Preanalytical errors in blood gas testing

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Biochemia Medica

EFLM WG-Preanalytical Phase

Bol, island Brač, Croatia

I will talk about…

- Errors in medicine
- Laboratory responsibility
- Blood gas testing
  - Patient condition
  - ID errors
  - Sampling procedure / errors
  - Sample type
  - Transport
  - Anticoagulans
  - Safety

Case # 1

- 8:00 a.m.
- lab receives arterial blood sample, for blood gas testing for an ICU patient. Sample has been delivered to the lab in a plastic syringe, on ice. Sampling time was 6:30 a.m. Sample is visibily sedimented. What would you do?

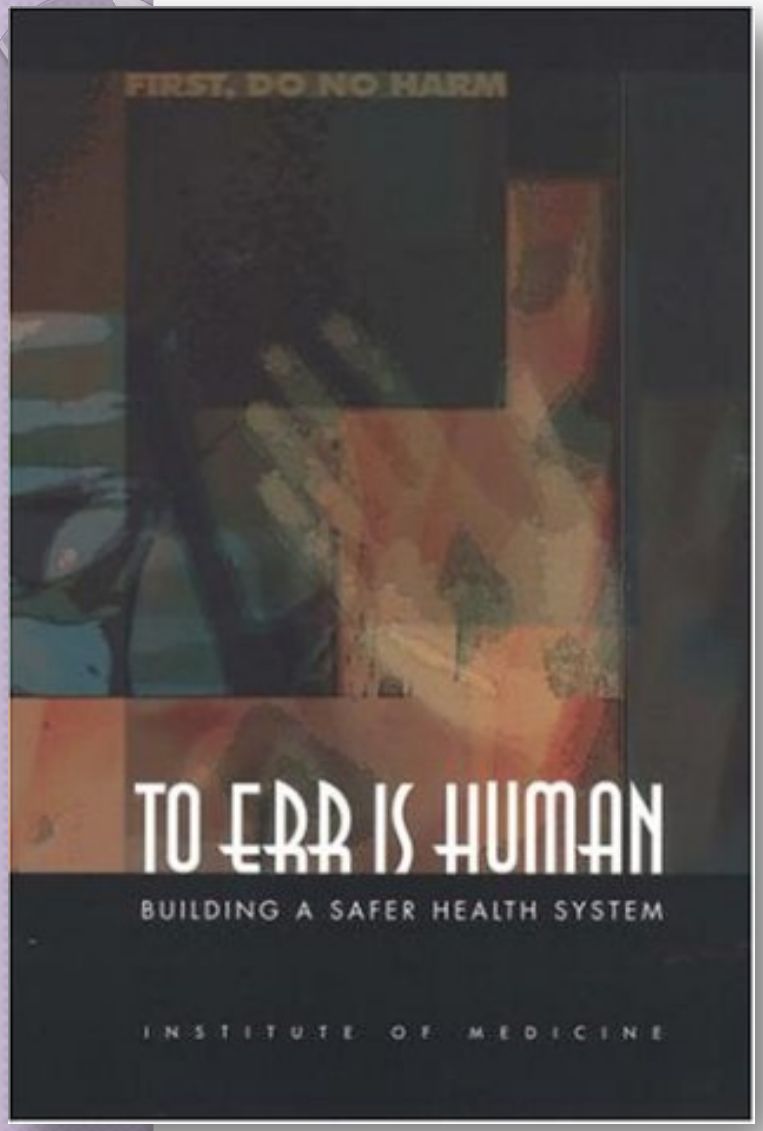
a) Sample is acceptable. I would thouroughly mix the sample and perform the analysis.
b) Sample is not perfect, but I would accept it for analysis after thouroughly mixing it. I would report the result with a comment .
c) Sample is not acceptable. I would reject the sample and request repeated sampling.
d) I would call a physician and ask him to decide what to do.

Healthcare system

- Healthcare is a system that frequently harms and routinely fails to deliver the appropriate standard of care.

Davis K, et al. (2002). Room for improvement: Patients report on the quality of their health care. New York: The Commonwealth Fund.

Errare humanum est



published on November 1, 1999

- 98,000 people die annually in USA as a result of preventable medical errors (268/day)
- proposal for error reducing strategy
- government, health care providers, industry, and consumers should be involved
- a minimum goal a 50 percent reduction in errors over the next 5 yrs

Healthcare errors are not rare

WHO acknowledges that patient safety is of global concern.

World Health Organization

www.who.int

Health topics | Data and statistics | Media centre | Publications | Countries | Programmes and pr

10 facts on patient safety

Patient safety is a serious global public health issue. Estimates show that in developed countries as many as one in 10 patients is harmed while receiving hospital care.

In developing countries, the probability of patients being harmed in hospitals is higher than in industrialized nations. The risk of health care-associated infection in some developing countries is as much as 20 times higher than in developed countries.

Patient safety - EU perspective

European Commission

HEALTH-EU

Your gateway to trustworthy information on pu

European Commission > Health-EU > Care for Me > Patient Safety

My health | My lifestyle | My environment | Health problems

Patient Safety

Patient safety is defined as freedom for a patient from unnecessary harm or potential harm associated with healthcare. It is a serious concern in the European Union. Recent studies consistently show, in an increasing number of countries, that healthcare errors occur in around 10% of hospitalisations, although adverse events take place in all settings where healthcare is delivered, including in primary care, secondary care, community care, social care and private care, in acute and chronic care.

Key factors contributing to this problem:

- the failure of health care providers to:
  - define the **safe practice standards**
  - consistently **enforce compliance**

Do we need to worry?

Large laboratory contribution to the decision/diagnosis (70%)

Laboratory errors can lead to:

- **mis**diagnosis
- **missed** diagnosis
- **delayed** diagnosis

Graber, M. L. et al. Diagnostic error in internal medicine. Archives of internal medicine. 2005;165

From: **Diagnostic Error in Medicine: Analysis of 583 Physician-Reported Errors**

Arch Intern Med. 2009;169(20):1881-1887. doi:10.1001/archinternmed.2009.333

The most common were radiology and laboratory errors

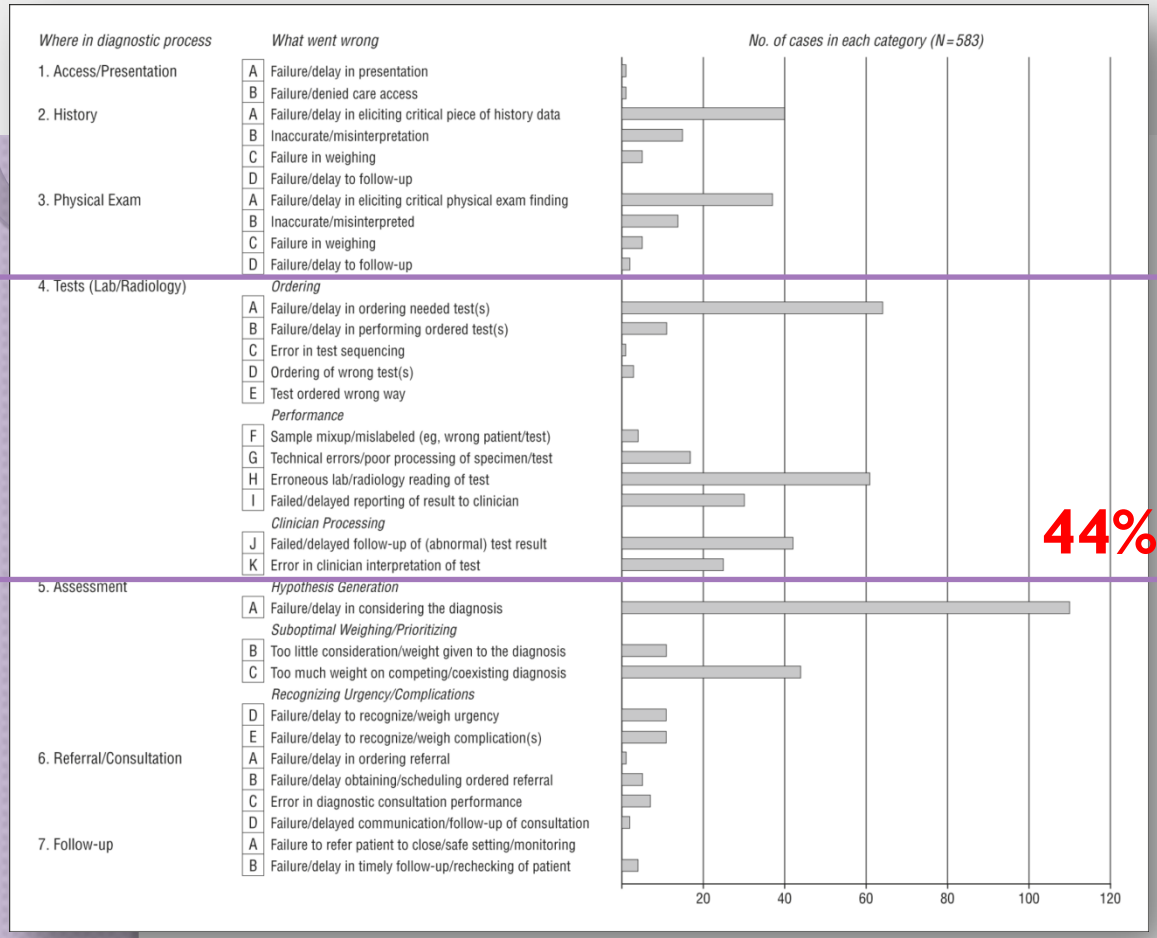
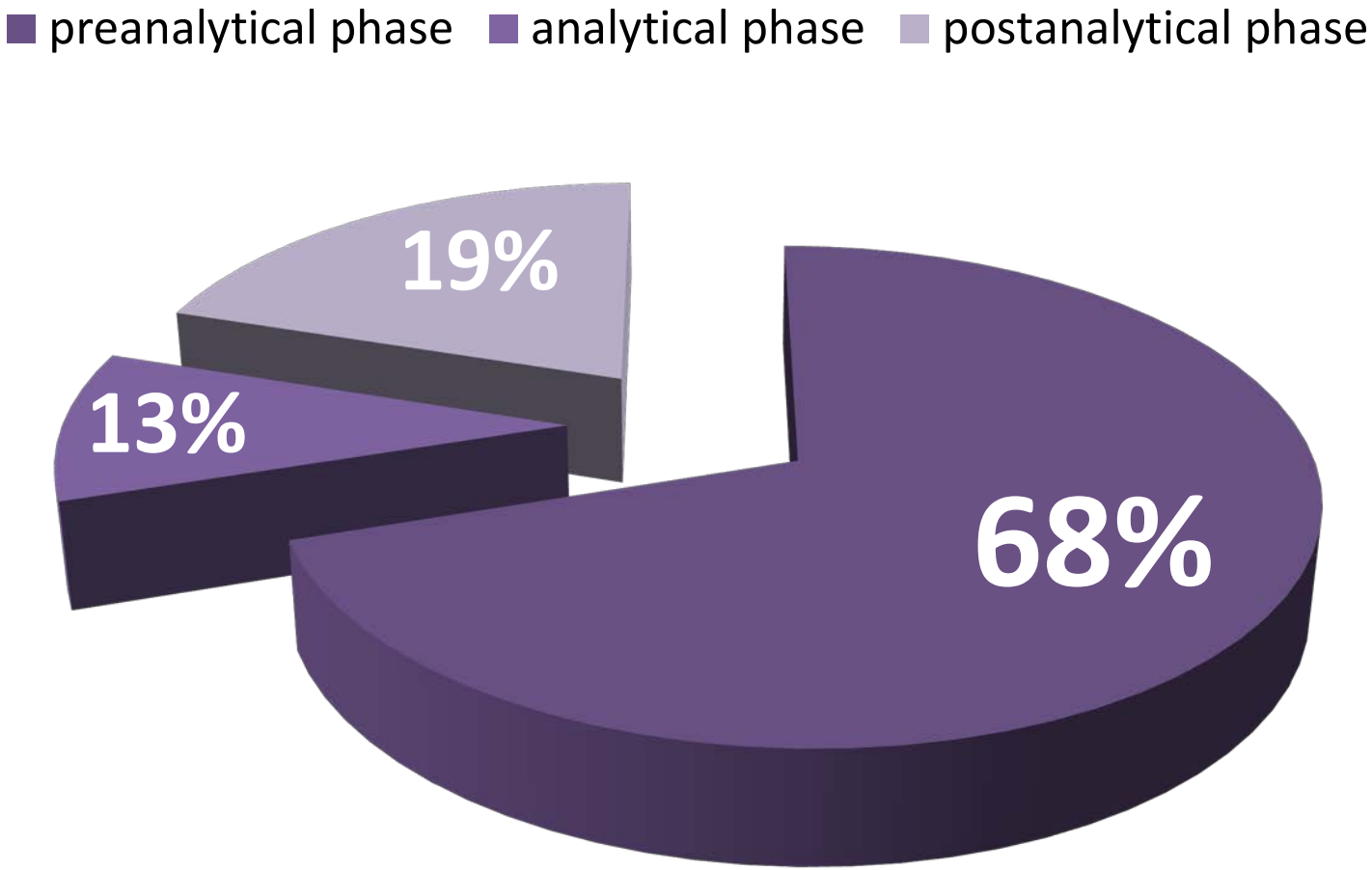


Figure Legend:

Classification of diagnostic errors in 583 physician-reported cases using the Diagnostic Error Evaluation and Research project tool to localize where in the diagnostic process error occurred.

