Hur kan man bäst följa och åtgärda preanalytiska felkällor?

Kjell Grankvist

Dept. of Medical Biosciences, Clinical Chemistry
Umeå University, Umeå, Sweden

Equalis, Nov 2014
### Scientific Committee:
- Ana-Maria Simundic, chair
- Stephen Church
- Michael Cernes
- Edméee van Dongen-Lases
- Pinar Ekici
- Kjell Granqvist
- João Tiago Guimarães
- Mercedes bars
- Svjetlana Rovale>evskaya
- Gunn B.B. Kristensen
- Giuseppe Lippi
- Mads Nybo
- Ludek Sprngl
- Zorica Sumarac

### Organizing Committee:
- Ana-Maria Simundic, chair
- Lora Dukic
- João Tiago Guimarães
- Marijana Milic

### Venue:
Porto Palácio Hotel
Portugal

### Abstract submission deadline:
1st December 2014

### Friday, 20 March, 2015
- **8:45 - 9:00** Introductory note; Ana-Maria Simundic
- **9:00 - 9:30** Welcome address on behalf of EFLM; Mauro Ponteghis
- **9:15 - 10:00** Honorary lectures: Preanalytical phase - past, present and future; Walter Guder
- **10:30 - 11:00** Unnecessary laboratory tests - a matter of concern?; Stuart Smelle
- **11:00 - 11:30** Managing test requesting - practical experience; Mercedes bars
- **11:30 - 12:00** Implementing the EU Directive on needlestick injury prevention - 2 years of experience; Gabriela De Carli
- **13:30 - 14:00** Harmonization of fasting requirements for blood sampling; Mads Nybo
- **14:00 - 14:30** Physical activity as an important preanalytical variable; Giuseppe Banfi
- **14:30 - 15:00** Interference of medical contrast media on laboratory testing; Giuseppe Lippi
- **15:30 - 16:00** The order of draw - myth or science?; Michael Cernes
- **16:00 - 16:30** Monitoring the time and temperature conditions of sample transport; Martina Zaninotto
- **16:30 - 17:00** Centrifugation - is there room for improvement?; Stephen Church

### Saturday, 21 March, 2015
- **8:30 - 9:00** Preanalytical quality indicators; Mario Plebani
- **9:00 - 9:30** External Quality Assessment Schemes for preanalytical phase; Gunn B.B. Kristensen
- **10:20 - 10:50** Results of the 3nd EFLM WG-PRE survey - compliance to the CLSI H3-A6 guidelines; Kjell Granqvist
- **10:50 - 11:20** Evidence based quality management of preanalytical phase; Ana-Maria Simundic
- **11:20 - 13:30** Short reports from EFLM National Societies

[www.preanalytical-phase.org](http://www.preanalytical-phase.org)
Establishment of a Preanalytical Working Group of the Nordic countries

• A scientific Working Group for the preanalytical phase is under establishment within the Nordic countries supported by the Nordic Federation of Clinical Chemistry (NFKK). All Nordic countries (i.e. Denmark, Finland, Iceland, Norway and Sweden) will be represented in the WG.

• The terms of reference is to promote the quality of the preanalytical phase of laboratory medicine in the Nordic countries; to conduct surveys using questionnaires, quality indicators or other instruments to assess the current pre-analytical practices; to define best practices and provide recommendations for some critical activities in the preanalytical phase; to organize meetings; and to promote e-learning or training courses on preanalytical phase issues.
Why are new scientific findings, best practices or clinical guidelines not easily implemented and adhered to in practice? What can we do about it?

• Why does not venous blood specimen collection staff always follow collection guidelines?

• (Why does not doctors always order laboratory test according to clinical guidelines?)

(Why does not accredited laboratories always follow the quality manual?)

An understanding of the obstacles and initiatives for change is crucial for the success or failure of quality-improvement interventions.
(Parallel: Hand Hygiene)

Priority to reduce hospital-acquired infections:

- Affect about one in eleven patients in the UK
- 13 percent mortality
- 2,5 times longer hospital stays
- Additional cost per infected patient of about £3000

15 to 30 % preventable particularly by better hand washing and disinfecting by professionals between contacts with patients.

