Learning Objectives

After participating in this session, you will be able to:

1) Develop valid means for comparing different blood gas analyzers and for confirming analytical measurement range.
2) Review QC results to detect important differences between instruments at an early time.
3) Institute procedures to detect and prevent preanalytical variation in blood gas results.

Requirements for the Blood Gas Laboratory

- There are a limited number of questions that are specific to the blood gas section of the laboratory.
- There are a number of questions in both the Lab General and Chemistry Checklists that may have special considerations in the blood gas lab.
- This presentation will attempt to address issues related to both.
Sample Collection

- Blood gases are typically collected from arteries; two questions relate to training for arterial puncture (CHM.33800) and procedure itself (CHM.33900)
- Question requires testing for adequate collateral circulation (such as Allen test), when appropriate; only applies if lab staff draw samples

Collateral Circulation

- Checklist does not specify a particular technique for testing collateral circulation, nor patients in whom it must be done
- Does say that consensus should be established between clinicians, laboratory on patients who should be assessed

Collateral Circulation

- Can most easily be established by hospital or lab policy, jointly approved by medical staff
- Best to document in lab report or medical record that test was performed
- Also required to specify site of collection (only mentioned in note)
Collateral Circulation

- Issue related to anatomy; in about half of individuals, palmar arterial arches incomplete, and in about 4%, loss of radial artery could compromise blood supply to the hand
- More of a concern if ulnar blood flow also compromised, as can occur with severe atherosclerosis

Collateral Circulation

- Henry’s textbook says modified Allen test should be performed in all patients prior to radial artery puncture
- Modified Allen test – occlude both ulnar radial arteries, have clench fist, release ulnar, open fist: assure adequate flow by return of red color; can repeat with radial artery decompression

Collateral Circulation

- “Automated” version – more reliable in hypotensive or unresponsive; use pulse oximeter on index finger, release ulnar, should see pulse detected within 15 sec
- Evaluation of oximeter reading itself produces false positive results (while Allen test has false negative results), so use of the pulse sensing portion of pulse oximeters may be most reliable
Ambient Air

• Final sample question requires system to prevent ambient air contamination
• Air bubbles cause equilibration between sample and room air.
• This always cause a fall in $P_{CO_2}$ and pH.
• Effect on $P_{O_2}$ depends on treatment; usually ↑, but may be ↓ if patient on high $FiO_2$

Ambient Air

• Most common cause: air bubbles; effect of bubbles increased if many small bubbles, by delay in analysis, or transported by pneumatic tube
• Policies/procedures should include sample examination and documentation of likely erroneous results

Instrument Questions

• Only 6 specific questions (CHM.34100-34600) on blood gas instruments; these apply in a lab doing blood gases and other chemistry tests with same director (even if in separate location(s))
• If physically separate lab, separate director, then full Chemistry Checklist must be evaluated for blood gas lab
Instrument Questions

• CHM.34100 – Straightforward function checks – assure you have documentation of maintenance, etc.
• CHM.34200 – Calibrators meet manufacturer’s specifications or NIST SRM – easily satisfied if use manufacturer’s calibrators

Instrument Questions

• CHM.34300 – Calibration and cal verification – Must follow manufacturers recommended schedule if used regularly; for self-calibrating instruments, not an issue
• If used infrequently, must be calibrated each time of use

Instrument Questions

• Question also mentions barometric pressure being considered, if appropriate; follow manufacturer’s recommendations in this case
• Note requires some procedure for verifying reliability of calibration; two expert reviewers have suggested deleting or modifying this note
Instrument Questions

- CHM.34400, 34500 – At least 1 level of control every 8 hours; at least 2 levels of control (high, low) every day
- Defined by 8 hours, day of use for patient testing
- Can use tonometered material or liquid commercial controls

Instrument Questions

- Except for assayed controls, each lab must establish own control range based on their measurements, and not use the ranges provided (CHM.14000)
- Use of too wide ranges can lead to failure to detect bias and to higher risk of PT failure

Instrument Questions

- CHM.34560 – Requires one control sample each time patients are tested unless auto-calibrated every 30 min
- This would likely apply to instruments that are used infrequently during the day, not to an instrument that is used multiple times during a shift
Proficiency Testing

• CHM.10200 requires PT to be integrated with regular workload; note suggests best rotated among all those who regularly perform testing
• Performance can be used as part of competency testing for employees if regularly rotated

Proficiency Testing

• If more than one instrument used, not required to be tested on all instruments, only primary instrument
• Important to pay careful attention to instructions for handling PT material for blood gases; results can be adversely affected if directions not followed

Calibration Verification

• CHM.13400 requires criteria for accuracy of calibration and/or for calibration verification
• Since blood gas instruments calibrated very frequently, calibration verification is not required
Sample Acceptability

- CHM.11900 requires lab to have specified criteria for sample acceptability
- Note indicates that samples that are unacceptable can still be reported, but with laboratory noting that results may be unreliable because of sample condition

