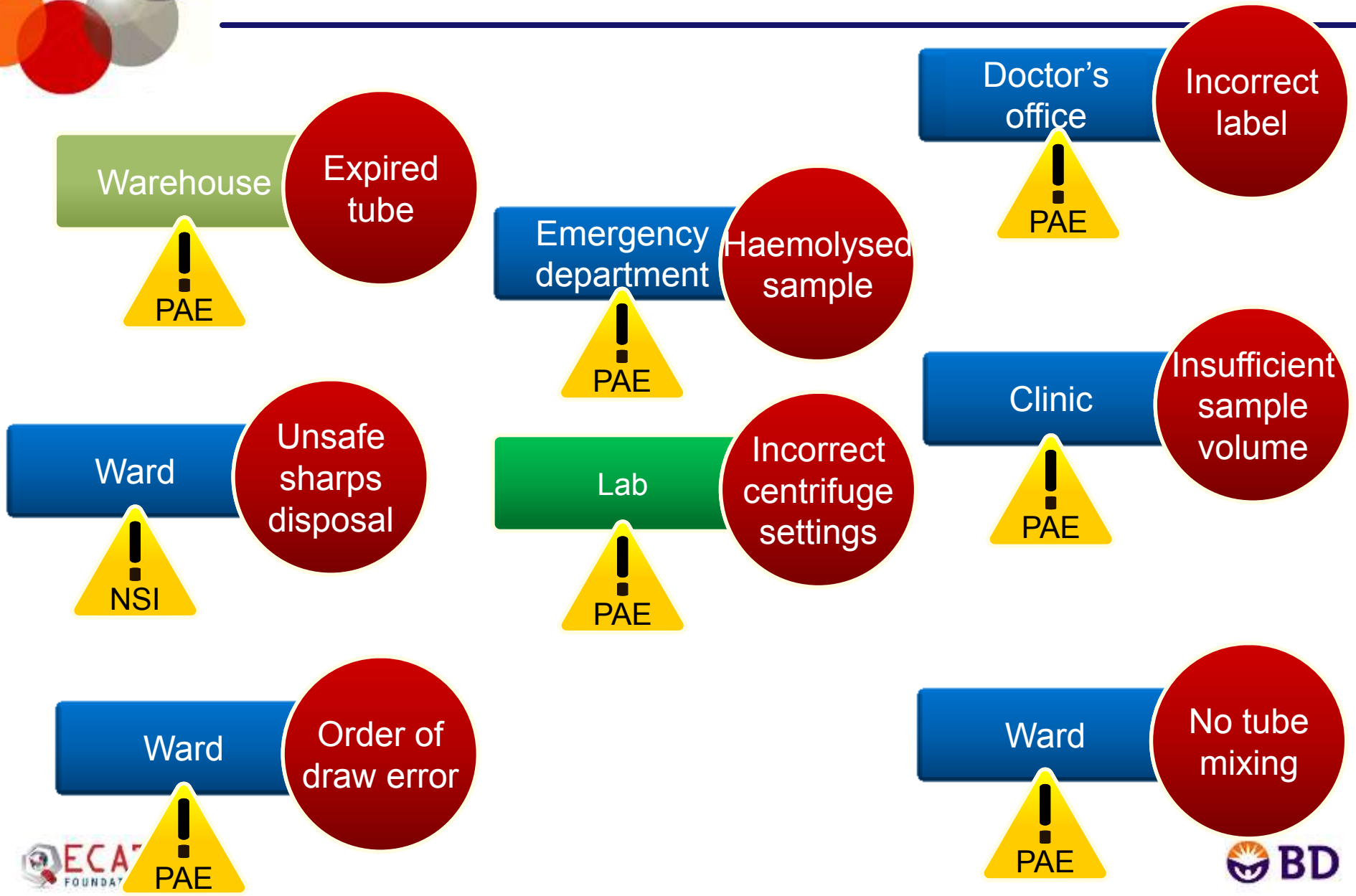
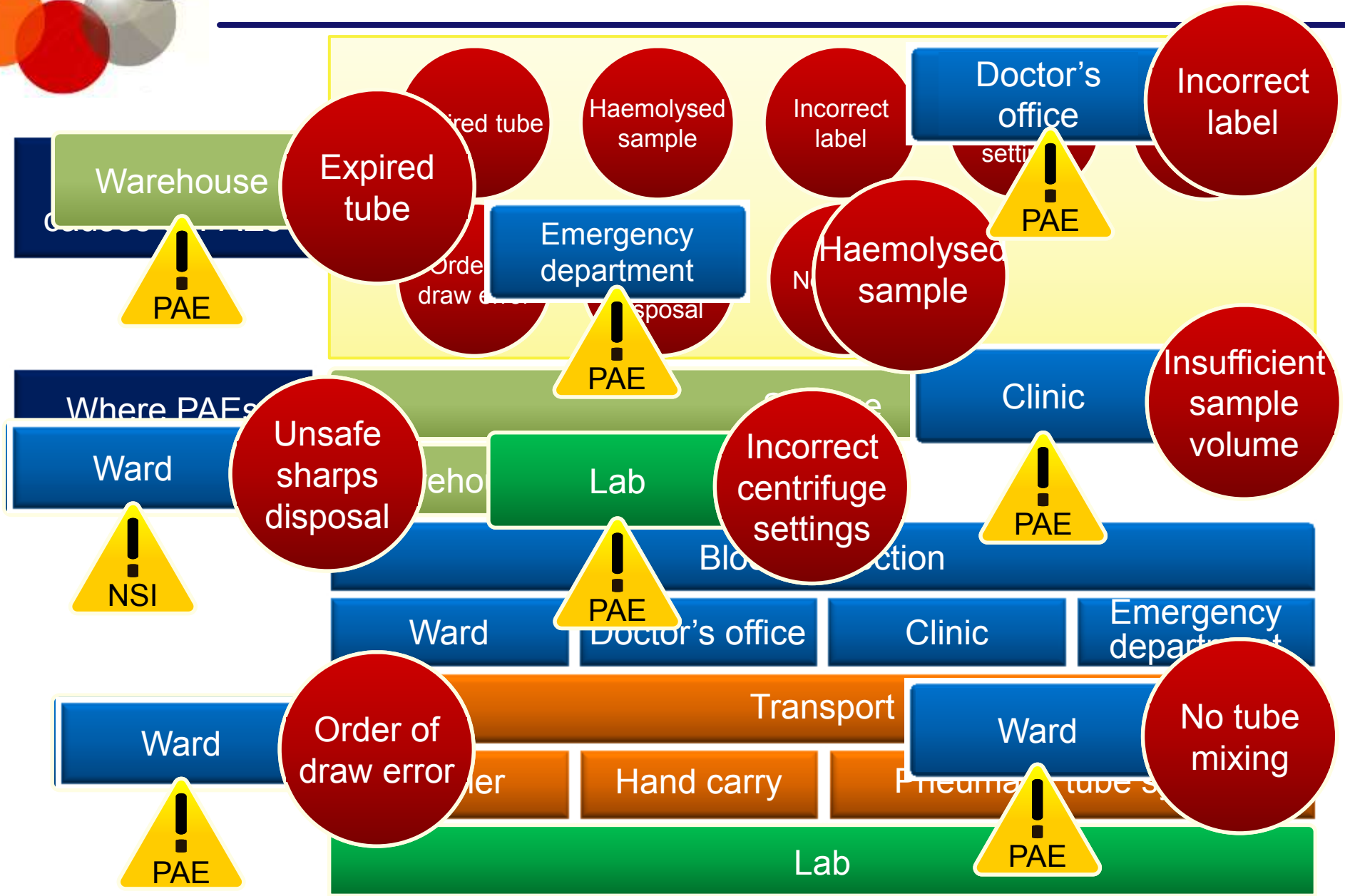
Errors in the PA phase



What Does Auditing Do For US?