Preanalytical phase



Plebani M, Carraro P. Mistakes in a stat laboratory: types and frequency. Clin Chem. 1997;43(8Pt 1):1348-51.

Case #2

- Lab receives arterial blood sample from emergency department. Blood gas testing is requested. Sample was transported by pneumatic tube within 10 minutes from sampling. You notice an air bubble in the syringe.
- What would you do?

a) Sample is acceptable. I would expel the bubble and perform the analysis.

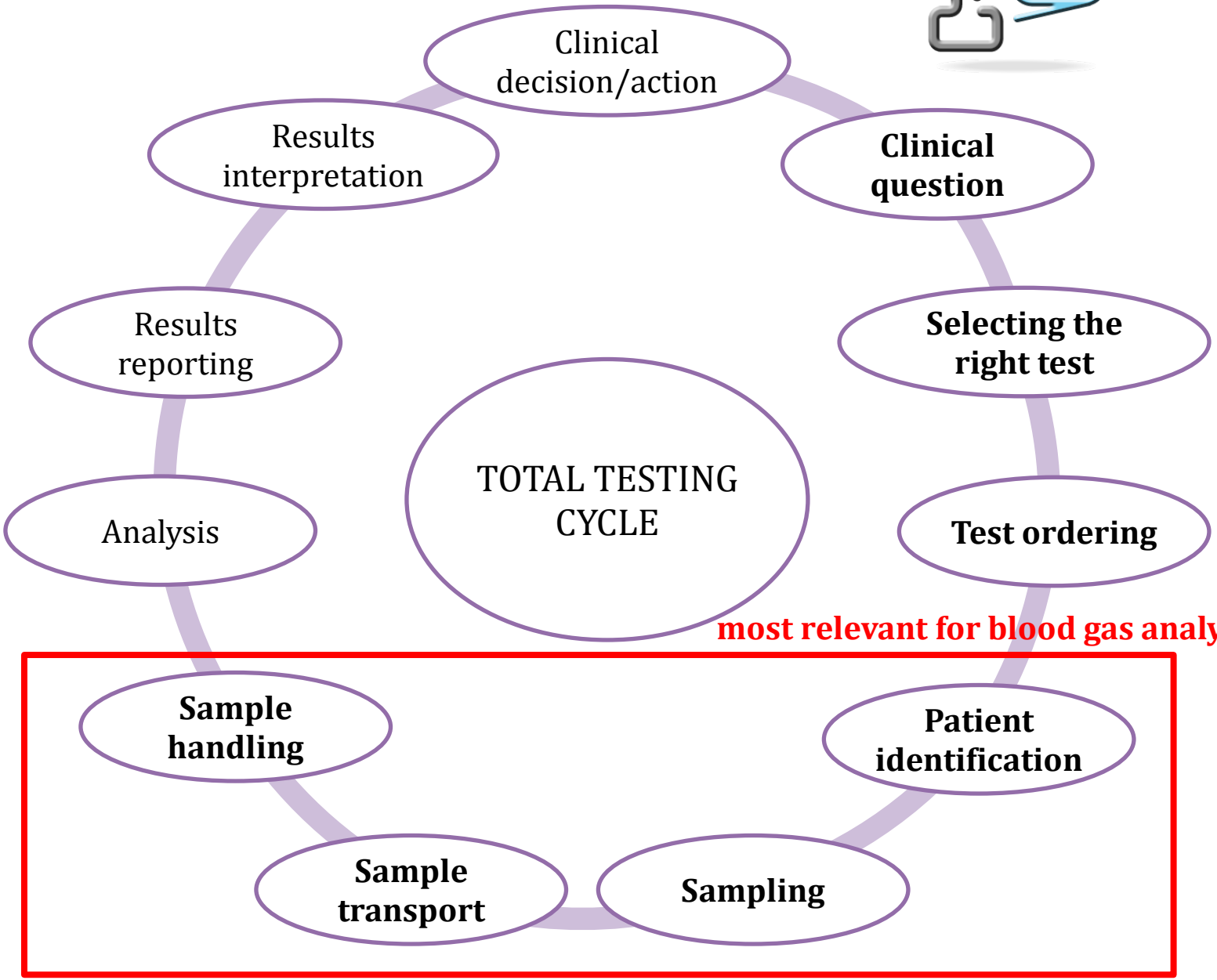
b) Sample is not perfect, I would expel the bubble and perform the analysis. I would report the result with a comment.

c) Sample is not acceptable. I would reject the sample and request repeated sampling.

d) I would call a physician and ask him to decide what to do.

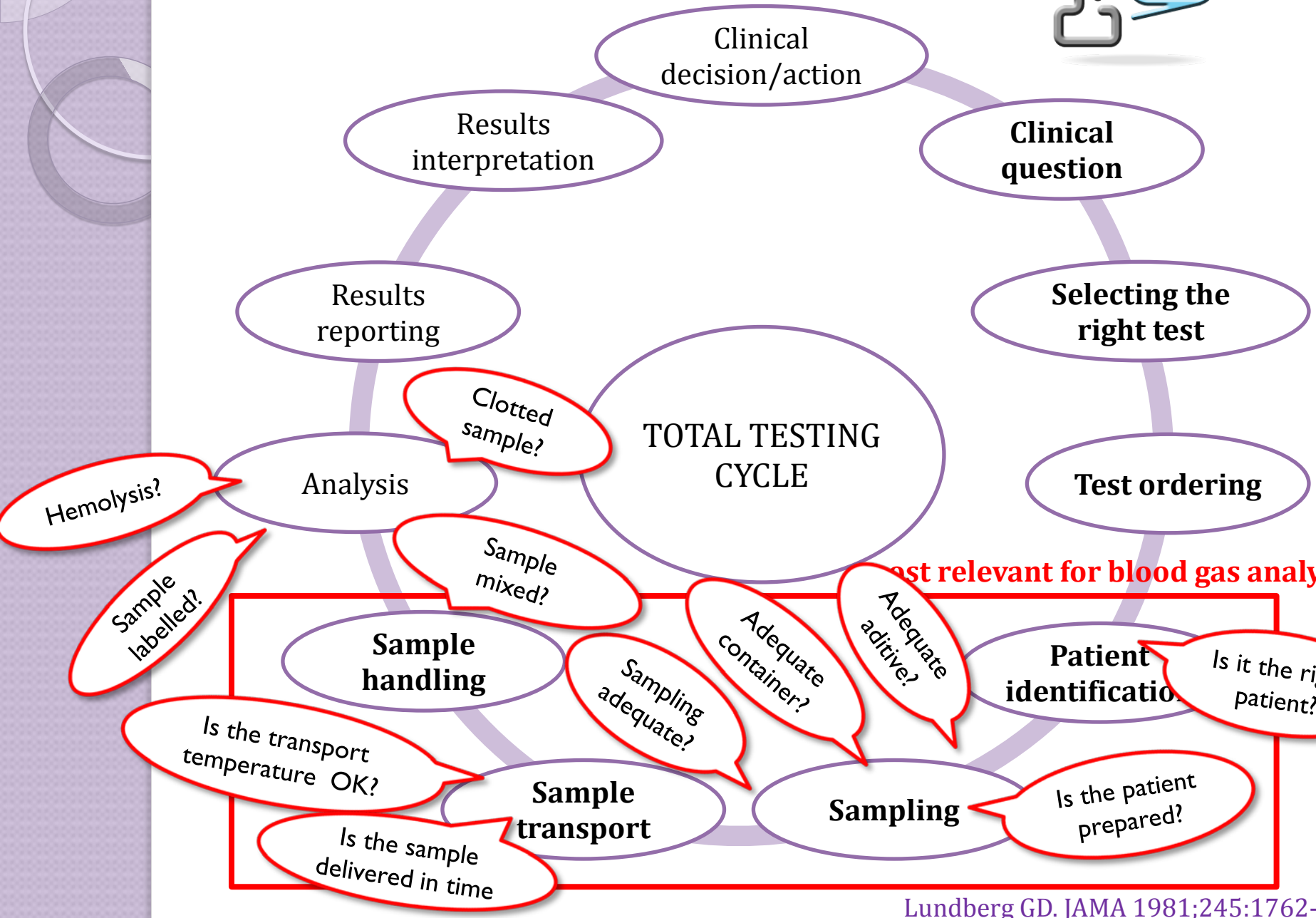
Why is preanalytical phase so vulnerable?

Brain-to-brain cycle



Lundberg GD. JAMA 1981;245:1762-3

Brain-to-brain cycle



Lundberg GD. JAMA 1981;245:1762-3

It is our responsibility

- ISO 15189 recognises **lab responsibility** for monitoring and improving the preanalytical phase:

  pre-examination processes include "*all steps starting in chronological order from the clinician's request, including the examination requisition, preparation of the patient, collection of the primary sample, transportation to and within the laboratory and ending when the analytical examination starts*".

How?

- define safe practice **standard**s
- consistently enforce **compliance**

Blood gas testing is unique in many ways

- patient condition
- urgent action needed
- invasive procedure
- limited sample stability
- low biological variability

Low biological variability

Parameter	Desirable specifications
Hemoglobin, g/L	±1.8%
pH	±1.0%
pO_2, mm Hg	±1.8%
pCO_2, mm Hg	±1.8%
HCO^{3-}, mmol/L	±1.6%
p50, mm Hg	–
sO_2, %	–
ABE, mmol/L	–
COHb, %	–
MetHb, %	–
Ca^{2+}, mmol/L	±0.6%
Potassium, mmol/L	±1.8%
Cell free hemoglobin, g/L	–

Lippi G, et al. Influence of spurious hemolysis on blood gas analysis. CCLM 2013;51:1651-4.

