Auditing the preanalytical phase – ISO assessors

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Auditing the preanalytical phase

- Many medical laboratories in Europe are accredited by the ISO15189 standard (ranging from 0-75% between countries (Huisman 2013))
- But how well is the preanalytical phase actually covered by the accreditation process?
- Of note, preanalytical errors will still be prevalent in an accredited laboratory (Simundic 2010) – but the impact will (or should?) be smaller
Auditing

- ISO accreditation 15189 2007 / 2012
Auditing

- Documentation
- Documentation
- Documentation

- Clarity and accessibility

- Say what you do and do what you say
Auditing

- Horizontal audit = follow the sample
- Vertical audit
- Preparation of the visit

Remember: No “true” solution
In- or outpatients?

**Inpatients**
Who is responsible for sampling?
Who is REALLY responsible for sampling?
And who TAKES responsibility for sampling?

**Outpatients**
Very different local arrangements
- Sampling at hospital
- External clinics
- At GPs
Preanalytical issues

- Request
- Preparation of the patient
- Identification
- Sample collection
- Sample transport
- Sample preparation
- Sample storage
- And interference issues
Inpatients

- Request
- Preparation of the patient
- Identification
- Sample collection
- Sample transport
- Sample preparation
- Sample storage
- And interference issues

5.1.4a + 5.4.1
5.4.3
5.4.6
5.4.7-12
5.4.14
5.5.3j + 5.6.2
In- and outpatients

- Request
- Preparation of the patient
- Identification
- Sample collection
- Sample transport
- Sample preparation
- Sample storage
- And interference issues

Continuous dialogue

SOP and sample collection book
Sampling performed elsewhere / other staff

Management
- 4.1.5g Demands on training of all staff
- 4.2.3d All personnel must be familiarized with quality documents
- 4.12.4 Implementation of QI

Technical requirements
- 5.1.4d QI again …
- 5.2.1-4 Appropriate facilities
Sampling performed elsewhere / other staff

- Request
- Preparation of the patient
- Identification
- Sample collection
- Sample transport
- Sample preparation
- Sample storage
- And interference issues

The challenge!

SOP
Sampling performed elsewhere

- They are often not lab-oriented
- They tend to be busy …
- A blood sample – how difficult can it be?

SO: Be more/very specific!!
Sampling performed elsewhere

- Request
Sampling performed elsewhere

- Preparation of the patient
Sampling performed elsewhere

- Identification
Sampling performed elsewhere

- Sample collection
Sampling performed elsewhere

- Request
- Preparation of the patient
- Identification
- Sample collection
- Sample transport
- Sample preparation
- Sample storage
- And interference issues

Dialogue
Sample coll. book
SOP
Measures?

- EQA? E.g. CAP, SEQC, new initiatives?
- QI? Plebani
- Audits?
- Certification?
- Accreditation of other samplers, e.g. GPs?

The new 15189:2012 has specified the demands for sampling, which should improve the assessment on this area.
Conclusions?

- Auditing should be a help, not an obstacle
- Use the standards to facilitate changes
- Although international EQA is not there yet, we **must** deal with the preanalytical phase
- Take responsibility – and ask others to do the same