PA Review Methodology

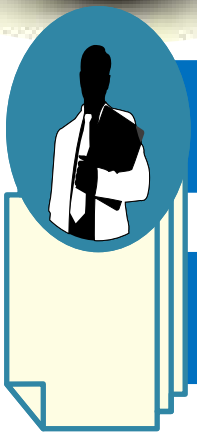
Storage

Blood Collection

Transport

Sample Preparation

Sample Quality



Trained Observers

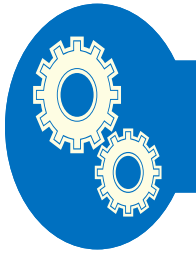
Standardised Collection Forms

PA Review Methodology

Driven by data & expert observation

Highlights areas for optimising work procedures & practices

Identifies potential areas for improving operating efficiency



Propose & prioritise potential solutions

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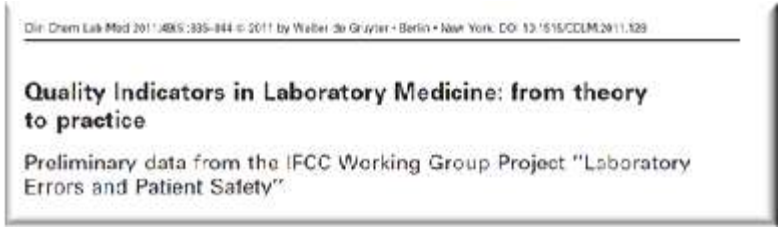
Key Quality Measures

- 40 Key Measures:
- Sample Storage
- Patient and specimen ID procedure
- Infection control procedures
- Collection Site & Device
- Phlebotomy technique
- Healthcare worker safety
- Sample management
- Sample preparation
- Sample quality



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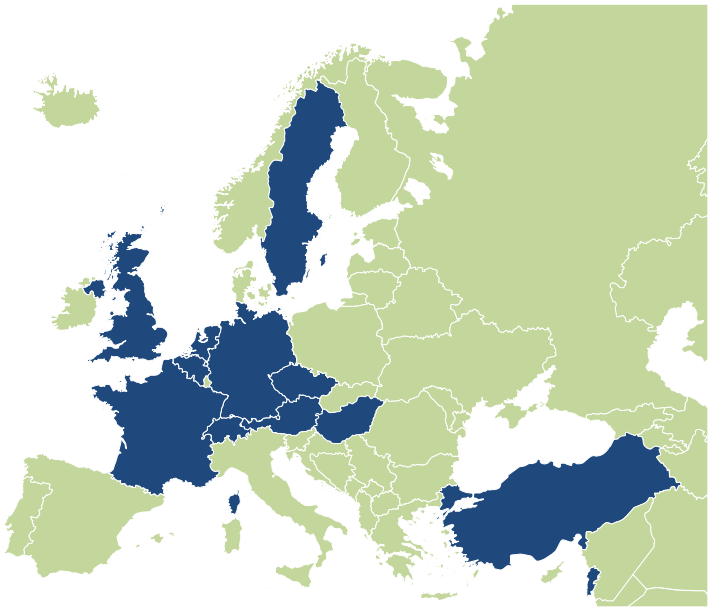
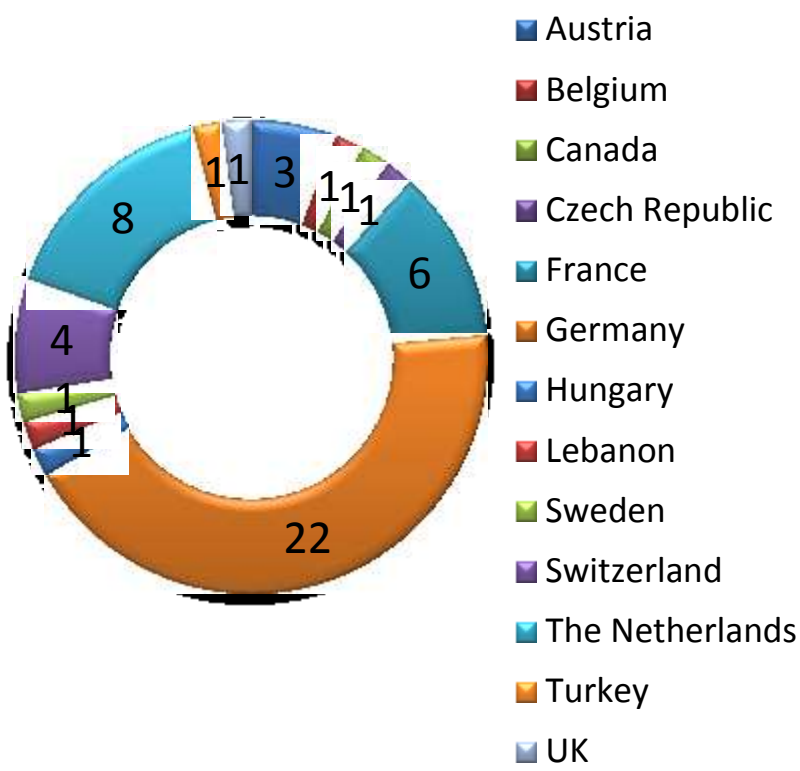
Completed PA Reviews