The well-established evidence of good hand hygiene has been summarized and disseminated in the form of clinical guidelines to prevent hospital infections, and most clinical professionals have been instructed about its importance.

Even so, guideline compliance by health workers in general and physicians in particular is known to be poor.
The total testing process and proportion of errors

Preanalytical 46-68%

Preanalytical

Post-analytical 19-47%

Post-postanalytical

Analytical 7-13%

Patient

 VBSC is one of the most common procedures in health care
Seven out of the 28 (25%) have national phlebotomy guidelines and five have implemented other guidelines. The estimated compliance with phlebotomy guidance for the laboratories in the countries that have national guidelines available is poor. Only a third (10/28; 36%) of the participating member countries has any specific training available as a continuous educational resource. A specific training for phlebotomy is not part of the education required to become qualified in 6/28 (21%) and 9/28 (32%) of countries for nurses and laboratory technicians, respectively. In countries and professions where training is required, most require more than 5 h of training.
Laboratory view of preanalytical errors

Registered errors – random, low frequency
Analytical sample reject – low frequency

Hard to make something specific about it!
Intervention/implementation?

Comparisons of error rates and the effect of interventions have hitherto been possible (although rarely performed) only between laboratories and not between individual hospital wards or PHCs.
Hospital ward/Care center view

It is at the hospital wards/primary health care centers that most of practical preanalytical procedures that increase the risks for or leads to adverse effects that jeopardize patient safety are performed.

No available quality indicators to cover most of the preanalytical process and to be used for benchmarking between wards/health care centers or to follow the effect of interventions/implementations at that level
“Near miss” events – more frequent to allow quantification also at ward/PHC level.

Focusing on the frequency of near misses would thus lead to better opportunities for quality improvement than mere focus on assessment of underreported incidents, registered rare adverse errors and sample reject.

The use of reliable quality indicators that effectively evaluate the quality of the steps of the preanalytical phase can thus drive improvement programs for better laboratory services and patient safety.
Two new preanalytical quality indicators/tools useful at laboratory as well as hospital ward/primary health care center level!

- Questionnaire on venous blood sampling practices
- Observational studies with error frequency and risk assessment
Questionnaire on venous blood sampling practices

“How do you usually perform.......”:

Patient rest before venous blood sampling
Patient identification
Find sampling guidelines/instructions
Test request management
Test tube labelling
Mix test tube content
Incidence reporting

The final questionnaire including 19 questions with 43 items. It was found to have content and face validity, test-retest-analysis demonstrated that the items were stable.

PhD-theses by Wallin and Söderberg

They investigated sources and frequencies of venous blood specimen collection practices errors in hospitals and primary health care units (PHCs) using a self-estimated questionnaire on collection staff:

**Hospital wards:**
20% labelled test tubes after sampling away from patient
18% reported always using (up-dated) online guidelines
10% did not always compare patient id with test request

**PHCs:**
12% released stasis as soon as possible
54% always used name and identification number
6% stated see to patient rest required time prior sampling
Theses conclusions

• A high proportion of preanalytical errors was found

• These errors endangers patient safety as they may lead to adverse events
PhD-thesis by Bölenius: Effect of large-scale educational intervention 2009 - 2010

• 2 h educational intervention focusing on national specimen collection guideline content, and especially patient identification and information search.

• All venous blood specimen collection staff (most of them enrolled and registered nurses) within the County Council (n approx. = 2500).

• Competence certificate after approved test

• Evaluation: Questionnaire
Practice performance before and after an 2h educational intervention for adherence to guidelines. Intervention group (n=55-61) and control group (n= 72-77). Paired data for primary health care staff attending both questionnaire surveys.