Case #3

1st sample

parameter	value	unit	Ref range	Repeated sample - OK
pO2	14.6 ↑	kPa	11 - 14.4	13.1
pCO2	3.70 ↓	kPa	4.7 - 6.4	4.8
K	3.2 ↓	mmol/L	3.5 – 5.0	4.3
Na	148 ↑	mmol/L	136 – 146	139
Cl	111 ↑	mmol/L	98 – 106	102
Glu	2.8 ↓	mmol/L	3.9 – 5.8	5.6

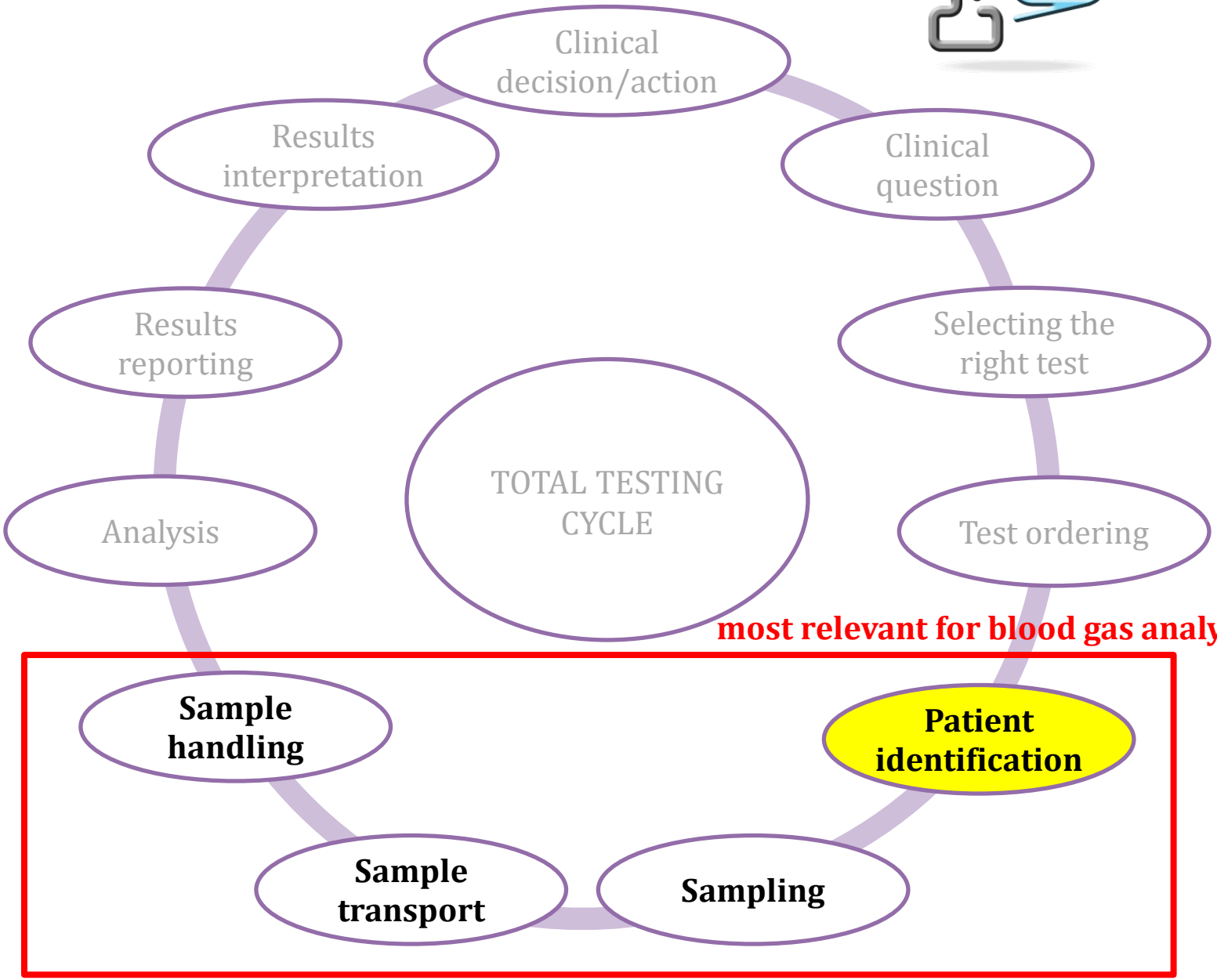
a) Sample hemolyzed.

b) Sample dilution.

c) Air bubble.

d) Clotted sample.

Brain-to-brain cycle



Lundberg GD. JAMA 1981;245:1762-3

Patient identification errors

- ID error frequency:
  - 0.1-1% in laboratory medicine
  - 0.05% in transfusion medicine
- **underreported** (most go undetected)
- **major healthcare issue**
- potentially associated with serious **adverse consequences**
- **zero tolerance!**

Any potentially mislabeled or misidentified specimen should be rejected.

Lippi G, et al. Preanalytical quality improvement: from dream to reality. CCLM 2011;49(7):1113–1126

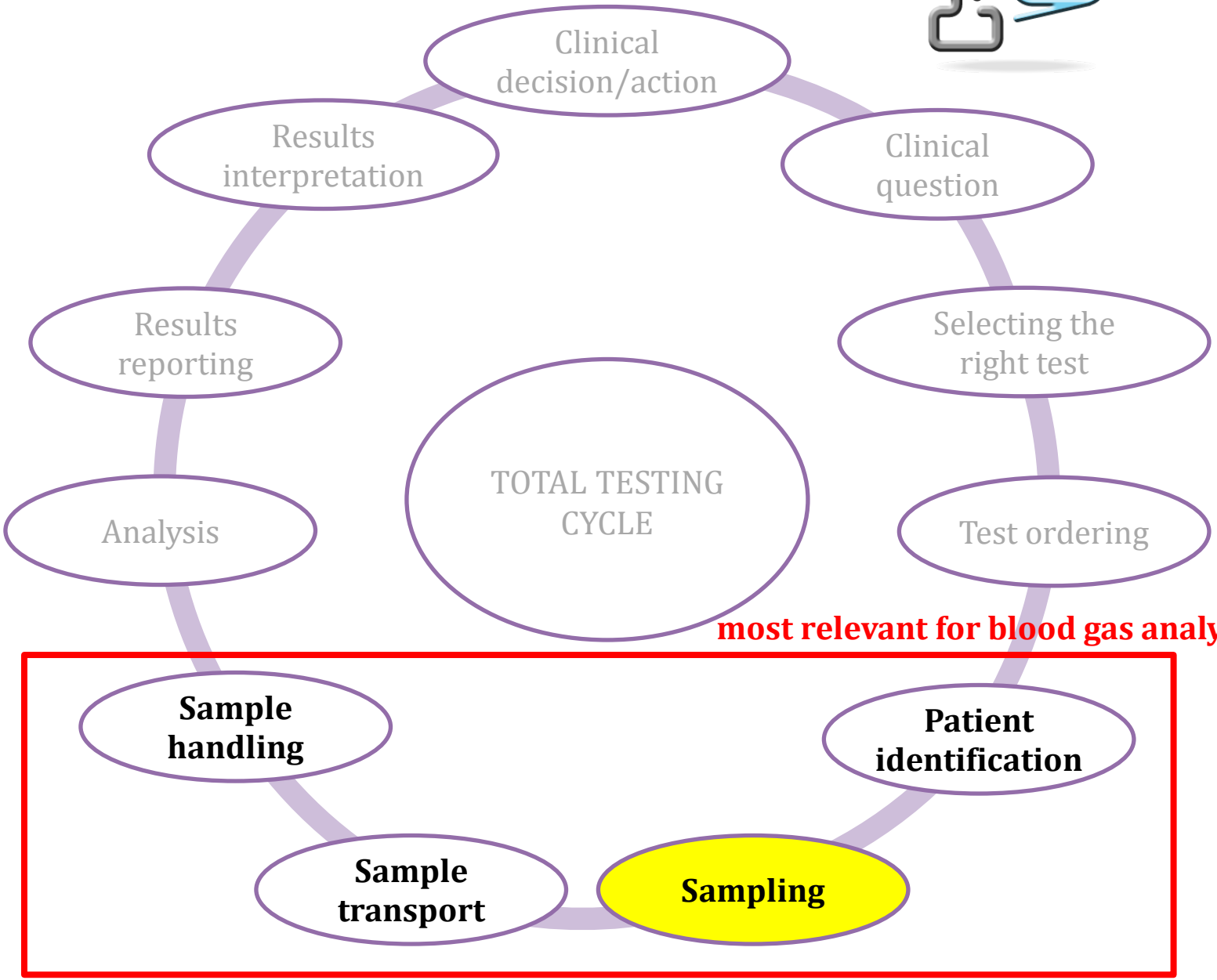
CLSI GP33-A Accuracy in Patient and Sample Identification

- **at least two** acceptable unique patient identifiers
  - full name
  - assigned ID number
  - date of birth
  - photo ID on goverment issued ID card (driver' s licence)
  - any other person specific identifier
- **active** ID (engaging the patient)
- **open ended question** (and check with sample label and request form):
  - what is your name?
  - what is your date of birth?

CLSI GP33-A Accuracy in Patient and Sample Identification

- if any discrepancies are identified, **do not collect samples** until issues are resolved
- if patient is not able to identify himself, ask a nurse, a friend or a relative to do that and record their names.
- to minimize the error risk:
  - use ID **bracelets** with barcodes or radiofrequency identifier devices (RFID) are recommended
  - use **barcoded** sample identifiers
  - generate labels **at the time and site of collection**
  - label the sample **in the presence of the patient**

Brain-to-brain cycle



Lundberg GD. JAMA 1981;245:1762-3

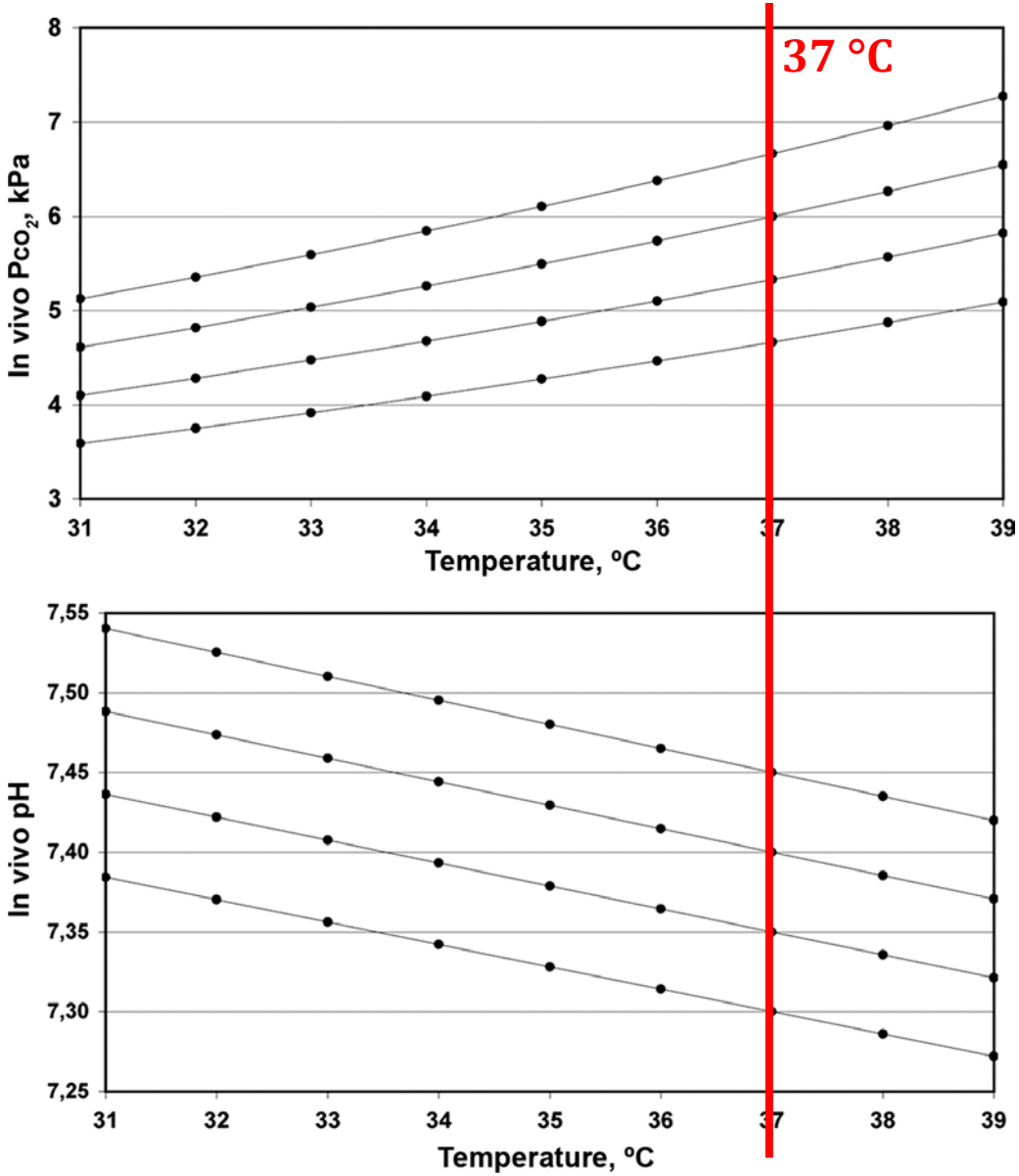
Sampling

- patient condition
- sample type
- sampling site
- anticoagulant

Patient condition

- CLSI 46-A2: *sampling should be done in the **steady state***
- patient condition **determinants** should be carefully considered and records kept for:
  - patient status (resting, exercising, crying, anxious),
  - change in the ventilatory setting (spontaneous breathing or assisted mechanical ventilation)
  - change in oxygen delivery settings (fraction of inspired oxygen (FiO2) through nasal cannula or Ventouri mask)
  - respiratory rate,
  - body temperature.