- **Data from 51 standardised reviews from 2004 to 2012 in 13 countries :**

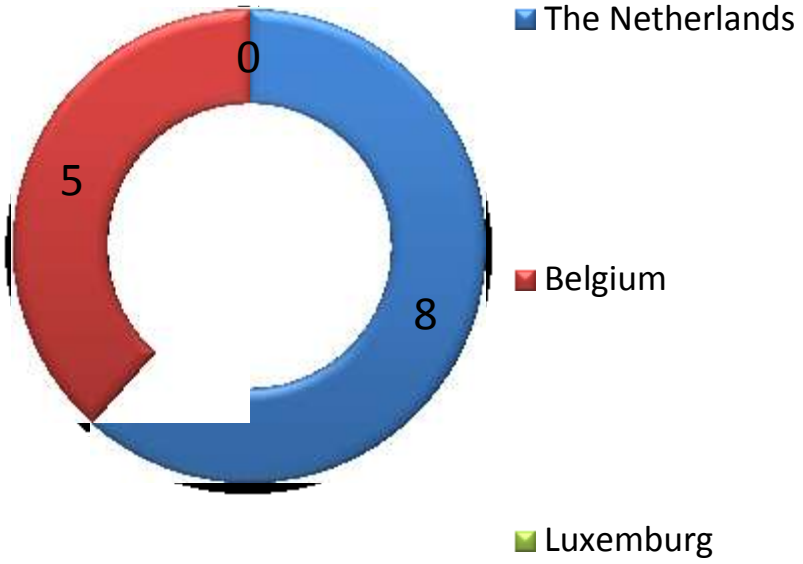




Extract from Using BD LABORATORY CONSULTING SERVICES™ to Understand the Impact of the Preanalytical Phase on Sample Quality and Safety, a Multi Country Perspective, Schlueter K, Church S, Euromedlab 2013

Completed PA Reviews - Benelux

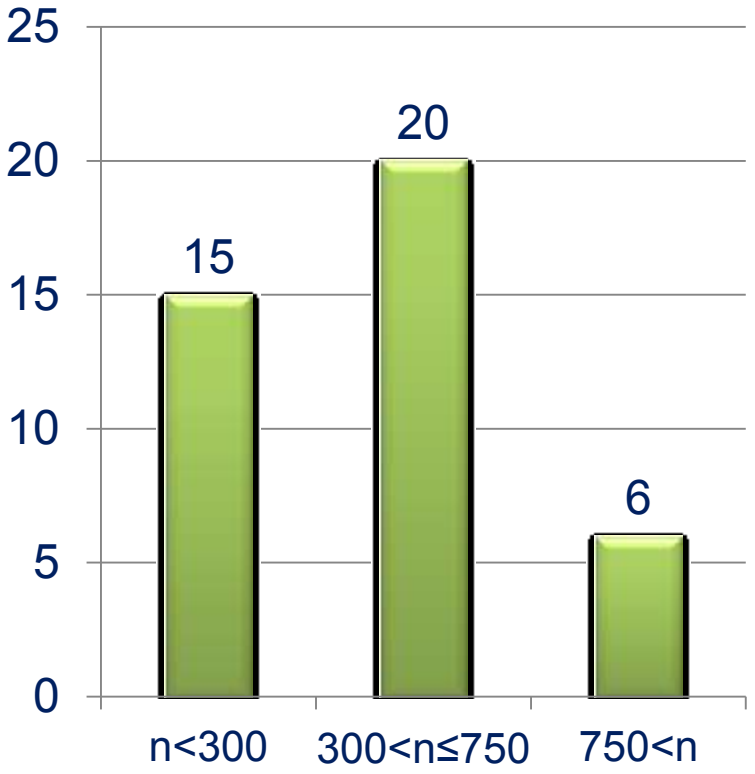
- **13 PA Reviews (On-going & Completed)***



*** 9 included in the data presented**

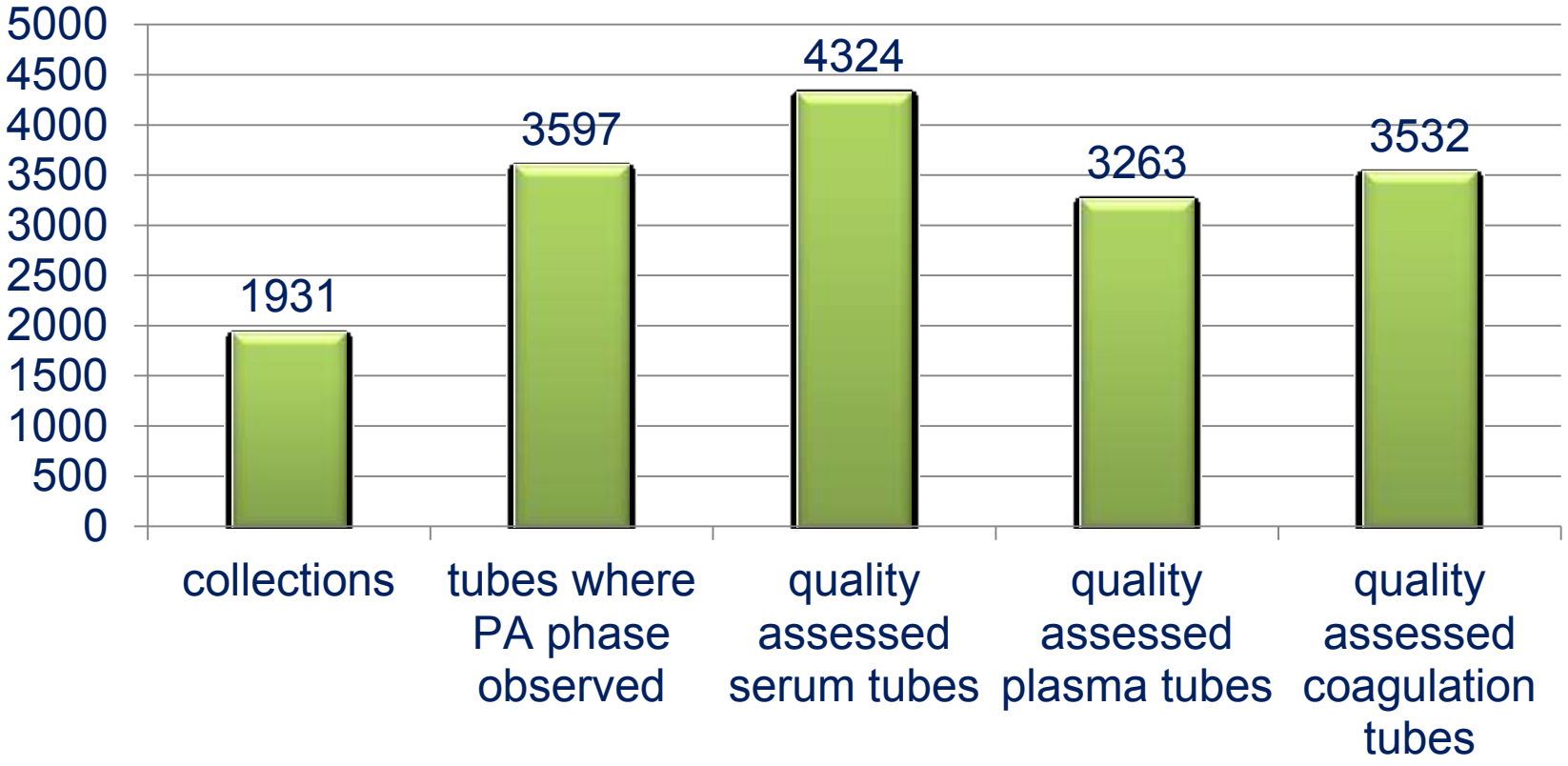
Results:
Institution Demographics

- Size of institutions (in number of beds) where reviews have taken place
- Different institutions used different blood collection systems
- Sample types to be investigated
  - Consultation with institution
  - Chemistry and/or coagulation