<table>
<thead>
<tr>
<th>Items</th>
<th>Intervention group</th>
<th>Control group</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2008 Yes (%)</td>
<td>2010 Yes (%)</td>
<td>P</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7e; Always identify by photo-ID</td>
<td>5</td>
<td>30</td>
<td>0.000</td>
</tr>
<tr>
<td>11b; I always check instructions on updated lab homepage</td>
<td>82</td>
<td>95</td>
<td>0.008</td>
</tr>
<tr>
<td>8d; I never keep the stasis even if, difficulty collecting the sample</td>
<td>38</td>
<td>49</td>
<td>0.021</td>
</tr>
<tr>
<td>9; Always allow the patient to rest &gt; 15 min</td>
<td>25</td>
<td>42</td>
<td>0.003</td>
</tr>
</tbody>
</table>
Thesis conclusions

- Better information search procedure
- Increase percentage of patient rest prior to phlebotomy
- Better patient identification procedures
- Better control request form vs test tube label
- Better labelling of test tubes
Focusing on patient safety is essential in order to establish a culture of safety throughout the entire health care system, so that all actors become aware of where, when and how to avoid errors and adverse events.

The patient safety perspective aims to improve both the quality of treatment and the financial sustainability of the health care sector (European Health Care Stakeholders position paper; Luxembourg Declaration on Patient Safety).
Plebotomy guidelines

Phlebotomy guidelines – only few steps are evidence-based, laboratory perspective only, all that might affect laboratory analyses included in chronological order, no grading of risk and frequency out of patient safety perspective.

In addition the guidelines are comprehensive and extensive, and consist of several pages and does not at all contain information on how to best implement the guidelines. (WHO guideline includes one on hygiene - but not on how to best avoid the consequences of practices affecting patient safety).
Plebotomy guidelines

Contains too many (of apparent equal importance – or at least not graded) consecutive steps to follow during phlebotomy. Hard for phlebotomist to remember and the most important steps may be forgotten or unintentionally missed.

As such, they thus are not really suited for daily healthcare practice or for risk management to minimize the risk for compromised patient safety.
Near-misses

Near-misses (surveys, observational studies) that monitors frequent practice errors at all health care levels seldom monitored.

Labs now monitor and register infrequent, random error registration at laboratory levels, errors that may not effectively be coped with.
Evidence-based implementation

Implementation advice is lacking in phlebotomy guidelines.

There exist evidence-based methods to improve/implement manual practices.
CLSI Guideline steps

Facilities
- Venipuncture chairs
- Hospital area

Supplies

Phlebotomy
- Step 1: Prepare accession order
- Step 2: Approach and identify the patient; Sanitize hands
- Step 3: Verify patient diet restrictions and latex sensitivity
- Step 4: Assemble supplies
- Step 5: Position patient
- Step 6: Apply tourniquet
- Step 7: Put on gloves
- Step 8: Cleanse venipuncture site
- Step 9: Perform venipuncture
- Step 10: Order of draw
- Step 11: Release of tourniquet
- Step 12: Place the gauze pad
- Step 13: Remove and dispose of needle
- Step 14: Bandage of arm
- Step 15: Label blood collection tubes and record time of collection
- Step 16: Observe special handling if required
- Step 17: Send blood collection tubes to proper laboratories

Additional considerations
- Monitoring blood volume collected
- Hematoma
- Hemolysis
- Nerve damage
Phlebotomy steps may be divided in the main practice topics a) patient id and other data information transfer, b) sample integrity and representativity, and c) phlebotomy practice safety and hygiene.
Methods

Collect near-miss frequencies of phlebotomy observational and survey studies
Observational studies (EFLM 2:nd survey (to be performed 2014, BD Laboratory Consulting Services™ (unpublished 2014?).

Staff self-reported adherence (Soderberg et al., 2009; 2010; Wallin et al., 2007; 2008; 2010). to national guideline phlebotomy practices (identical to the CLSI H3-A6 guideline) using a validated questionnaire (Bolenius et al., 2012).
Non-adherence frequencies tabulated.