Sample Acceptability

- In blood gas laboratory, common causes for sample unacceptability are:
  - 1) Low volume (esp. with liquid heparin, causes falsely high PO₂)
  - 2) Air bubbles (causes falsely high PO₂, falsely low PCO₂)
  - 3) Inadequate icing/delayed arrival (causes falsely low pH)

Sample Acceptability

- CHM.12000 requires documentation of action taken on unacceptable samples
- Can be either in patient records (as result or notation), or in sample error log/form
- Latter approach makes review easier for QA purposes
Reagent Validation

• CHM.12900 requires that all new lots be validated before being put into use
• Most easily performed by analyzing patient samples with old, new lots (we use same form as for method comparison done every 6 months, and same criteria for acceptability)

Reagent Validation

• Other materials (QC, for example) can also be used
• Lab must have documentation that this behaves similarly to patient samples
• Not as much an issue in blood gas testing as in many other areas of lab

Verify Reportable Range

• Reportable range includes:
  – Analytical measurement range (AMR) – range of values that instrument can report directly (less accurately called linearity)
  – Clinically reportable range (CRR) – range of values that can be reported with dilution or concentration of samples; for blood gas lab, not applicable
Analytical Measurement Range

- CHM.13600 requires determination of AMR before method used, and reverification at least every 6 months, using at least 3 samples that span entire measurement range
- Not required separately if at least 3 calibrators that span range used

Analytical Measurement Range

- For PCO₂, PO₂, difficult to get patient samples that span measurement range, and these are not stable on storage
- Various vendors (including CAP) produce linearity materials that can be used to verify AMR; in our lab, we use CAP LN-13 survey for this purpose

Analytical Measurement Range

- For most recent survey, ranges covered were:
  - pH: 6.8-8.8, allowed difference ± 0.3%
  - PCO₂: 12-91.5, allowed difference ± 5%
  - PO₂: 37-445, allowed difference ± 8%
- Remember, values outside AMR must be reported > or < limits
Method Comparison

- CHM.13800 requires that, if more than one method used for measuring same parameter, labs check against each other at least 2x yearly for patient results
- Requires development of criteria for acceptable agreement

Method Comparison

- Note indicates patient samples are preferable, but may not be possible for unstable analytes if instruments located at some distance (often an issue with blood gas instruments/samples)
- If controls or reference material used, lab must verify they perform similarly to patient samples

Method Comparison

- Does not require that single set of samples be used to compare all instruments; may compare instrument 1 and 2 with one set, instrument 1 and 3 with another set
- Criteria should be based on patient care needs and/or criteria needed to pass proficiency testing
Method Comparison

- Be careful to not use “blanket” criteria for whole laboratory; for example, in recent inspection I performed, acceptable agreement for all tests was ± 10%
- For pH, at target value of 7.40, this would mean “acceptable” was between 6.66 and 8.14!

Method Comparison

- For CAP proficiency testing (based on CLIA-88 regulations), acceptable performance is within:
  - pH: ± 0.04
  - PCO₂: ± 5 mm Hg or 8%, whichever is lower
  - PO₂: ± 3 s.d.

Method Comparison

- Question and note do not specify actual method to be used or number of samples; in our lab, we perform this analysis with 5 samples
- Best to use a range of values (both normal and abnormal high and low) to detect any biases
Method Comparison

- We use form, fill in test, ID of samples used, results from different instruments, and director review of acceptability
- We have a single sheet for each section on allowable differences between methods developed by director, based on typical variation in patients (see Tietz or Kaplan & Pesce for tables)

Reference Intervals

- CHM.15000 requires all results to be reported with reference intervals
- With point of care instruments, printout often does not have this information on it, and is sometimes the only "report" available to clinicians
- Lab must assure that some form with reference intervals is attached to report

Critical Values

- CHM.15100 requires labs to establish criteria that require immediate notification
- It is not required that all areas have such critical values, but it is common for blood gases to have critical values
- May want to have separate critical values by age (for example, high PO2 dangerous in infants, not so in children, adults)
Critical Values

- CHM.15200 requires documentation of prompt notification of physician
- If blood gas lab is under separate leadership (e.g., respiratory medicine), important that similar approach used to what is done in central lab
- Often, critical values are hospital, not laboratory, policies

Carryover

- CHM.24400 requires labs to evaluate automatic pipetting systems for carryover
- Since blood gas instruments often use pipetting systems, needs to be done for these instruments as well
- Protocol involves running high sample several times, then repeat low sample

Carryover

- Degree of difference for low sample (from when run previously) should be within lab’s criteria for acceptable difference between instruments
- Seldom an issue in blood gas lab because of the limited range of results obtained, but needs to be done once
Quality Management

- A number of questions on QM are found in lab general section
- Remember that QM provisions apply to blood gas laboratory, and some QA monitor must be done if blood gas section is separate from main laboratory

Summary

- If blood gas lab is part of main laboratory, there are few specific requirements
- If separate section with different director (common situation), blood gas lab must comply with full Chemistry, Lab General, and Team Leader Checklist requirements

Summary

- Important to note differences in how some questions apply to blood gas labs because of differences in type of samples and their stability
- This session covered some of the most common areas where these differences are important
Assistance

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