Management of the quality in the pre-analytical phase

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Clinical practice guidelines

- Clinical practice guidelines **aim to guide** healthcare staff **in decision making** and are an indispensable part of professional quality systems.
- Clinical practice guidelines aims to **standardize medical care**; **raise care quality** and **reduce patient risks** by reducing inappropriate variations in practice.
- Clinical practice guidelines are usually consensus statements on **best available practice** in a particular area.

Phlebotomy practice guideline CLSI H3-A6 steps

Facilities

- Venipuncture chairs
- Hospital area

Supplies

Phlebotomy

- Step 1: Prepare accession order
- Step2: 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 practice guideline CLSI H3-A6 drawbacks

- Few practice steps are evidence-based
- Comprehensive and extensive.
- Many discrete chronological practice steps, all of which can be subject to error.
- The numerous phlebotomy practice steps are difficult to remember - important steps may be forgotten or unintentionally missed.
- Limited to the collection procedure (of the preanalytical phase).
- To a large extent focused on patient and collectors safety at the collection and not on the overall effects of a bad quality sample on patient safety.
- Does not contain risk evaluation of the different practice steps.
- Lacks advice on how to best implement and sustain practices recommended by the guideline.

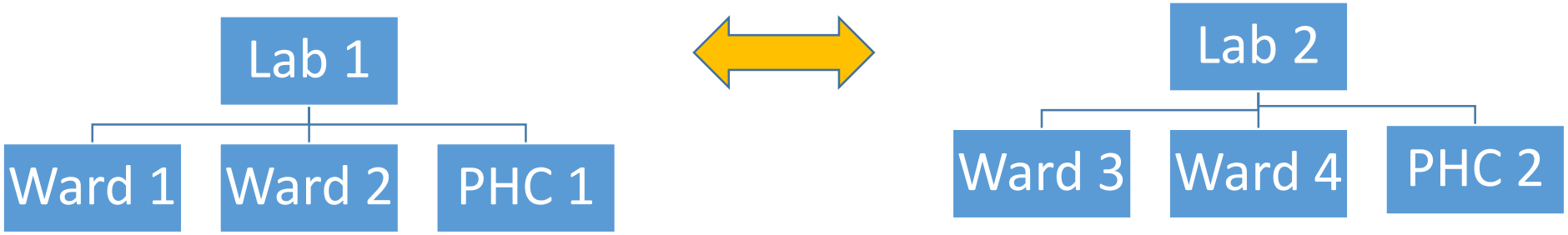
Preanalytical errors in the laboratory

- Analytical laboratories often monitor, register and address the **seemingly randomly distributed and infrequent preanalytical errors** that arise throughout the healthcare organisation.

Low registered error frequency, typically < 1%

At best comparison between labs only!!

QI:s of IFCC WG-LEPS, National programmes



Preanalytical errors in the laboratory

- These errors are **not effectively managed** and still pose a challenge to laboratory professionals and constantly jeopardise patient safety.

Preanalytical errors in the laboratory

- **Modifying staff behavior** to conform to practice guidelines and other recommended practices **is difficult**.

- One reason is that efficient and accurate **methods for measuring guideline practice adherence** are not applied.

“Modifying staff behavior to conform to practice guidelines and other recommended practices **is difficult”**.

Effectiveness and efficiency of guideline dissemination and implementation strategies

JM Grimshaw, RE Thomas, G MacLennan, C Fraser, CR Ramsay, L Vale, P Whitty, MP Eccles, L Matowe, L Shirran, M Wensing, R Dijkstra and C Donaldson

Health Technology Assessment 2004; Vol. 8: No. 6

Planning and Studying Improvement in Patient Care: The Use of Theoretical Perspectives

RICHARD P.T.M. GROL, MARIJE C. BOSCH, MARLIES E.J.L. HULSCHER, MARTIN P. ECCLES, and MICHEL WENSING

The Milbank Quarterly, Vol. 85, No. 1, 2007 (pp. 93–138)

Evidence-based factors for improving guideline adoption:

- evidence that the context is accessible to change,
- the appropriate monitoring and feedback mechanisms, **Ward, PHC level**
- available time for personnel to discuss findings. **Ward, PHC level**

Nilsson K et al.:

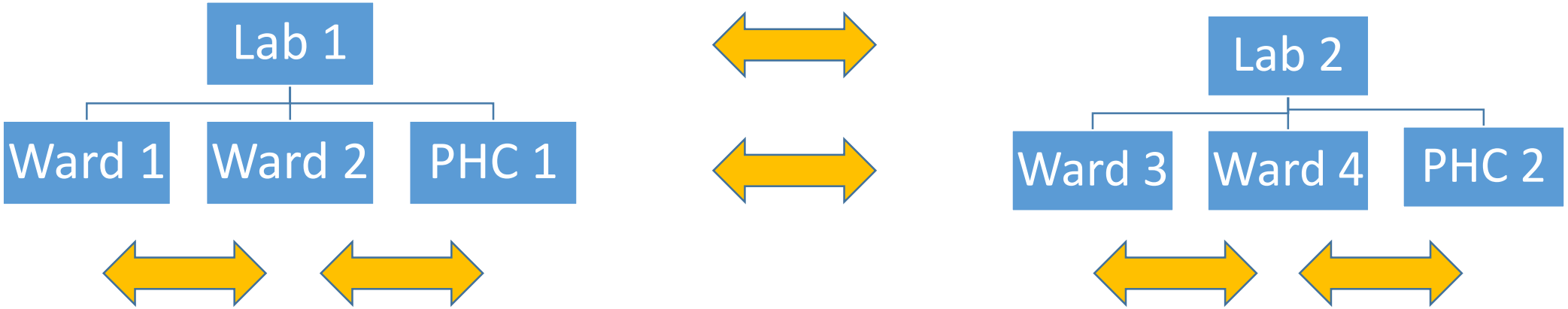
Associations between workplace affiliation and phlebotomy practices regarding patient identification and test request handling practices in primary healthcare centres: a multilevel model approach

BMC Health Servic Res, in press 2015.

Conclusion: Workplace affiliation largely (40%) explains variances in self-reported adherence to venous blood specimen collection guidelines for patient identification and test request handling practices among phlebotomy staff. Characteristics of the workplace, as well as of the individual phlebotomist, need to be identified in order to design strategies to improve clinical practice in this and other areas

”Near miss” events (practice non-adherence) – the high frequency allows quantification also at ward/PHC level

Comparisons between all health care levels possible!



”Near miss” events (practice non-adherence) – the high frequency allows quantification also at ward / PHC level

Focusing on the frequency of near misses (practice non-adherence) 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.

Preanalytical quality indicators / tools useful at monitoring "near-misses" at laboratory as well as hospital ward / primary health care center level!

- Questionnaires on preanalytical practices
- Observational studies of preanalytical practices

A content validated questionnaire for assessment of self reported venous blood sampling practices

Karin Bölenius, Christine Brulin, Kjell Grankvist, Marie Lindkvist and Johan Söderberg

BMC Research Notes 2012, 5:39

Questionnaire surveys have several benefits as they are practical to handle, self-administered, economical and give the respondents anonymity. It is also easy to reach a large study group in a large geographic area.

When using questionnaires it is important to confirm validity (i.e. how well an instrument measures what it is supposed to measure) and reliability (i.e. stability) of the included items.

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

Results of 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

Ana-Maria Simundic*, Stephen Church, Michael P. Cornes, Kjell Grankvist, Giuseppe Lippi, Mads Nybo, Nora Nikolac, Edmee van Dongen-Lases, Pinar Eker, Svjetlana Kovalevskaya, Gunn B.B. Kristensen, Ludek Sprongl and Zorica Sumarac

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)

CCLM 2015, Aug 1;53(9):1321-31.

The **observational** survey aimed:

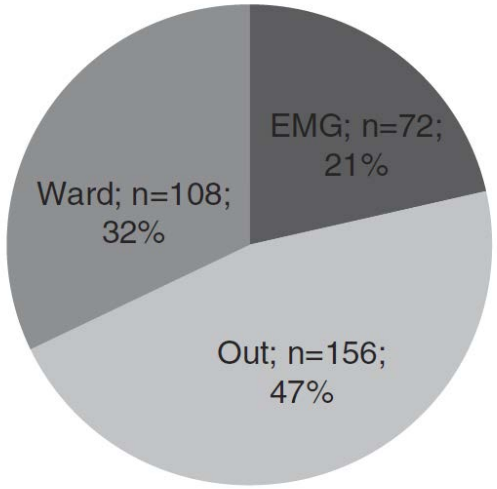
- to assess the level of compliance of phlebotomy procedures with CLSI H3-A6 guideline;