Grading phlebotomy steps at highest risk to compromise patient safety
Risks of individual phlebotomy steps to compromise patient safety graded by the authors 1 -5 according to risk and 1 – 5 according to frequency. An over-all table with the estimated risk of each individual phlebotomy step created.
Compliance of blood sampling procedures with CLSI H3-A6 standard for the collection of diagnostic blood specimens by venipuncture and risk assessment analysis: An observational study by the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) working group for the preanalytical phase (WG-PRE)

To assess the level of compliance of phlebotomy procedures with CLSI H3-A6 guideline we have used a structured checklist with 29 items. A risk occurrence chart of individual phlebotomy steps was created from the observed error frequency and severity of harm of each guideline key issue, according to the assessment by the working group members.

The risk-occurrence chart was used to grade the severity of errors occurring during phlebotomy.
Table 1. Probability of occurrence scoring system.

<table>
<thead>
<tr>
<th>Probability of Harm</th>
<th>Abbreviation</th>
<th>Textual Definition</th>
<th>Probability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incredible</td>
<td>O1</td>
<td>Harm almost certainly will not happen</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Improbable</td>
<td>O2</td>
<td>Harm is very unlikely</td>
<td>&gt;0.01 - 0.1</td>
</tr>
<tr>
<td>Remote</td>
<td>O3</td>
<td>Harm is not a strong likelihood</td>
<td>&gt;0.1 - 0.2</td>
</tr>
<tr>
<td>Occasional</td>
<td>O4</td>
<td>Harm is sporadic</td>
<td>&gt;0.2 - 0.5</td>
</tr>
<tr>
<td>Probable</td>
<td>O5</td>
<td>Harm is almost certain</td>
<td>&gt;0.5 - 0.75</td>
</tr>
<tr>
<td>Frequent</td>
<td>O6</td>
<td>Harm is virtually assured</td>
<td>&gt;0.75</td>
</tr>
<tr>
<td>Ranking</td>
<td>Abbreviation</td>
<td>Textual Definition</td>
<td></td>
</tr>
<tr>
<td>--------------</td>
<td>--------------</td>
<td>--------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>S1</td>
<td>No impact</td>
<td></td>
</tr>
<tr>
<td>Limited</td>
<td>S2</td>
<td>Additional (unnecessary) sample collection</td>
<td></td>
</tr>
<tr>
<td>Moderate</td>
<td>S3</td>
<td>Delayed diagnosis</td>
<td></td>
</tr>
<tr>
<td>Severe</td>
<td>S4</td>
<td>Inappropriate therapy based on inaccurate lab results</td>
<td></td>
</tr>
<tr>
<td>Life-Threatening</td>
<td>S5</td>
<td>Incorrect transfusion</td>
<td></td>
</tr>
<tr>
<td>Q</td>
<td>Question</td>
<td>Severity score</td>
<td>Rationale</td>
</tr>
<tr>
<td>---</td>
<td>--------------------------------------------------------------------------</td>
<td>----------------</td>
<td>--------------------------------------------------------------------------</td>
</tr>
<tr>
<td>1</td>
<td>Did the collector assemble all necessary supplies prior to collection?</td>
<td>S1</td>
<td>No real harm</td>
</tr>
<tr>
<td>2</td>
<td>Did the collector have an identified request form?</td>
<td>S4</td>
<td>Incorrect patient identification, therefore incorrect treatment or transfusion</td>
</tr>
<tr>
<td>3</td>
<td>Did the collector check the expiry dates of devices in use?</td>
<td>S3</td>
<td>Expire stock may result in underfilled tubes or reduced potency of additives</td>
</tr>
</tbody>
</table>
## Risk occurrence chart for various phlebotomy steps