- Which wards are the samples to be collected from
  - Consultation with institution
  - Wards where there is an increased risk of sample quality issues:
  - Oncology, Emergency, Geriatrics, Intensive Care

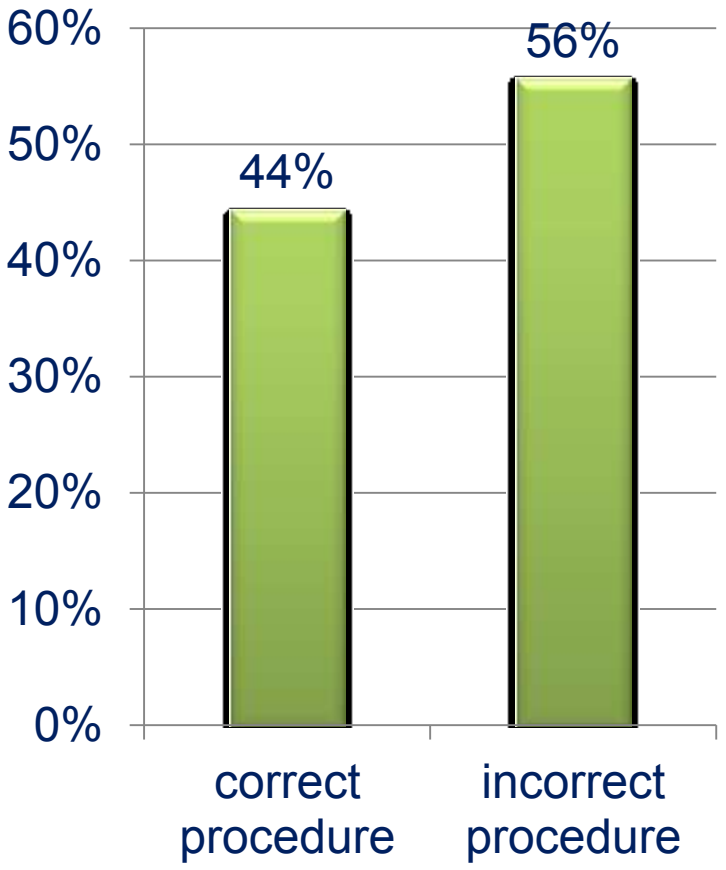
Results:
Observation Demographics



- Majority (6931; 86%) of chemistry samples collected in tubes with a gel barrier

Results:
Patient Identification

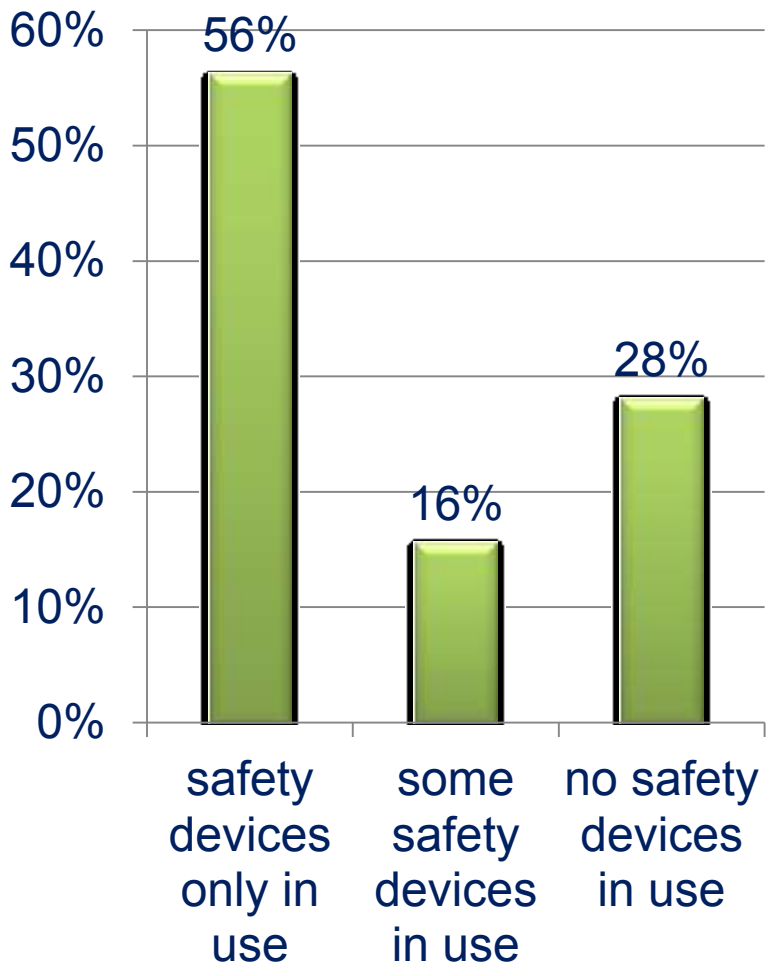
- Correct procedure: ask patient to identify themselves using an open question & collecting the minimum data
  - Other locally acceptable procedures may apply
- Incorrect identification can lead to
  - Test results being associated with wrong person
  - Two patients impact



Data from 1076 collections

Results: HCW Safety

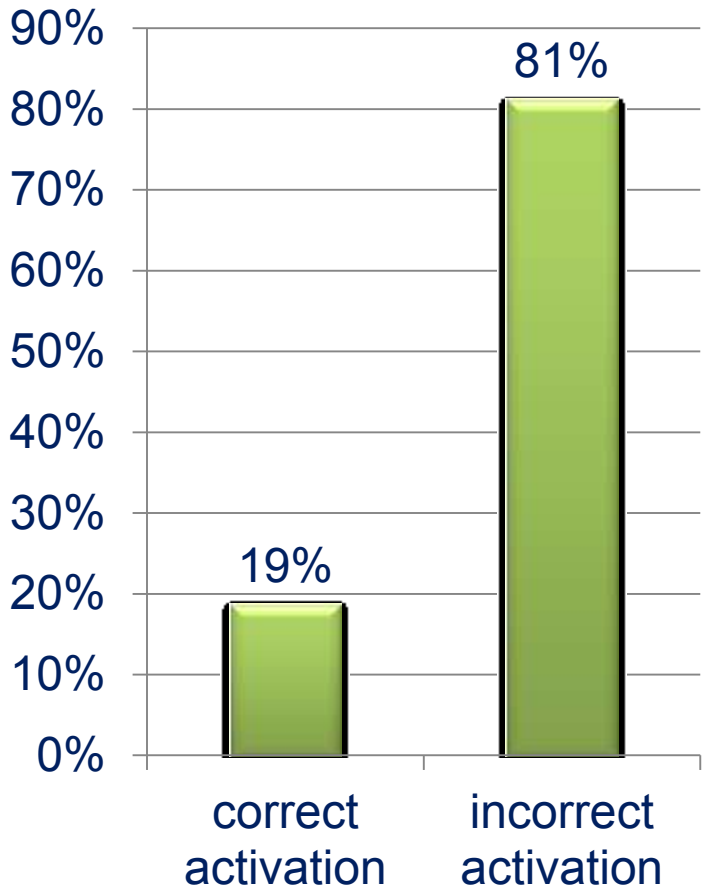
- Legal requirements vary from country to country
- EPINet Data 2003-2008 : 21% needle stick injuries associated with blood collection
- Use of safety engineered devices can reduce incidence of needlestick injuries
  - Reduce exposure
  - Reduce probability of seroconversion
  - Or having to undergo prophylaxis