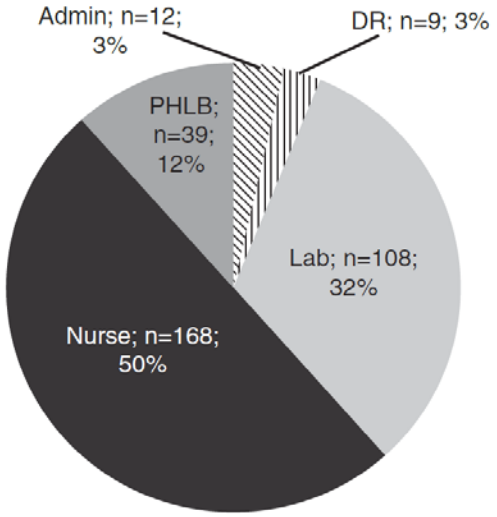
- to identify the most critical steps which need immediate attention and improvement in EFLM member countries by creating a risk occurrence chart based on the observed error frequency and severity scoring.

Staff members performing blood collection observed three times in three different settings:

1) an outpatient phlebotomy unit;
2) a hospital clinical ward; and
3) an emergency department

Twelve European countries participated with a median of 33 (18 – 36) audits per country, and a total of 336 audits.





Methods

A structured **checklist** including 29 items (the CLSI H3-A6 guideline practice steps).

A **risk occurrence chart** of individual phlebotomy steps was created from the **observed practice error frequency** and **ranking the severity of harm** of each guideline key issue.

The **severity of practice errors** occurring during phlebotomy were **graded** using the risk occurrence chart.

Checklist with CLSI H3-A6 guideline practice steps

PHLEBOTOMY COLLECTOR OBSERVATION FORM												
Observer name												
Ward												
Hospital												
Country												
Phlebotomist name/ID												
Phlebotomist profession												
Collection number	Collection 1				Collection 2				Collection 3			
Date of collection												
Question 1												
Did the collector assemble all necessary supplies prior to collection?	Yes		No		Yes		No		Yes		No	
Question 2												
Does the collector have an identified request form?	Yes		No		Yes		No		Yes		No	
Question 3												
Did the collector check the expiry dates of devices in use?	Yes		No		Yes		No		Yes		No	
Question 4												
Did the collector identify the patient according to CLSI or local guidelines	Yes		No		Yes		No		Yes		No	
Question 5												