Relation between temperature and PCO2 (upper) and pH (lower)



Groenendaal F et al. Pediatrics 2009;123:170-172

PEDIATRICS®

Steady state?

- 3-5 minutes are usually enough for patients without pulmonary disease to stabilize
- 20-30 minutes for COPD patients

- CLSI 46-A2: *a stable ventilatory status for 20-30 minutes is adequate for most patients following ventilatory changes.*

- recent evidence* shows that oxygen equilibration relevant for clinical interpretation in patients with COPD receiving long-term oxygen therapy requires:
  - **10 minutes** following an increase in oxygen delivery
  - **16 minutes** following a decrease in oxygen delivery

* Weinreich UM, et al. Time to steady state after changes in FIO(2) in patients with COPD. COPD. 2013;10(4):405-10.

Time and site of sampling

- Exact **time** of the blood collection and the **site** of sampling should always be recorded and reported on the test report.
- **difficulties** during blood collection

Table III: ABG values based on neonatal age

	Pre-birth (Scalp)	5 min after birth	1-7 days after birth
pH	>7.20	7.20-7.34	7.35-7.45
pCO_2	<6.65	4.6-5.9	4.6-5.9
pO_2	3.3-5.3	6.5-9.7	9.3-9.9
Sat%	>50	>80	>90
HCO_3	>15	16-19	20

Ashok Deorari. Blood gas analysis.
All India Institute of Medical Sciences. 2008

Difficulties with blood sampling

- Male patient, 82 years, chest pain, addmited to ED
- 1. sample – capillary - difficulties during blood collection
- 2. sample – arterial blood, after 10 minutes

	capillary			artery	
	Rezultat		**Jedinica**	**Rezultat**	**Referentni interval**
pH	7,28	L	pH jedinic	7,45	7,35 do 7,45
pCO2	6,89	H	kPa	4,70	4,66 do 6,38
BE	-3,4	L	mmol/L	0,8	-2 do +3
HCO3-	23,9	H	mmol/L	24,1	18 do 23
tCO2	25,5		mmol/L	25,2	22 do 29
pO2	4,4	L	kPa	10,27	11 do 14,4
sat O2	55	L	%	94,9	95 do 98

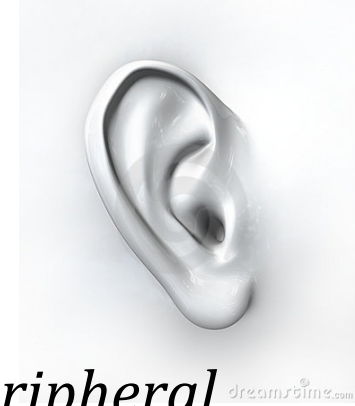
Sample type

- CLSI 46-A2 guideline state:

  "Blood gas measurement for the purpose of evaluating the gass exchange function of the lungs (pO2 and pCO2) should be performed on ***arterial blood only****. ...*

  The blood should be collected under ***anaerobic*** *conditions, mixed immediately to dissolve heparin anticoagulant and promptly analysed."*

Alternative?



- CLSI 46-A2 guideline state:

  *"if arterial blood can not be collected directly, peripheral capillary blood may be collected using an **arterialization** technique (warming the skin to 40-45 ℃ with a warm towel or vasodilating cream).*

  *...blood gas **results may differ**, especially those for pO2, sO2, FO2Hb and ctO2."*

- **earlobe** is better than a fingertip
- **there is really no substitute for arterial blood** if accuracy of pO2 measurement is important

  (oxygen therapy)

Arterial vs. capillary sample?

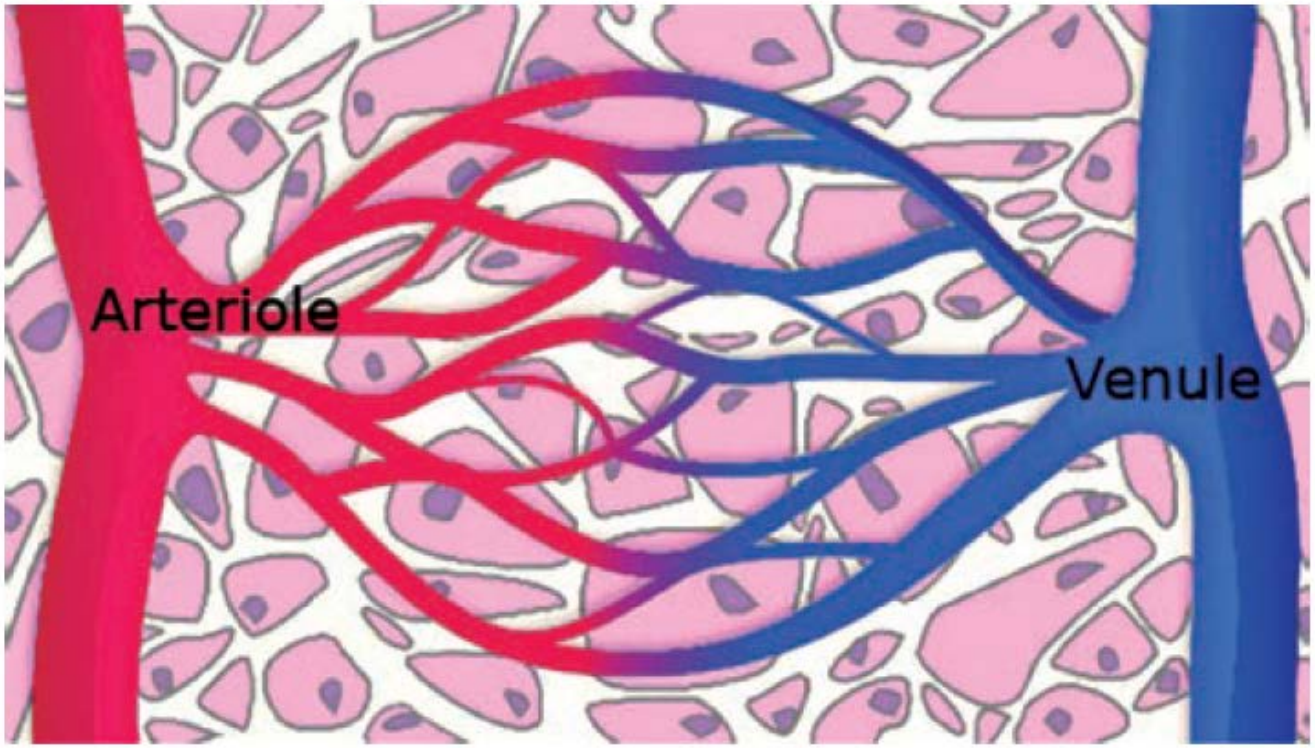
- large debate over the years...
- Zavorsky *et al.* (2007) in their meta analysis showed that:
  - *earlobe is prefered over the fingertip*
  - *capillary sampling accurately reflects arterial pCO(2) and pH over a wide range of values.*
  - *capillary blood **is not an adequate substitute** for arterial blood for accurate pO2 measurement*

- many subsequent recent studies have confirmed this
- capillary sample acceptable alternative only during medical transport and pre-hospital critical care.

Zavorsky GS, Cao J, Mayo NE, Gabbay R, Murias JM. Arterial versus capillary blood gases: a meta-analysis. Respir Physiol Neurobiol. 2007;155(3):268-79.

Arterial vs. capillary sample?

Figure 1: Capillary network



Arterial blood		AV Difference		Venous Blood	
pH	7.40	pH	0.2	pH	7.38
pCO_2	5.3 kPa	pCO_2	0.7	pCO_2	6.0
pO_2	13.0 kPa	pO_2	8.0	pO_2	5.0

Higgins C. Capillary-blood gases: To arterialize or not. MLO. November 2008:42-47

Arterial sample vs. arterialized earlobe?

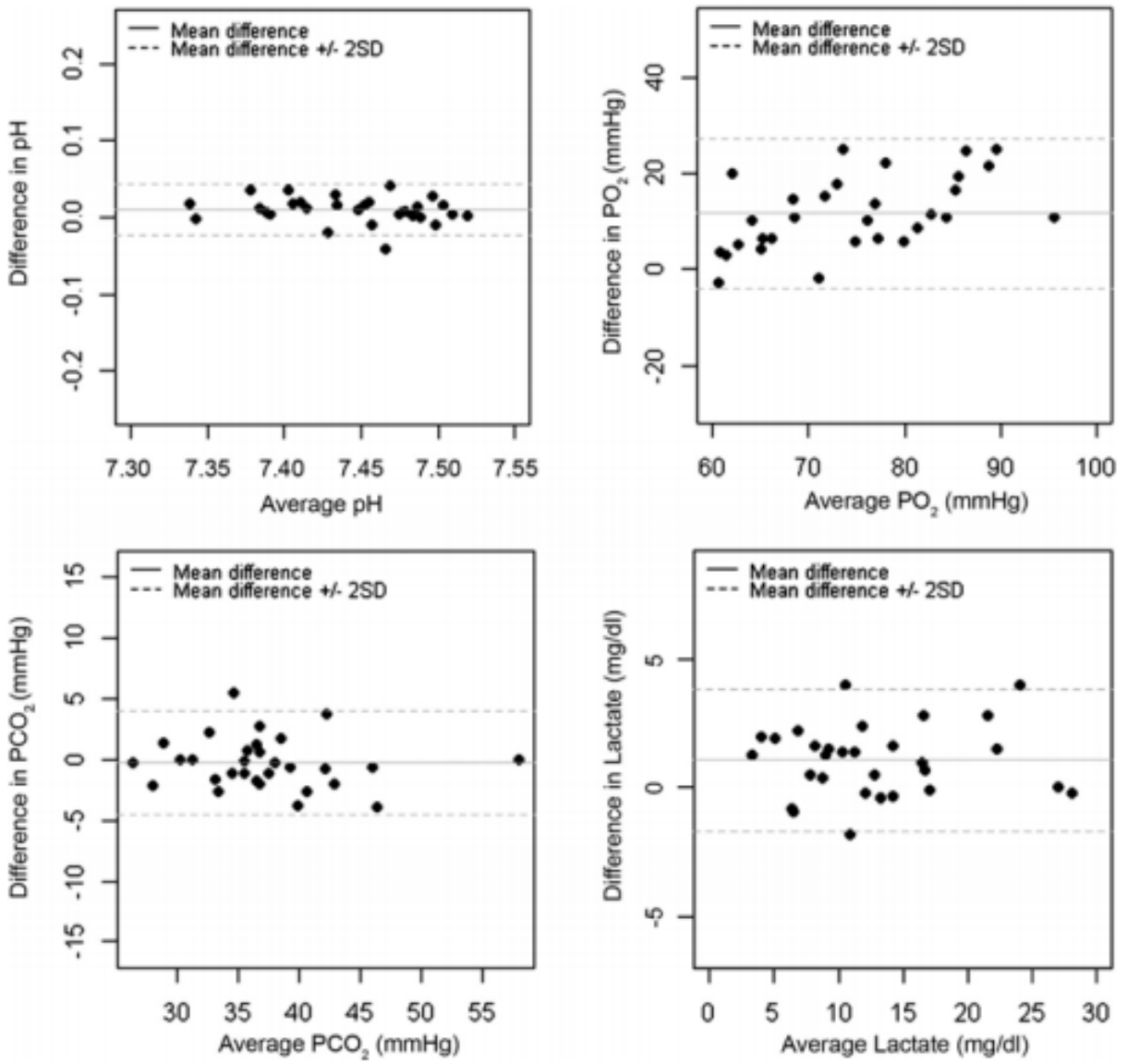
vasodilation cream
(2% nitro-glycerin cream)

Results:

Poor PO2 concordance (CCC = 0.45; CI 95% = 0.26 to 0.6) of arterialized earlobe with arterial blood.