<table>
<thead>
<tr>
<th>OCCURRENCE PROBABILITY</th>
<th>SEVERITY of Harm</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>None</td>
</tr>
<tr>
<td></td>
<td>S1</td>
</tr>
<tr>
<td>Frequent</td>
<td>Q7,Q11,Q24</td>
</tr>
<tr>
<td>O6</td>
<td>Q5,Q13,Q28,Q29</td>
</tr>
<tr>
<td>Probable</td>
<td>Q5,Q13,Q28,Q29</td>
</tr>
<tr>
<td>O5</td>
<td>Q8,Q9,Q21</td>
</tr>
<tr>
<td>Occasional</td>
<td>Q1</td>
</tr>
<tr>
<td>O4</td>
<td>Q1</td>
</tr>
<tr>
<td>Remote</td>
<td>Q1</td>
</tr>
<tr>
<td>O3</td>
<td>Q1</td>
</tr>
<tr>
<td>Improbable</td>
<td>Q1</td>
</tr>
<tr>
<td>O2</td>
<td>Q1</td>
</tr>
<tr>
<td>Rare</td>
<td>Q1</td>
</tr>
<tr>
<td>O1</td>
<td>Q1</td>
</tr>
</tbody>
</table>
Conclusion

Local, national or international observational studies with venous blood specimen collection error frequency assessment using a template checklist and risk analysis is an efficient method to assess critical steps in phlebotomy.

Combined with feed-back, discussions and reflection amongst phlebotomy personnel this could to be an efficient tool to implement and sustain adherence to phlebotomy guideline practice and lead to long-term improvements in patient safety.

According to our results, the overall level of compliance of phlebotomy procedures with CLSI H3-A6 guideline in 12 European countries is unacceptably low. The most critical steps are patient identification and tube labelling. Those steps need immediate attention and improvement in EFLM member countries.
When does nurse student start to deviate from collection guidelines?

Fifth semester campus students were 21 times (OR 21, CI 2.5 – 181) and 6th semester students 45 times (OR 45, CI 4.6 – 457) more likely to refrain from comparing patient name and id number with test request and test tube label.

Hypothesis: Deviation from guideline practices starts immediately when on hospital/PHC training!
Organization vs individual

- Workplace affiliation partly explains variances in self-reported adherence to VBSC guidelines among PHC phlebotomy staff. PCH factors, as well as individual phlebotomist factors, could be barriers contributing to poor levels of adherence – barriers that need to be identified to plan for improvement strategies.
Organization vs individual

Based on our results, the highest risks for errors in patient identification is in small PHCs in rural areas and among phlebotomists employed at the site for more than 5 years.

By recognizing the association between these specific risk factors and guideline adherence, healthcare managers can tailor interventions to ascertain patient safety.
Organization vs individual

Our findings also indicate that there is no reason for staff to perform VBSC daily and that VBSC guidelines adherence are better followed when staff perform a variety of tasks and not solely VBSC.

Thus, from a safety perspective, to reduce non-adherence to VBSC guidelines it could be beneficial to organize PHC staff to perform a variety of tasks, and not just the one specific procedure.
Overall conclusions

Most preanalytical procedures that increase the risks for or lead to adverse effects that jeopardize patient safety are performed locally at primary health care centers and hospital wards. Assessing the frequent “near-misses” during venous blood specimen collection allow for general and directed corrective interventions and also permit comparison and benchmarking of preanalytical practices not only between laboratories but also between wards and health care centers.

Use of methods such as validated self-assessed practice questionnaire surveys and observational studies now gives an opportunity for assessing quality improvements instead of more or less meaningless assessments of underreported incidents or registered rare adverse events.
Preanalysis group

*Nursing*
Christine Brulin
Christina Juthberg
Karin Bölenius

*Clinical Chemistry*  *Laboratory Instructors*
Kjell Grankvist  Susanna Hermansson
Johan Söderberg  Ann-Britt Lindström
Johan Hultdin  Marie Backlund
Lotta Harnevik  Marie Lundgren

*Statistics*
Marie Lindkvist

*PhD Student*
Karin Nilsson
Haemolysis

- A consequence of preanalytical errors
- Marker for the quality of venous blood specimen collection practices and specimen handling
- Release of haemoglobin

- Of 37 208 specimens from primary health care centers, 130 tests were rejected because of haemolysis (analytical interference)
Haemolysis is the release of haemoglobin and other intracellular components from erythrocytes into the surrounding plasma following damage of the cell membrane.

Haemolysis is the most common reason for specimen rejection, accounting for 40%–70% of all unsuitable specimens sent to the laboratory.