Data from 32 reviews

Results: HCW Safety

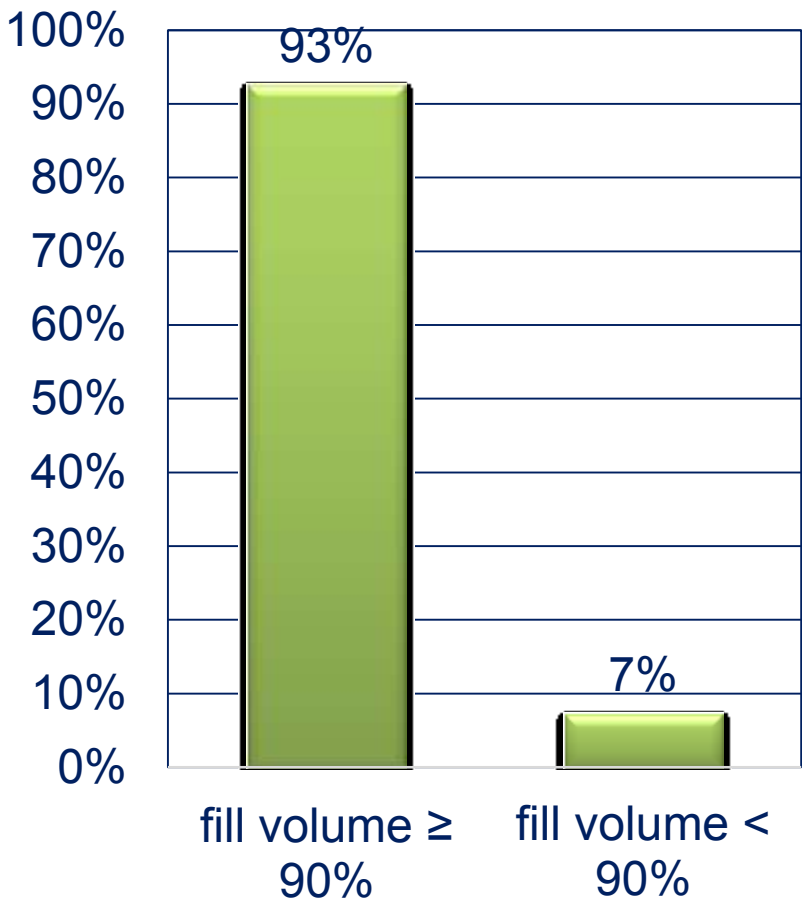
- Introducing safety devices only part of the story
- Full protection from needlestick injuries only results from correct activation of the device after collection, according to manufacturers' instructions
  - Eg single handed rather than double handed activation
  - Correct training after introduction
  - Reminder posters
  - Training of new staff due to turnover



Data from 469 collections

Results
Tube Filling: Coagulation

- Tubes filled to less than 90% of nominal tube volume will not have the correct blood to additive ratio
- Inaccurate coagulation measurements
- Potential causes of underfilling:
  - Removing tube too early
  - Low volume citrate tube is the first tube to be collected using a wing set (dead volume of tubing)

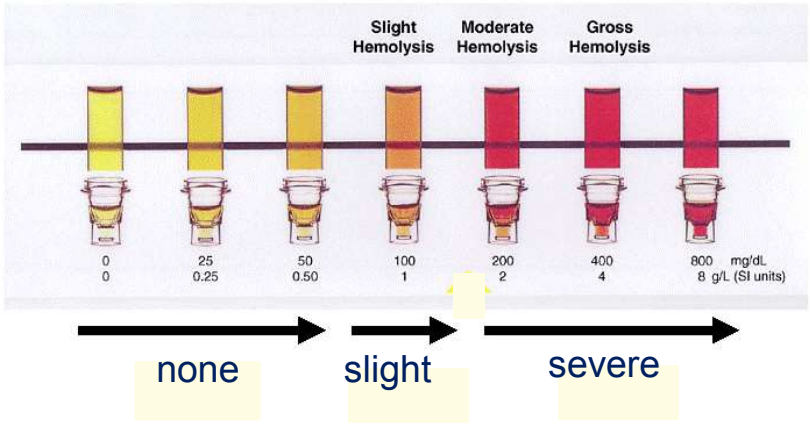


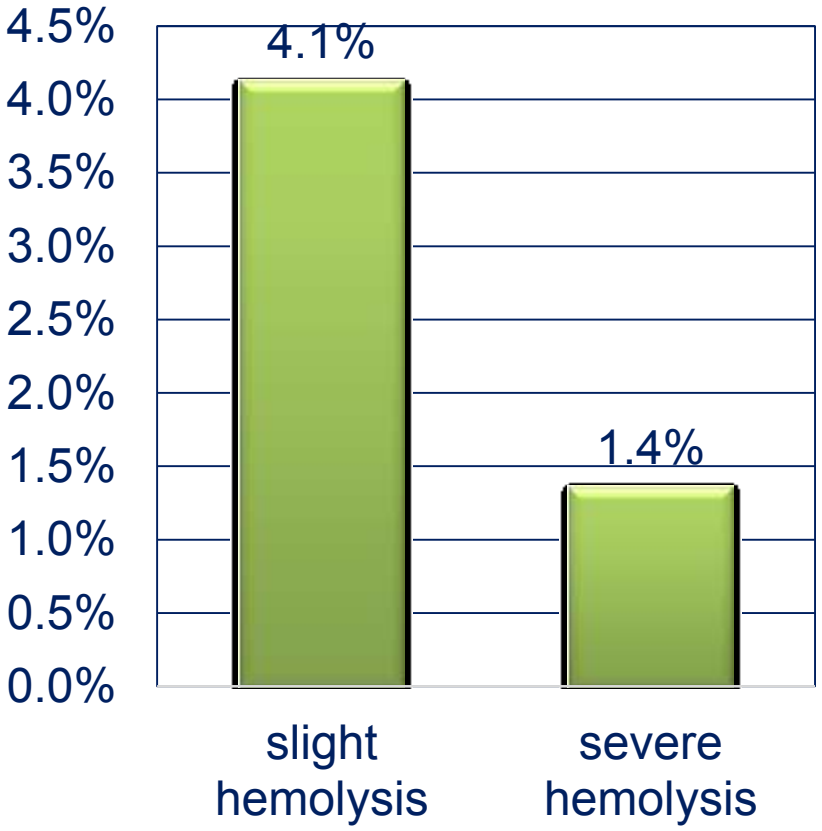
Data from observation of 3167 coagulation samples