Mean PO2 difference was12 mmHg (P< 0.001) (Figure 1).

The higher the arterial PO2, the greater the difference (slope = 0.54).



Vaquer S, et al. Earlobe arterialized capillary blood gas analysis in the intensive care unit: a pilot study. Ann Intensive Care. 2014;4:11.

Arterial blood sampling

- CLSI H11-A4: Procedures for the Collection of Arterial Blood Specimens (2004)

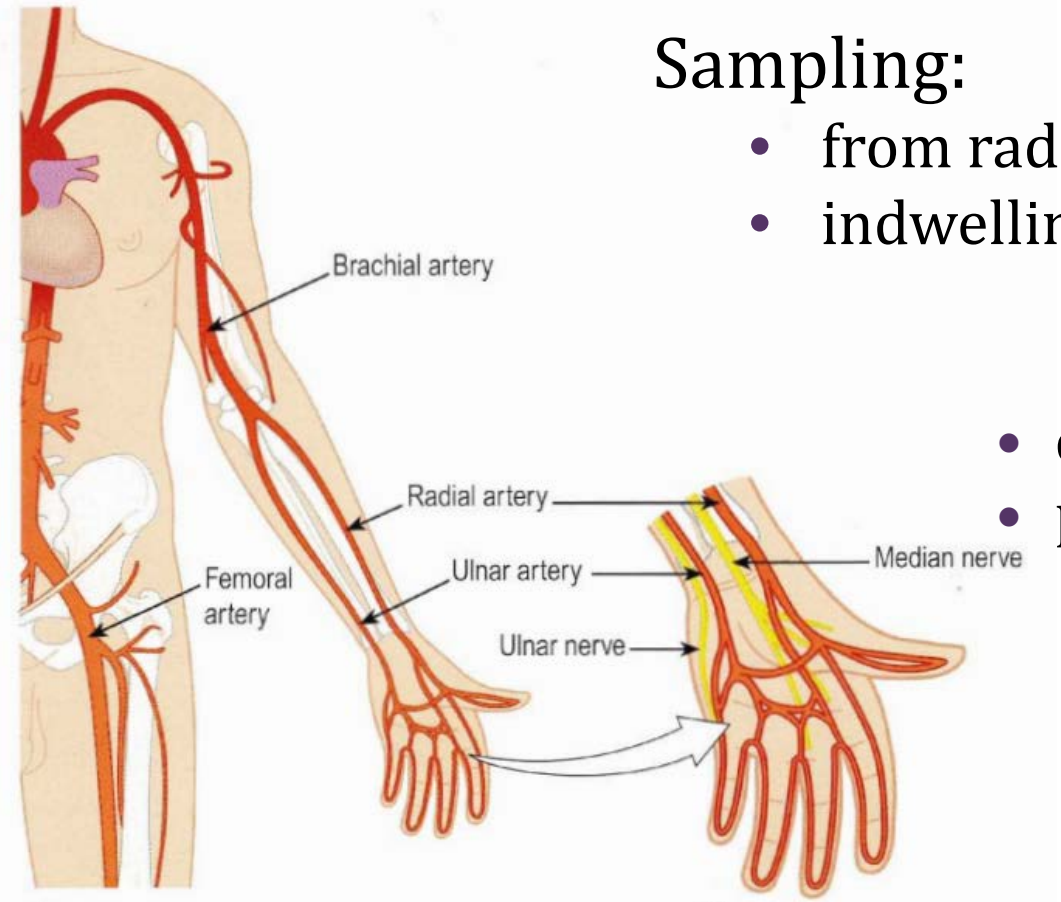


Figure 18 *Arterial puncture sites.*

Sampling:

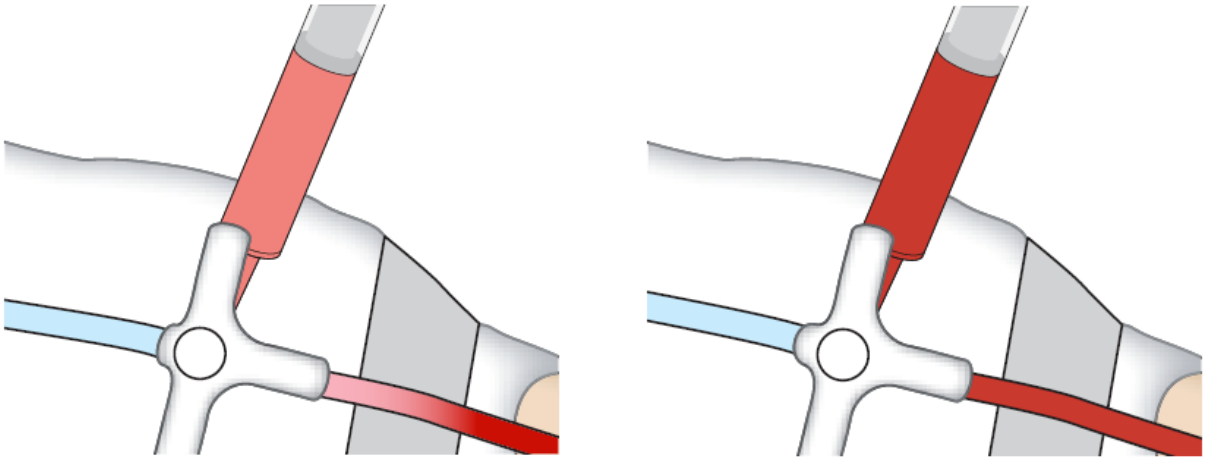
- from radial artery
- indwelling arterial catethers

- discomfort and pain
- possible complications
  - bleeding,
  - bruising,
  - arterial thrombosis,
  - infection.

http://www.gla.ac.uk/media/media_168894_en.pdf
ABG SAMPLING TECHNIQUE. University of Glasgow.

Sample contamination with flush solution

- during sampling from arterial catheters, there is a risk of diluting the sample with flush solution.



↑ pO2 ↓ pCO2
↓ K+ ↑ Na+ ↑ Cl– ↓ Ca2+
↓ cGlu ↓ cLac ↓ ctHb

To avoid errors:

- discard at least 3 times the dead space when sampling from catheter
- check catheter package for the exact volume of dead space

Case #3 results

1st sample

parameter	value	unit	Ref range	Repeated sample - OK
pO2	14.6 ↑	kPa	11 - 14.4	13.1
pCO2	3.70 ↓	kPa	4.7 - 6.4	4.8
K	3.2 ↓	mmol/L	3.5 – 5.0	4.3
Na	148 ↑	mmol/L	136 – 146	139
Cl	111 ↑	mmol/L	98 – 106	102
Glu	2.8 ↓	mmol/L	3.9 – 5.8	5.6

a) Sample hemolyzed.

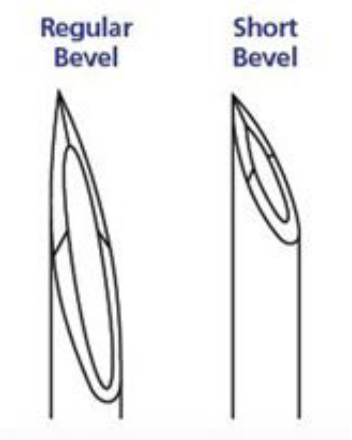
b) Sample dilution.

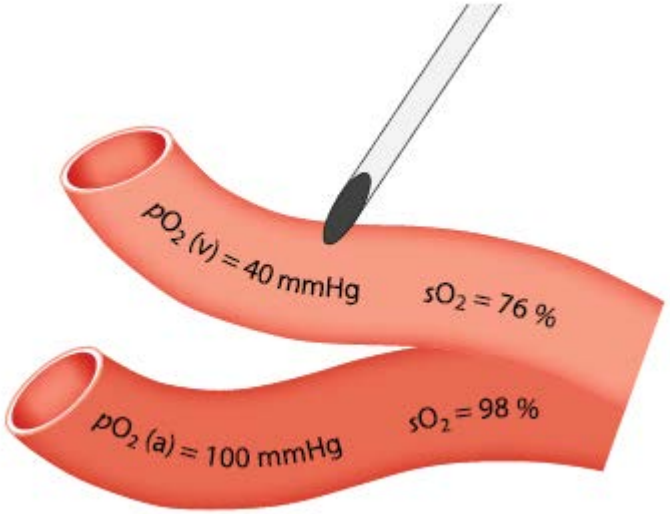
c) Air bubble.

d) Clotted sample.

Sample contamination with venous blood

- during arterial blood sampling, there is a risk of accidentaly puncturing the vein and contaminating the sample with venous blood.





To avoid errors: ↓ pO2 ↓ sO2 ↑ pCO2

- use self-filling syringes – they fill readily when puncturing an artery but not when hitting a vein
- use short-bevelled needles – easier to position inside the artery
- make the puncture at an angle of 45°

Sample filling time

Table. P_{aO_2} and Sampler Filling Times in Arterial and Venous Subjects

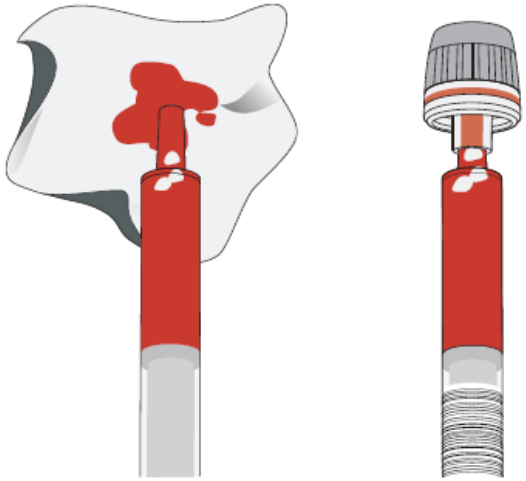
	Arterial (n = 22)	Venous (n = 16)	P
Filling time, s/mL	15 ± 4	115 ± 48	< .001
P_{aO_2}, mm Hg	89 ± 17	29 ± 9	< .001

Values are mean ± SD.

Bender JJ, et al. Arterial sampler filling time during arterial and venous punctures, and its relationship with mean arterial pressure in human subjects. Respir Care. 2012;57(11):1945-8.

Sample contamination by air bubbles

- even bubble as small as 1% of the sample volume is significant



To avoid errors: ↑pH ↑pO2 ↑sO2 ↓pCO2

- visually inspect the sample immediately after sampling
- expel bubbles by gently tapping the syringe, immediately after sampling and before mixing!
- use syringes with vented tip caps that will allow you to expel air and seal the sampler without getting in contact with blood

Case #2 - results

- Lab receives arterial blood sample from emergency department. Blood gas testing is requested. Sample was transported by pneumatic tube within 10 minutes from sampling. You notice an air bubble in the syringe.
- What would you do?

a) Sample is acceptable. I would expel the bubble and perform the analysis.

