Auditing of the preanalytical phase – a practical overview

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- Maximum medical care facility
- 888 beds, 2 ICU, 1 Stroke Unit
- 110,000 ambulant patients per year
- 36,000 inpatients per year
- 19 Institutes and 21 Clinics
INTRODUCTION – PREANALYTICAL VARIABILITY

- Major source of errors in the total testing process
- Complex
- Difficult to standardise

![Pie chart showing preanalytical variability](image)
COMPLEXITY OF THE PREANALYTICAL PHASE

**PA Phase outside the laboratory**
- Receive test order
- Complete order form
- Deploy staff for collection
- Note urgency level
- Collect supplies

**PA Phase inside the laboratory**
- 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)
- 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
INTRODUCTION – PREVIOUS STUDIES

- Laboratory based
  - Primarily retrospective
  - Samples that are rejected or have erroneous results, i.e. where errors have been detected
  - Unnoticed errors have a bigger potential to harm patient
  - Blood collection process itself is not observed
  - No causal link between sample quality issue and PA procedures

- For healthcare worker and patient safety
  - Use of safety devices in routine

- Different study designs are difficult to compare
AUDITING THE PREANALYTICAL PRACTICES: STUDY DESIGN

- Complete history of PA processes for samples from collection to storage
- Audit conducted via observation
- Trained observers
RESULTS – DEMOGRAPHICS - COUNTRIES

- Data from 48 standardised reviews from 2004 to 2011 in 13 countries:
  - Austria
  - Germany
  - Switzerland
  - UK
  - Hungary
  - Lebanon
  - Netherlands
  - Sweden
  - Canada
  - France
  - Czech Republic
  - Belgium
SIZE OF HOSPITALS

- Size of institutions (in number of beds) where audits have taken place
- Different institutions used different blood collection systems
STUDY DESIGN – OBJECTIVES

- Patient and specimen identification procedure
- Infection control procedures
- Phlebotomy technique
- Healthcare worker safety
- Sample management
- Sample quality
RESULTS

- Total blood collection: 1,931
RESULTS – PROFESSION OF PERSON COLLECTING BLOOD

- Nurse: 65%
- Physician: 19%
- Phlebotomist: 17%
RESULTS – PATIENT IDENTIFICATION

- Correct procedure: ask patient to identify themselves using an open question

- Incorrect identification can lead to
  - Test results being associated with wrong person
  - Two patients affected, not one
  - Serious error because value of test is not based on the patient’s status, but the status of a different patient

![Bar chart showing the percentage of correct and incorrect procedures.]
RESULTS – TUBE LABELLING

- Correct procedure: label tubes EITHER immediately before OR after collection

- Labelling before collection can lead to
  - Tube being used for collection from another person
  - Test results being associated with wrong person

- Labelling after collection can lead to
  - Not receiving label at all
  - Receiving wrong label

22% of institutions where labelling was done after collection on ≥80% of occasions
50% of institutions where labelling was done before collection on ≥80% of occasions
28% of institutions where there was no consistent labelling policy

Nauck Zagreb 2013
- Legal requirements vary from country to country

- EPINet Data 2003-2008
  Germany: 21% needle stick injuries associated with blood collection

- Use of safety engineered devices can reduce incidence of needlestick injuries
• Introducing safety devices is only one part of the story

• Full protection from needle injuries only results from correct activation of the device after collection, according to manufacturers’ instructions
RESULTS – DISPOSAL OF NEEDLES

- Needles should be disposed into an appropriate container immediately after collection.

- Incorrect disposal increases the risk of needle injuries.

![Bar chart showing correct disposal at 70% and incorrect disposal at 30%](image-url)
RESULTS – WEARING OF GLOVES

- Wearing gloves provides a physical barrier that can help to prevent from contact with infectious patient blood.
- Gloves can help to prevent the patient from exposure to infectious agents from the healthcare worker.

![Bar graph showing percentages of gloves worn and not worn]

- 63% of participants wore gloves.
- 37% of participants did not wear gloves.
RESULTS – DISINFECTION OF COLLECTION SITE

- Site should be sterile before collection begins – should not be touched after disinfection

- Disinfectant should be allowed to dry before collection
RESULTS – TOURNIQUET DURATION

- Tourniquet should not be tightened for more than 60s
- Tourniquet should be released as first tube is collected
RESULTS – RATE OF HEMOLYSIS

Evaluation of Haemolysis

- None
- Slight
- Severe

Graph showing:
- 6.4% moderate hemolysis
- 1.8% severe hemolysis
RESULTS  HEMOLYSIS – PA FACTORS

- Prolonged use of tourniquet: 47% (hemolysed samples) vs 48% (all samples)
- Disinfectant not dry: 38% (hemolysed samples) vs 35% (all samples)
- Catheter collection: 31% (hemolysed samples) vs 15% (all samples)
- Fibrin formation can block instrument probes
- Fibrin formation can lead to a smaller aliquot used for the test by instrument
RESULTS – FIBRIN FORMATION

81% tubes not mixed
26% insufficient clot time
The in vitro release of potassium from cells and platelets during blood clotting [...] increases serum potassium, on average, by 0.4 mmol/L.

Tubes filled to less than 90% of nominal tube volume will not have the correct blood to additive ratio.

Inaccurate coagulation measurements.
RESULTS – COAGULATION HEMOLYSIS RATE

![Bar chart showing slight hemolysis at 4.1% and severe hemolysis at 1.4%.]
CONCLUSIONS

- Auditing PA processes bears the potential of linking sample quality to root causes.

- Written standards (SOP) and routine conditions deviate considerably for some aspects.

- Whereas analytical quality can be monitored by classical indicators such as CV or bias, comparable instruments are not generally implemented for process quality of the PA.

- Auditing PA processes is a suitable tool to monitor PA quality.

- Large knowledge base of correct PA processes is available, but continuous education is a pre-requisite for reliable implementation in daily routine patient care.
Thank you for your attention!