Results
Haemolysis: Coagulation

- All samples, ie both those where PA phase had been observed or had not been observed

Evaluation of Haemolysis



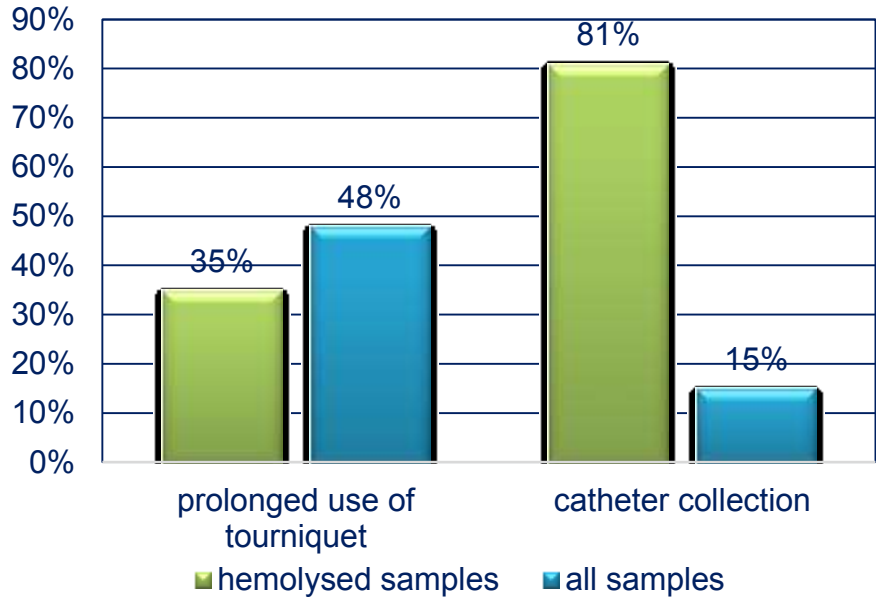


Data from observation of 3363 coagulation samples

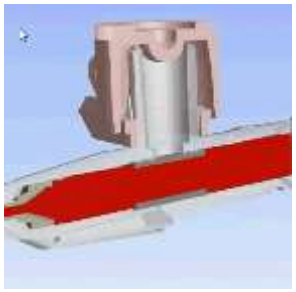
Results:
Haemolysis: Coagulation: PA Phase

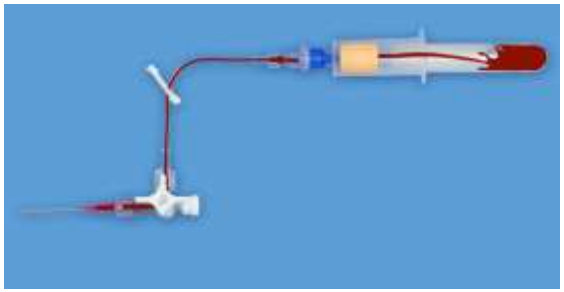
- No difference between prolonged use of tourniquet between all samples and hemolysed samples

- % of hemolysed samples where catheter used much greater than % of catheters used for all samples
  - Use of catheter increases risk of hemolysis
  - Catheter has many edges
  - Turbulence in blood flow during collection
  - Red blood cells more likely to rupture



26 PA phase observed samples were hemolysed





EFLM PRE-WG: Survey 2014

Compliance of blood sampling procedures with the CLSI H3-A6 guidelines: An observational study by the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) working group for the preanalytical phase (WG-PRE)

Simundic AM, Church S, Cornes MP, Grankvist K, Lippi G, Nybo M, Nikolac N, van Dongen-Lases E, Eker P, Kovalevskaya S, Kristensen GBB, Sprongl L, Sumarac Z. CCLM Ahead off print

- A structured checklist including **29 items based on CLSI H3-A6 guideline**.
- A **risk occurrence chart** of individual phlebotomy steps was created from the observed error frequency and severity of harm of each guideline key issue.
- 12 European countries participated June 2013 to March 2014
- 336 Audits Median of 33 audits (18 – 36)
- Wards (32%), Emergency (21%) & Outpatients (47%)
- Phlebotomists (12%), Nurses (50%), Doctors (3%), Lab Staff (32%)

Probability of Occurrence			
Probability		Textual Definition	Probability
Incredible	O1	Harm almost certainly will not happen	<0.01
Improbable	O2	Harm is very unlikely	>0.01 - 0.1
Remote	O3	Harm is not a strong likelihood	>0.1 - 0.2
Occasional	O4	Harm is sporadic	>0.2 - 0.5
Probable	O5	Harm is almost certain	>0.5 - 0.75
Frequent	O6	Harm is virtually assured	>0.75

Severity		
None	S1	No impact
Limited	S2	Additional (unnecessary) sample collection
Moderate	S3	Delayed diagnosis
Severe	S4	Inappropriate therapy based on inaccurate lab results
Life-Threatening	S5	Incorrect transfusion

EFLM PRE-WG: Survey 2014

OCCURANCE PROBABILITY	SEVERITY of Harm				
	None	Limited	Moderate	Severe	Life Threatening
	S1	S2	S3	S4	S5
Frequent					
O6					
Probable		7,11,24			
O5					
Occasional		5,13,28, 29	6,14,15,16, 19,20,23		
O4					
Remote		8,9,21	12	2	
O3					
Improbable	1	27,18	17	22	
O2					
Incredible			10		
O1					

Broadly acceptable region	**No further risk reduction required**
ALARP Region	**A decision is required regarding action**
Intolerable Region	**Risk is unacceptable action is required**

3:Did the collector check the expiry dates of devices in use?

4:Did the collector identify the patient according to CLSI or local guidelines?

25: When were the sample tubes labelled?

26: Were the tubes labelled in the presence of the patient?