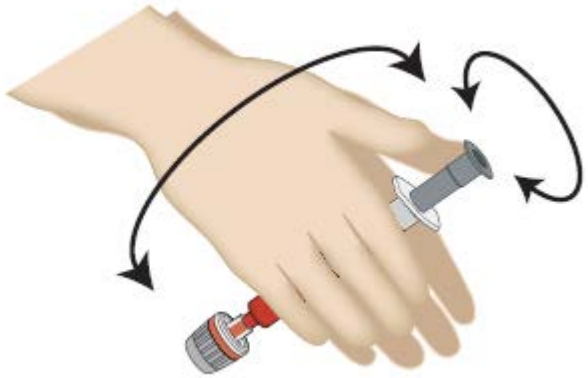
b) Sample is not perfect, I would expel the bubble and perform the analysis. I would report the result with a comment.

c) Sample is not acceptable. I would reject the sample and request repeated sampling.

d) I would call a physician and ask him to decide what to do.

Sample mixing

- Blood samples will coagulate if not mixed properly immediately after sampling.



↑K, clotted sample
analyzer malfunction

To avoid errors:

- mix by inverting the syringe several times and rolling it between the palms
- syringes with a metal ball

Capillary sampling

- anaerobic???
- excessive repetitive pressure (milking) causes **hemolysis** and sample **contamination** with tissue fluid

without milking

ELECTROLYTES	
Na^+	140.1
K^+	3.76
Ca^{++}	0.97↓
$Ca^{++}(7.4)$	0.99
Cl^-	104

milking applied

ELECTROLYTES	
Na^+	137.1
K^+	4.12
Ca^{++}	0.70↓
$Ca^{++}(7.4)$	0.71
Cl^-	101

same patient, 2 minutes time difference, resting

↑ K+
↓ Na+ Cl- Ca++
↓ pO2, ↓ Hb

To avoid errors:

- avoid milking, arterialization, take preferably arterial samples

Hemolysis – significant source of errors

Parameter	Desirable specifications	Non-hemolyzed blood	Hemolyzed blood	p-Value	Bias
Hemoglobin, g/L	±1.8%	147±7	148±7	0.13	0.7% (−0.6% to 2.0%)
pH	±1.0%	7.39±0.01	7.38±0.01	0.01	−0.2% (−0.3% to −0.0%)
pO_2, mm Hg	±1.8%	34.6±3.2	32.9±3.0	0.04	−4.9% (−9.6% to −0.2%)
pCO_2, mm Hg	±1.8%	45.6±1.0	47.5±1.1	<0.01	4.1% (1.7% to 6.6%)
HCO^{3-}, mmol/L	±1.6%	27.1±0.6	27.5±0.6	<0.01	1.4% (0.4% to 2.4%)
p50, mm Hg	–	27.9±0.4	27.5±0.4	<0.01	−1.5% (−2.5% to −0.4%)
sO_2, %	–	61.7±6.0	58.9±5.9	<0.01	−4.9% (−8.0% to −1.9%)
ABE, mmol/L	–	2.1±0.5	2.2±0.6	0.23	−14% (−69% to 40%)
COHb, %	–	1.2±0.1	1.0±0.1	<0.01	−11% (−14% to −8%)
MetHb, %	–	0.6±0.01	0.6±0.1	0.50	0.0% (−9.2% to 9.2%)
Ca^{2+}, mmol/L	±0.6%	1.06±0.01	0.99±0.02	<0.01	−7.0% (−11.3% to −2.8%)
Potassium, mmol/L	±1.8%	3.7±0.1	6.6±0.8	<0.01	152% (150% to 155%)
Cell free hemoglobin, g/L	–	0	8.9±1.5	<0.01	–

Lippi G, et al. Influence of spurious hemolysis on blood gas analysis. CCLM 2013;51:1651-4.

To avoid errors:

- Do not store the sample directly on ice cubes
- Avoid vigorous mixing, sample turbulence caused by narrow needles, high vacuum and older pneumatic tube systems

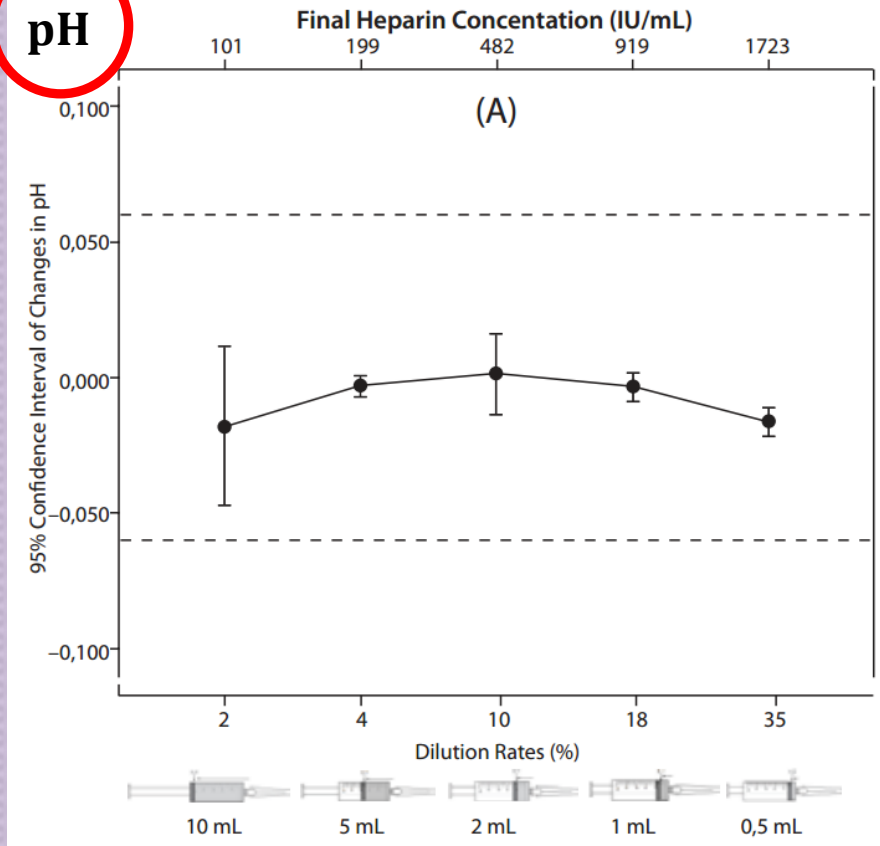
Anticoagulant

- lyofilized balanced Li-heparin is recommended
- caution!
  - **dilution** of electrolytes, HCO3-, pCO2 by liquid heparin
  - liquid heparin has atmospheric pO2 (150 mmHg/20 kPa) and **affects pO2** results
  - Na-heparin falsely elevates sodium
  - heparin **binds cations** (Ca++, Na+, K+)
  - CLSI 46-A2 states that final sample heparin concentration should be **20 IU/mL** blood *(flushing with **therapeutic heparin** is not recommended – it contains high heparin concentration and my alter sample pH and electrolytes)*
  - **mix** as soon as possible to ensure proper anticoagulation and avoid clot formation

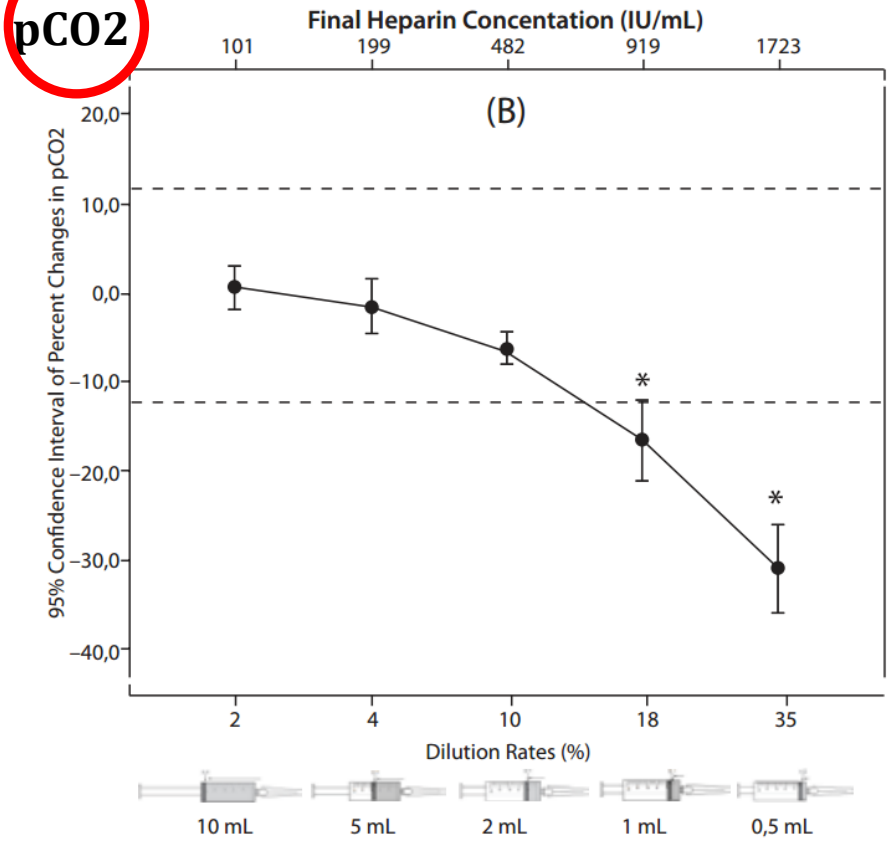
Baird G. Preanalytical considerations in blood gas analysis. Biochemia Medica 2013;23(1):19-27.