Observed error frequencies

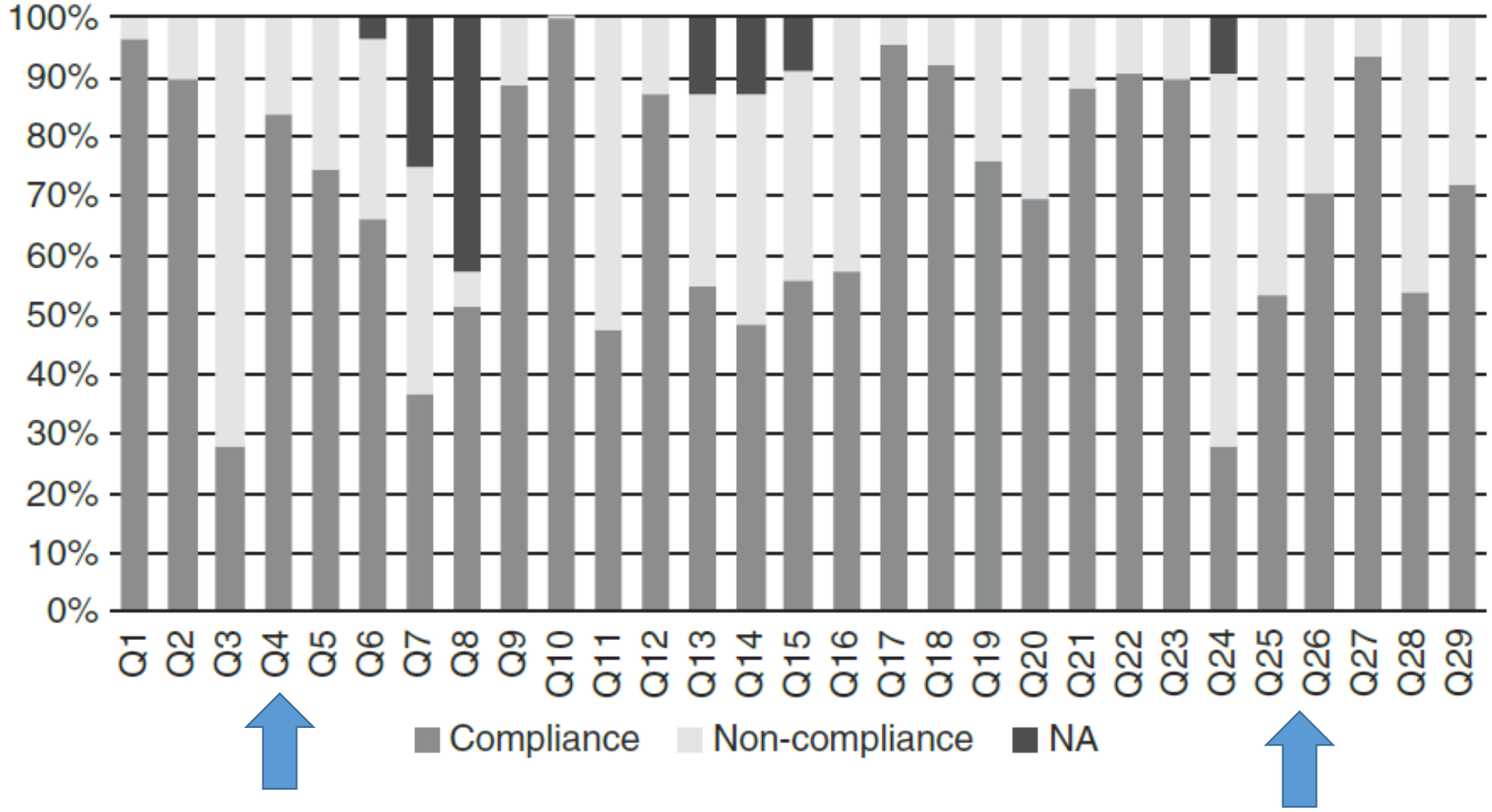


Table 1 Probability of occurrence scoring system.

Probability of occurrence			
Probability of harm	**Abbreviation**	**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 of harm ranking

Table 2 Severity scoring system.

Severity		
Ranking	**Abbreviation**	**Textual definition**
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	Potential fatal outcome

Risk occurrence chart

Occurrence probability	Severity of harm				
	None	Limited	Moderate	Severe	Life threatening
	S1	S2	S3	S4	S5
Frequent O6					
Probable O5		Q7, Q11, Q24	Q3		
Occasional O4		Q5, Q13, Q28, Q29	Q6, Q14, Q15, Q16, Q19, Q20, Q23		Q25, Q26
Remote O3		Q8, Q9, Q21	Q12	Q2	Q4
Improbable O2	Q1	Q27, Q18	Q17	Q22	
Rare O1					

ISO14971:2012 Medical devices: application of risk management to medical devices. International Organization for Standardization: Geneva, 2012.

Study conclusions

- **Observation is an efficient and very useful tool** to assess the compliance to phlebotomy practices.

- **Severity of error grading** of the guideline steps possible by creating a risk occucurrence chart from the **observed practice error frequency** and a **severity of harm ranking** of guideline key issues.

- The **most critical practice steps** in need of immediate attention were patient identification and tube labelling (CLSI H3-A6).

Next step

Observational studies with practice error frequency assessment and risk analysis extended to cover whole preanalytical phase.

The risk analysis will sort out the most important preanalytical steps to consider when implementing and sustaining good preanalytical practices.

Preanalytical practice guidelines to cover whole preanalytical phase.

Evidence-based factors for improving guideline adoption:

- evidence that the context is accessible to change,
- the appropriate monitoring and feedback mechanisms,
- available time for personnel to discuss findings.

Overall conclusion

Repeated local observational studies with practice error frequency assessment and risk analysis

combined with

feed-back, discussions and reflection amongst involved personnel…

is an efficient strategy to implement and sustain good guideline practices and increase patient safety.