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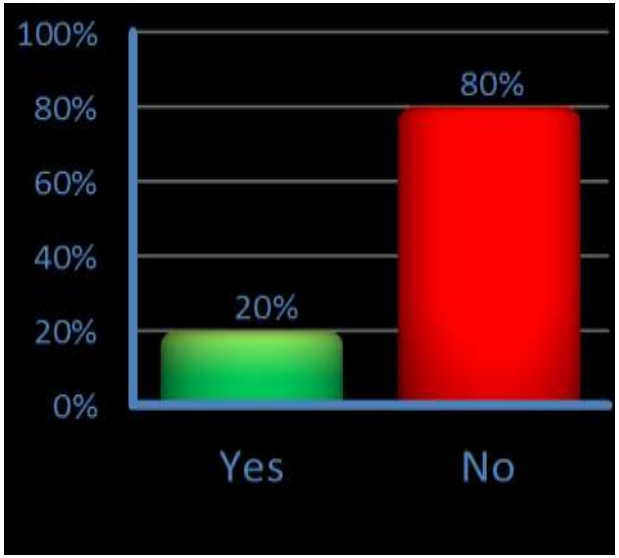
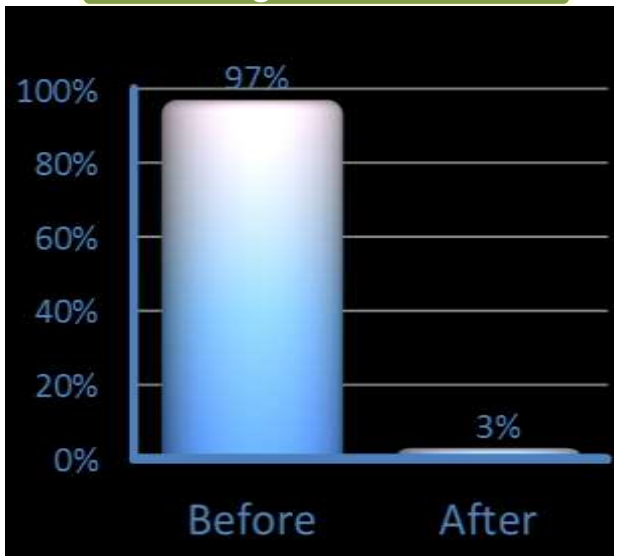
So Can We Improve?
Patient Identification

Patient ID Confirmation

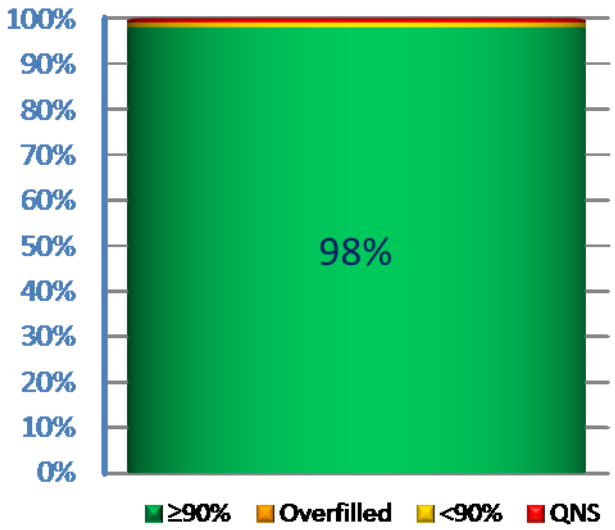


Specimen Labelling

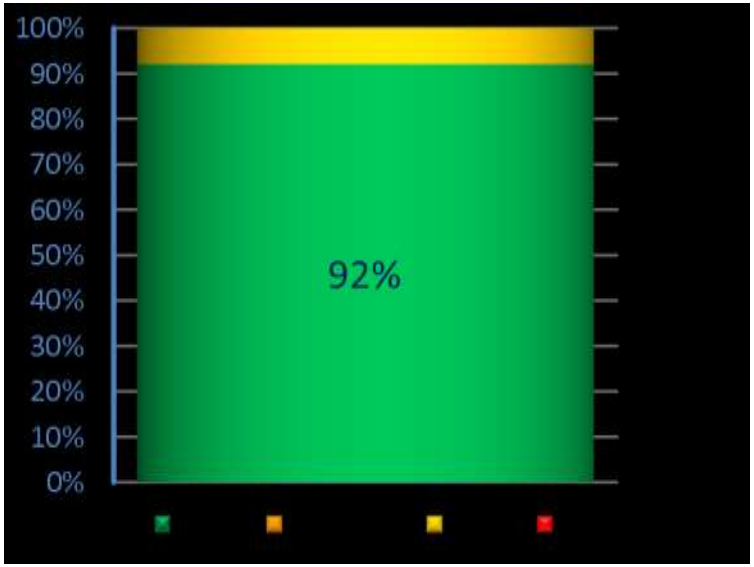


So Can we Improve?
Fill Volume

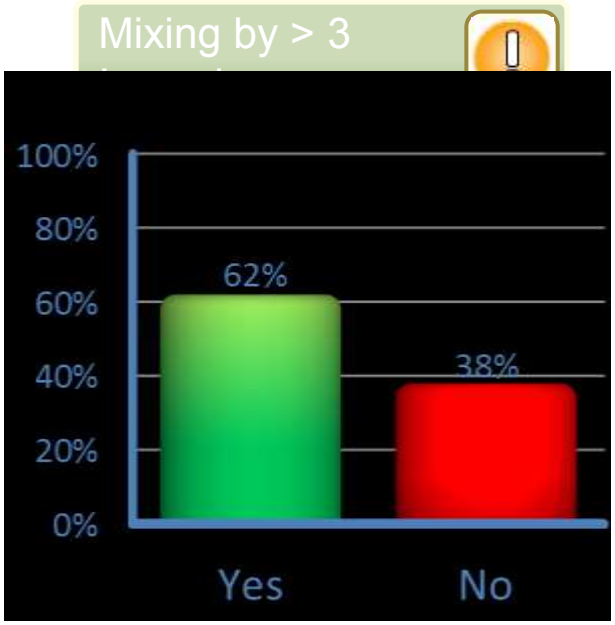
Fill Volume Coag



Fill Volume Chemistry

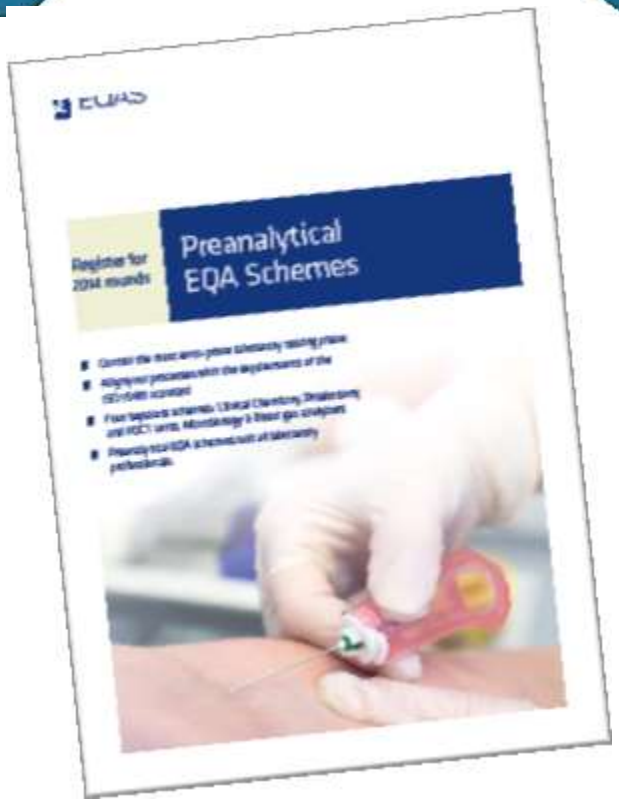


So Can we Improve?
Clotting & Fibrin



Preanalytical EQA

1



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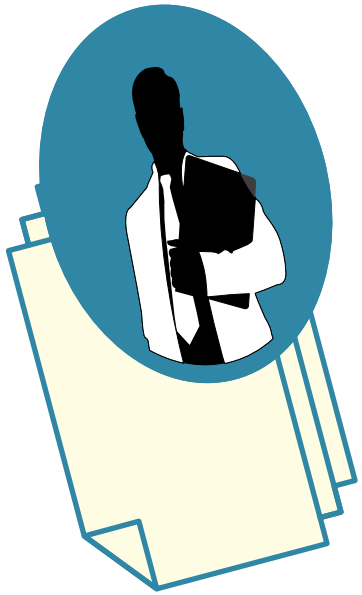