Dilution by liquid sodium heparin – 1/4

pH



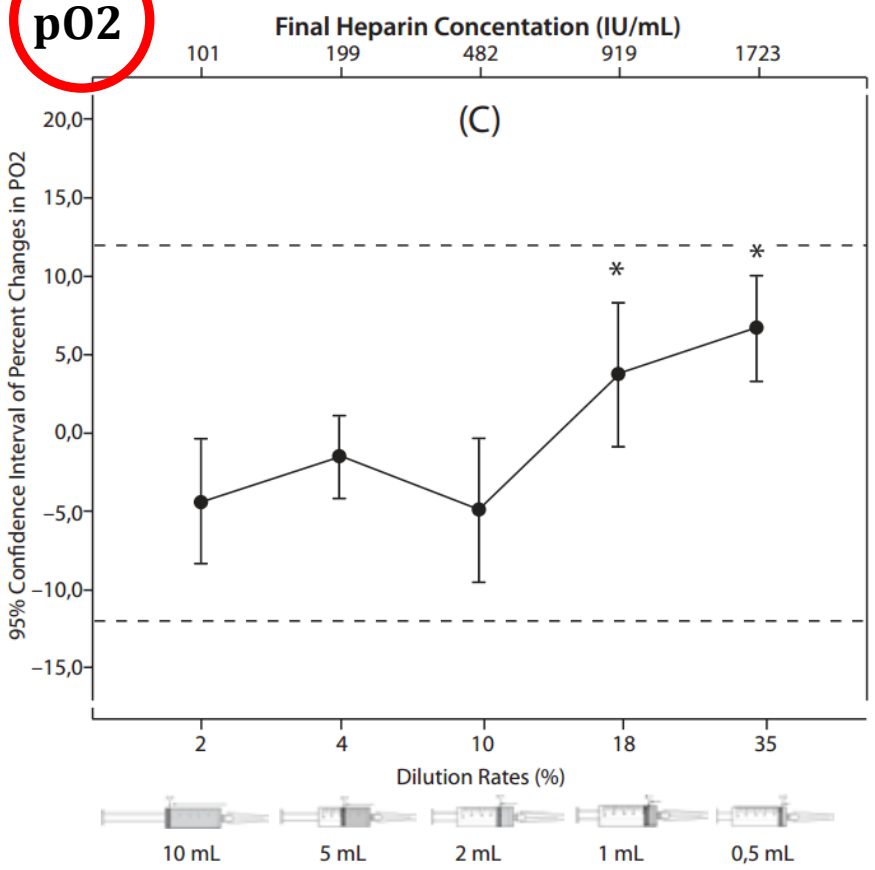
pCO2



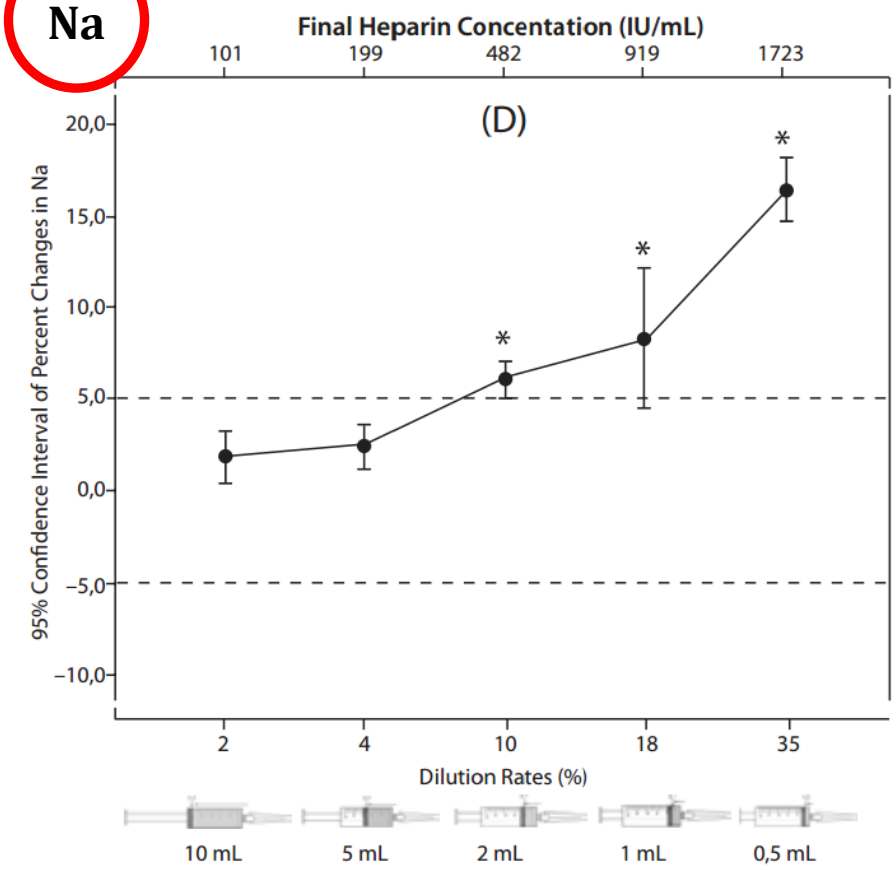
Tuncay Küme, Ali Rıza Şişman, Ahmet Solak, Birsen Tuğlu, Burcu Çinkooğlu, Canan Çoker. The effects of different syringe volume, needle size and sample volume on blood gas analysis in syringes washed with heparin. Biochemia Medica 2012;22(2):189-201.

Dilution by liquid sodium heparin – 2/4

pO2



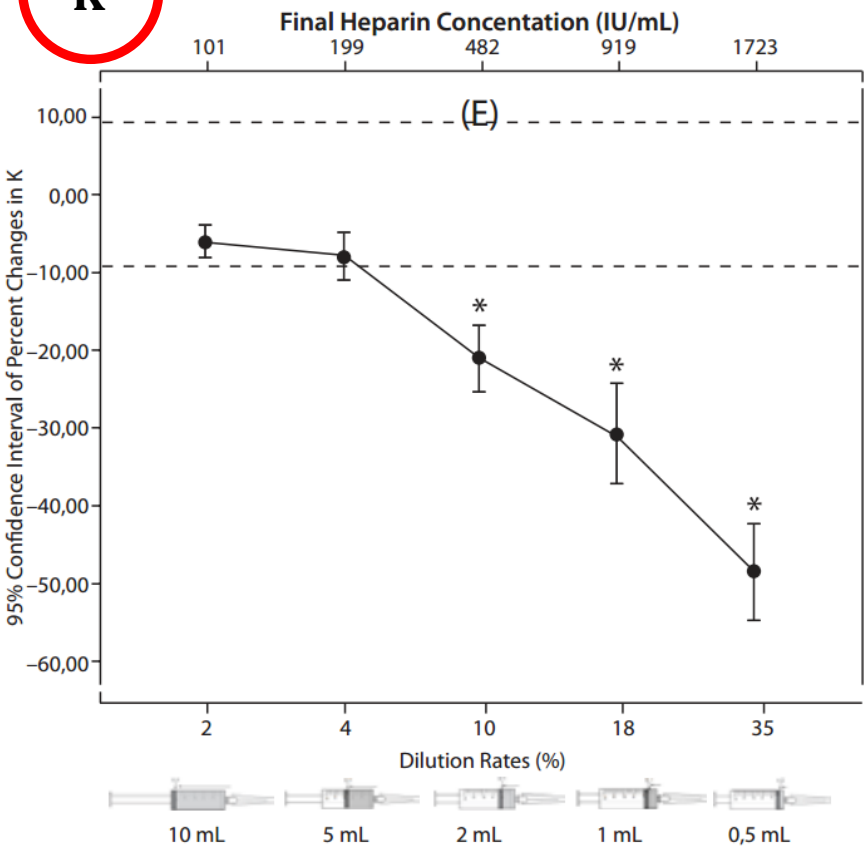
Na



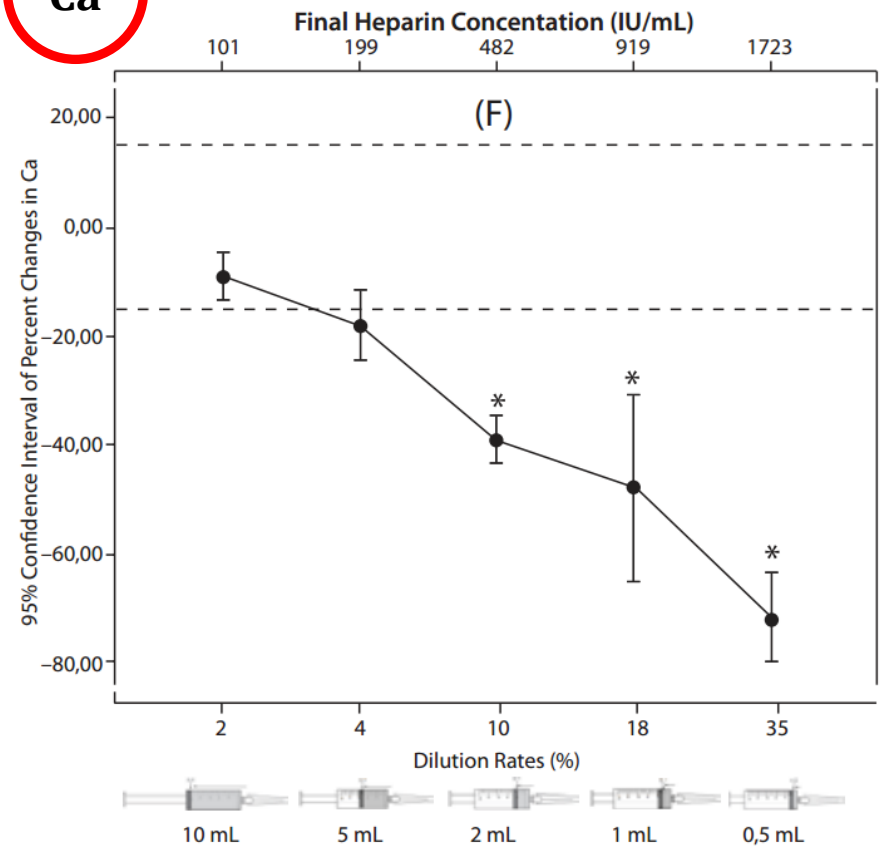
Tuncay Küme, Ali Rıza Şişman, Ahmet Solak, Birsen Tuğlu, Burcu Çinkooğlu, Canan Çoker. The effects of different syringe volume, needle size and sample volume on blood gas analysis in syringes washed with heparin. Biochemia Medica 2012;22(2):189-201.