In vitro haemolysis is caused primarily by inappropriate specimen collection and handling, such as:

- Inappropriate collection
- Venous blood collection devices and primary tubes
- Sampling through i.v. catheters
- Tube filling and mixing
- Centrifugation, storage, transport
Haemolysis

Most previous studies have used subjective visual assessment or the analysis of free haemoglobin with laborious manual spectrophotometric techniques to evaluate the prevalence of haemolysis.

The hemolysis index (HI) in automated analysers is a more efficient method for detecting haemolysis. For many years now, the HI has been used in laboratories to automatically reject samples that are haemolysed in order to avoid analytical interference.
Haemolysis distribution of samples

The use of all samples with detectable HI from each hospital ward or primary health care unit as a marker of the overall preanalytical quality of the blood sample has not been thought of.

We therefore analysed the HI distribution of all serum samples from 13 PHCs sent to the laboratory over a three month period.

All samples above the cut-off level (HI 15 =150 mg/L free haemoglobin) of the analyzer were used.

(International) collection guidelines.

BD Vacutainer® SST II Advance tubes.
Heamolysis (HI) determined with a microspectrofotometer that utilizes diffraction grating and a 256-element photodiode array and calculates HI by using the first derivative of the absorbance spectrum.
All Health Care Centers (n = 6121 samples)

HI 95th percentile

Analytical reject:
S-LD, S-Fe

Vitros Cut-off
HI 15 = free Hb 150 mg/L
11.8% of all samples above

0.9% of all samples above HI 50
<table>
<thead>
<tr>
<th>PHC</th>
<th>Samples</th>
<th>HI ≥15, %</th>
<th>HI 95th</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>574</td>
<td>6.6</td>
<td>17</td>
</tr>
<tr>
<td>2</td>
<td>237</td>
<td>31.7</td>
<td>33</td>
</tr>
<tr>
<td>3</td>
<td>492</td>
<td>6.7</td>
<td>17</td>
</tr>
<tr>
<td>4</td>
<td>1425</td>
<td>9.1</td>
<td>19</td>
</tr>
<tr>
<td>5</td>
<td>622</td>
<td>12.5</td>
<td>24</td>
</tr>
<tr>
<td>6</td>
<td>963</td>
<td>6.6</td>
<td>16</td>
</tr>
<tr>
<td>7</td>
<td>790</td>
<td>15.8</td>
<td>24</td>
</tr>
<tr>
<td>8</td>
<td>598</td>
<td>8.5</td>
<td>18</td>
</tr>
<tr>
<td>9</td>
<td>484</td>
<td>15.1</td>
<td>22</td>
</tr>
<tr>
<td>10</td>
<td>1096</td>
<td>8.5</td>
<td>17</td>
</tr>
<tr>
<td>11</td>
<td>443</td>
<td>6.8</td>
<td>16</td>
</tr>
<tr>
<td>12</td>
<td>333</td>
<td>16.8</td>
<td>23</td>
</tr>
<tr>
<td>13</td>
<td>731</td>
<td>8.6</td>
<td>19</td>
</tr>
</tbody>
</table>
Results

Men had higher HI (10.5% vs 9.3% above HI 15) than women.

Samples from patients with median age ≥ 63 had higher HI than those below (11.8% vs 9.2% above HI 15).

PHCs located outside the urban area (> 17 km) were haemolysed 1.7 times more often compared to the PHCs close to the laboratory.
The significant variation in HI among the investigated units reflect varying preanalytical conditions (i.e. all steps in the preanalytical procedure that contributes to sample haemolysis).

The HI is a valuable tool for estimation and follow-up of venous blood specimen collection practices.

Suggestions

• HI 95th percentile mirrors preanalytical sample quality due to inappropriate specimen collection and handling at all health care levels (laboratory/health care unit/PHC/individual phlebotomist).

• The HI 95th percentile can be used for benchmarking, and to follow the effect of interventions and implementations at all health care levels.

• Laboratory medicine profession urge instrument manufacturers to have open instruments for HI retrieval and traceable to free Hb g/L.