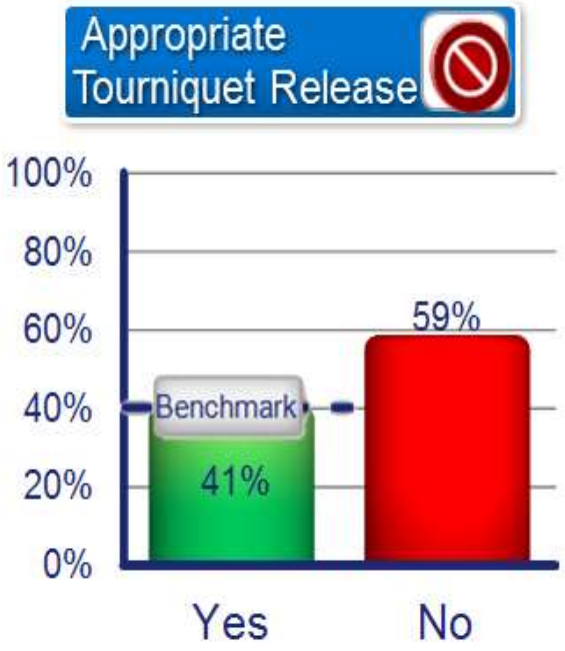
New iPad Based Audit Tool

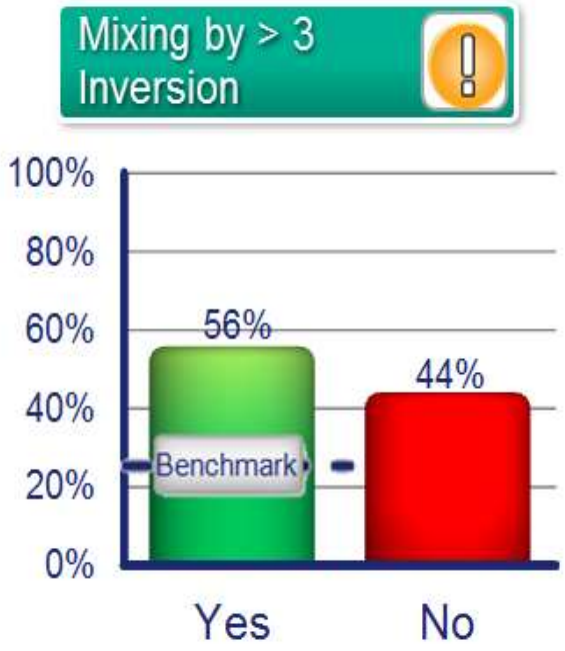
BD Laboratory Consulting Services®
PA QC

iPad Based Auditing System Implemented Jan 2013

Can Be Expanded to Cover Other Areas

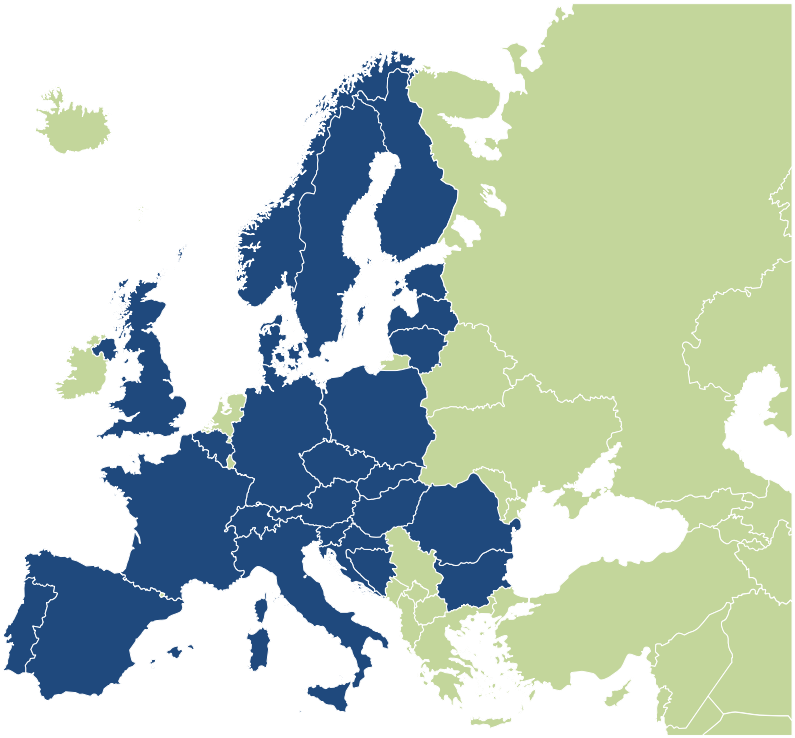
Benchmarking Capability

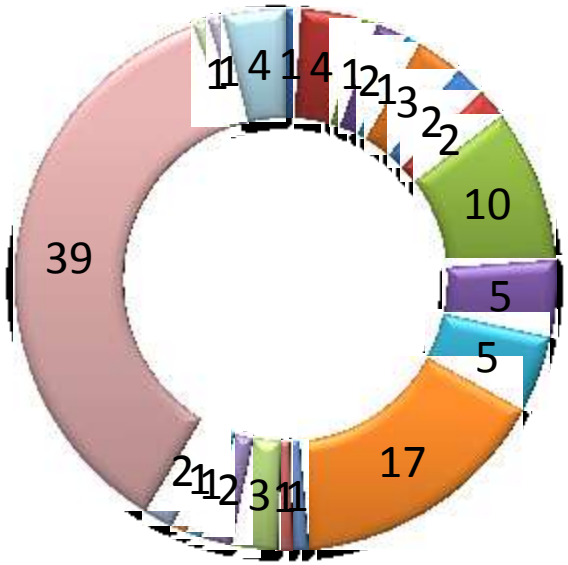




Completed PA Reviews

- iPad Systems has enabled 109 BD PAQC to be completed in 2014





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Conclusions

PA Factors have significant impact on the sample

Each Institution will have different areas for improvement

A standardised process to enable comparisons

By implementing recommendations it is possible to improve

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Helping all people
live healthy lives