Dilution by liquid sodium heparin – 3/4

K

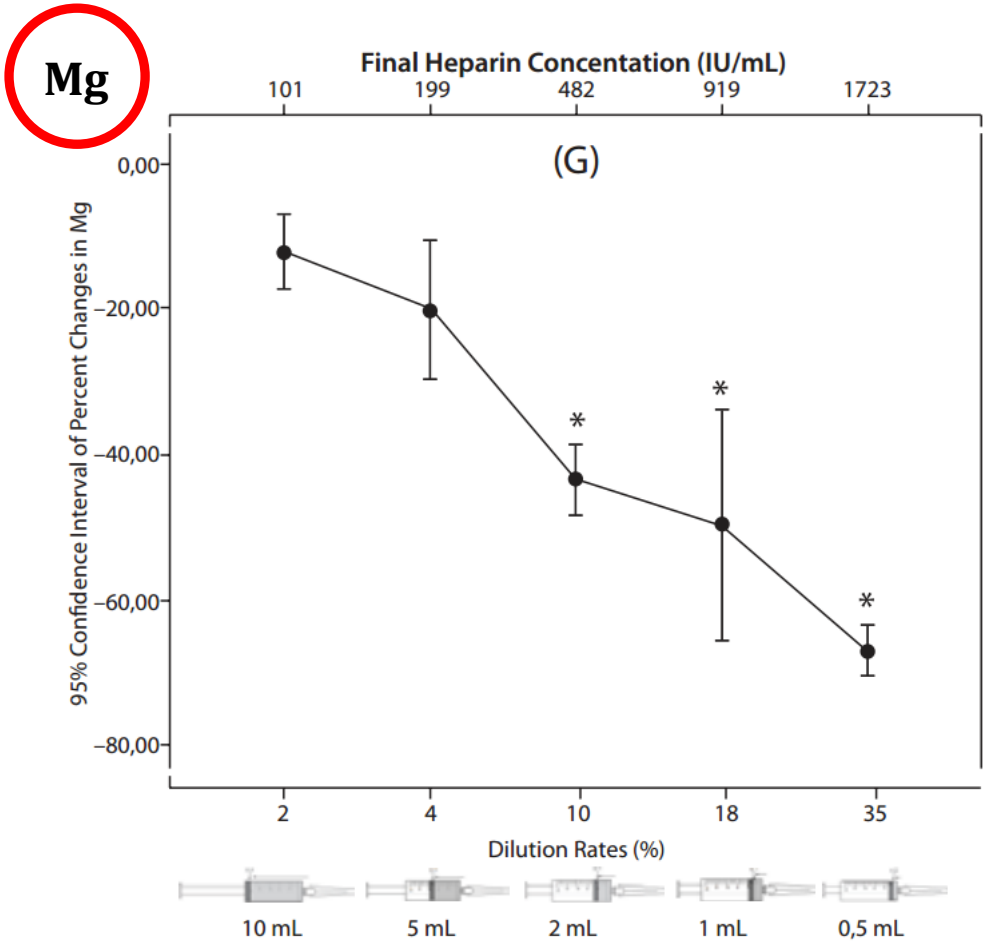


Ca



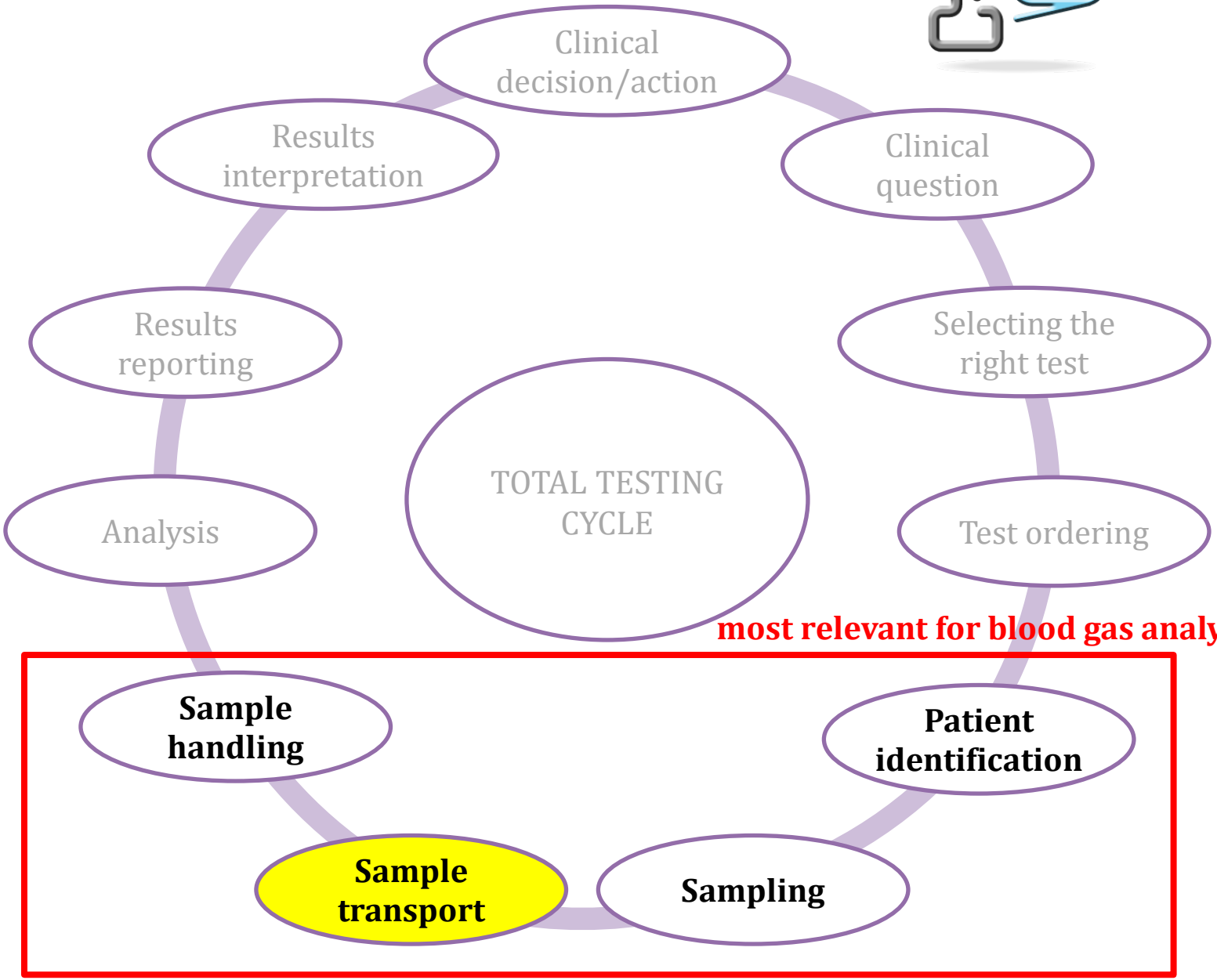
Tuncay Küme, Ali Rıza Şişman, Ahmet Solak, Birsen Tuğlu, Burcu Çinkooğlu, Canan Çoker. The effects of different syringe volume, needle size and sample volume on blood gas analysis in syringes washed with heparin. Biochemia Medica 2012;22(2):189-201.

Dilution by liquid sodium heparin – 4/4



Tuncay Küme, Ali Rıza Şişman, Ahmet Solak, Birsen Tuğlu, Burcu Çinkooğlu, Canan Çoker. The effects of different syringe volume, needle size and sample volume on blood gas analysis in syringes washed with heparin. Biochemia Medica 2012;22(2):189-201.

Brain-to-brain cycle



Lundberg GD. JAMA 1981;245:1762-3

Time is the key to sample quality

Sample transport

- CLSI H11-A4 defines transport condition:
  - analyse the sample within **30 minutes** of collection in a plastic syringe, at **room temperature**
  - if expected delivery time is longer than 30 minutes, use glass syringes, cool the sample

- CLSI 46-A2: samples should be **delivered by hand**,
- **vigorous movement** should be avoided
- **exposure to air** should be avoided (↑ pO2, ↓ pCO2, ↑↓ pH – *mixed effect due to ↓ pCO2 and cell metabolism)*
- **pneumatic tube transport** introduces bias in pO2 due to vigorous sample shaking

Case # 1 - results

- 8:00 a.m.
- lab receives arterial blood sample, for blood gas testing for an ICU patient. Sample has been delivered to the lab in a plastic syringe, on ice. Sampling time was 6:30 a.m. Sample is visibily sedimented. What would you do?

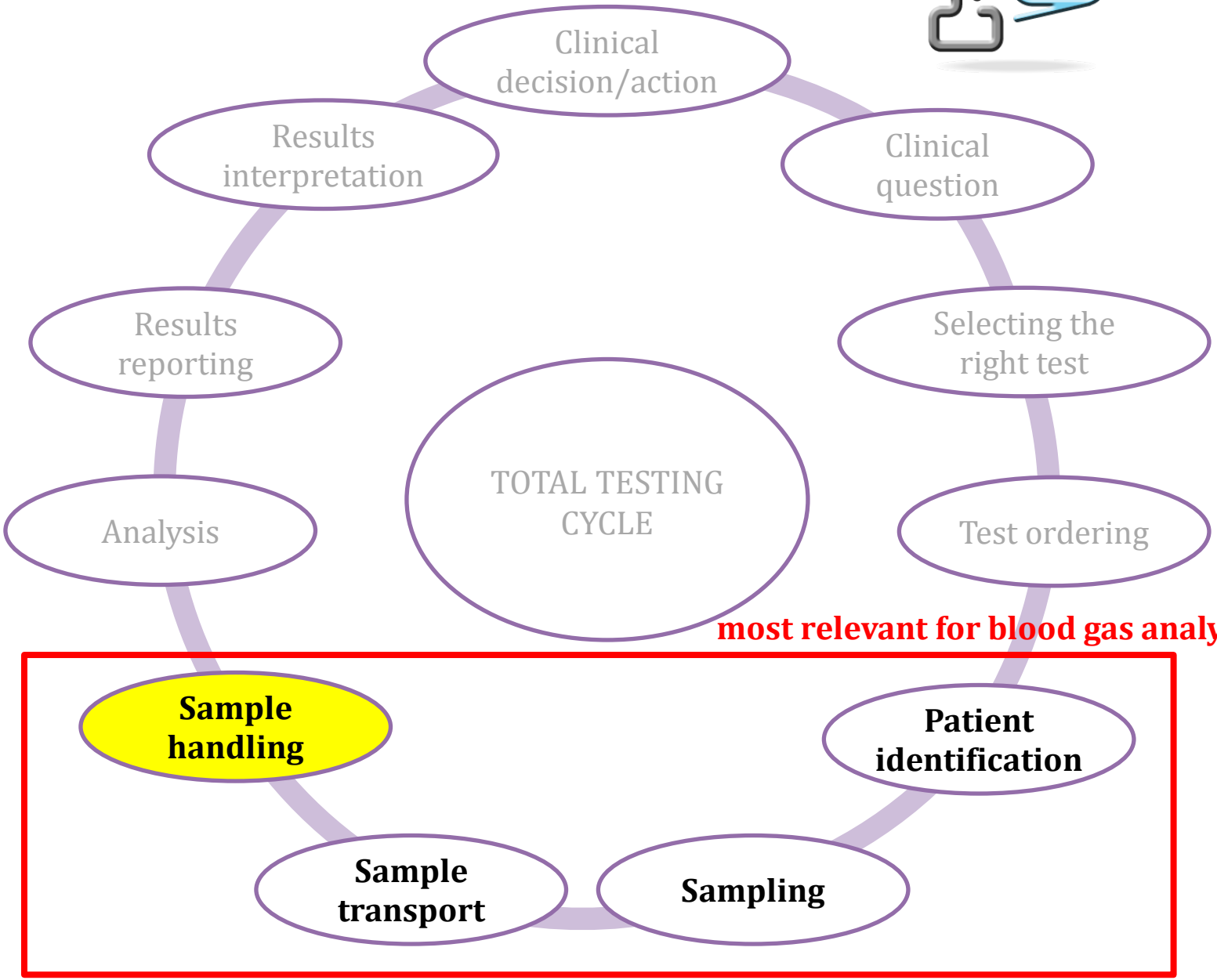
a) Sample is acceptable. I would thouroughly mix the sample and perform the analysis.

b) Sample is not perfect, but I would accept it for analysis after thouroughly mixing it. I would report the result with a comment .

c) Sample is not acceptable. I would reject the sample and request repeated sampling.

d) I would call a physician and ask him to decide what to do.

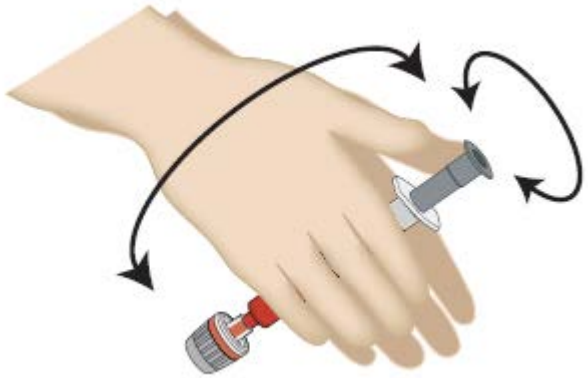
Brain-to-brain cycle



Lundberg GD. JAMA 1981;245:1762-3

Sample handling

- Proper sample **mixing** prior to analysis to obtain a homogeneous sample



To avoid errors:

- mix by inverting the syringe several times and rolling it between the palms
- have a written policy and procedure for mixing
- mix gentle to avoid hemolysis!

Safety issues

- Needle-stick injury and unwanted contact with patient blood are everyday daily risks
- in 2000 occupational HCWs exposure has led to:
  - 16,000 HCV,
  - 66,000 HBV,
  - 1,000 HIV infections *.
- To avoid risks:
  - Use a **safety devices** (contact with patient blood is limited)
  - Use a protection device for the **safe removal** of needles
  - Lab has a **procedure for operator safety** and lab staff is **compliant** with the procedure

* Prüss-Üstün, A., et al. Estimation of the global burden of disease attributable to contaminated sharps injuries among health-care workers. Am J Ind Med, 2005;48: 482–90.

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DIRECTIVES

COUNCIL DIRECTIVE 2010/32/EU

of 10 May 2010

implementing the Framework Agreement on prevention from sharp injuries in the hospital and healthcare sector concluded by HOSPEEM and EPSU

- measure must be taken to specify and implement **safe procedures** for using and disposing of sharp medical instruments and contaminated waste.
- **…** providing **medical devices incorporating safety-engineered protection mechanisms**.

Tips for safer blood gas testing:

- patient properly identified
- patient is in a steady state
- proper sampling site
- self-filling plastic syringes with short-beveled needles, vented caps and balanced dry heparine
- 45° aspiration
- visually inspect the sample,
- expel any bubbles,
- mix the sample,
- deliver on room temperature,
- analyse within 30 minutes
- if visibly sedimented, mix >5’

Quality management

- standardize procedures
- provide written instructions
- enforce compliance
- educate yourself and educate others
- monitor the quality
- continuous improvement
- **No result is always better than the wrong result!**

lab responsibility!


Thank you
Rovinj, Croatia