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6.1.3.3 Quality Specifications for pH and Blood Gases

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ABSTRACT

This presentation is built upon experience with use of blood gas results in clinical work during 25 years,experience from the external quality control of 120 blood-gas-analyzers participating in the Norwegian Control Survey 1984-1991, and at last 3 different pH/blood gas inter-analyzer comparisons in Oslo and Bergen in 1980, 1990 and 1992 (1, 2, 3). It is discussed the pure biological variations of the three parameters pH, pCO_2 and pO_2 as well as the variations in results caused by preanalytical and analytical factors. My proposal for goal of quality for determinations of blood gases (the pure analytical variations, given as EA, Error Allowable (4 and 5)) are;
pH: 0.02 units on all levels as SD, pCO_2: 1-2 % (CV) depending on level and the clinical situation. pO_2: 2-4%(CV) depending on the level and clinical situation.

CLINICAL SITUATION

In the literature there are much documentations from clinical work of the pure analytical variations when analyzing pH and gases in blood. Many laboratories have given reference values for pH, pCO_2 and pO_2 measured in arterial blood. These reference values include both preanalytical, analytical and interindividual biological variations. There are few documented results from the literature concerning only the preanalytical and the pure biological variations.

CHARACTERISTICS OF THE METHODS

In a publication of Linnet from 1989 (6), the author uses in his calculations a preanalytical variation for 17 common clinical-chemical parameters which is 50% of the pure analytical variation. From my experience in the blood gas field, I will propose the preanalytical

variation to be of the same size as the analytical. This is especially pronounced for the decentralized instruments in use in acute medicine and used by clinical staff (intensive care unit, pre-, per- and postoperatively).

The main preanalytical factors are:

a. The position of the patient. (Upright or lying.)
b. The type of sample container.
c. The use of anticoagulant.
d. From where the sample is taken. (Arteries,capillaries and central veins.)
e. The technique of sample collection. (Strict anaerobic conditions.)
f. The storage and transport of the specimen.
g. Wrong mixing of the samples just before analyzing.

We have knowledge about how much the single factors above contribute to the variation, but less exact knowledge about the "sum" of the preanalytical factors. There is very much information about the pure analytical variations when measuring pH, pCO_2 and pO_2 in blood. This information is both from international and national surveys of inter-analyzer comparisons and from intra-analyzer determinations. The most used QC-materials for distribution in inter-laboratory surveys are:

a. Aqueous solutions.
b. Fluorocarbon emulsions.
c. "Stabilized" hemoglobin solutions.

Blood is the best material within the single laboratory. Tonometry is recommended, but is only suitable for determinations of pCO_2 and pO_2. In general for both pH-, pCO_2- and pO_2-determinations the within-series variation is acceptable. Also the day-to-day variation when the instruments are used by skilled staff, is acceptable. The bias may some time be out of control for a specific instrument. This is most frequent for pO_2. We have experienced situations where it has not been advisable to measure blood gases from the same patient on two different instruments.

MODELS AND EVALUATION OF QUALITY SPECIFICATIONS

In the last years the in vivo monitoring of pH, pCO_2 and pO_2 have thrown more light upon the pure biological variations intraindividually for the three mentioned parameters. The biological variation of all the three parameters is in general of the same magnitude as the

pure analytical variation. The reference values for the blood gas parameters given by the single laboratory include preanalytical, analytical and biological factors. These reference values can be used to get some impression of the pure biological variation (interindividually) by subtracting the variance of preanalytical and analytical factors from the total variance.(Expressed as reference values, mean ±2SD). The preanalytical variation in this consideration is chosen to the same magnitude as the analytical variation.

We know from the physiology that the pH-, pCO_2- and pO_2-values in the blood is strictly regulated in a single person. In cerebrospinal fluid the values are even better regulated to a very narrow range. The pCO_2-values show some increase during sleep. It is also well known that the mean pO_2-value in arterial blood is decreasing with increasing age owing to increased shunting of blood in the lungs and also caused by decreased elasticity of the lung tissue. The mean homeostatic pO_2 for a person of 20 years of age is 13.3 kPa. In comparison the 75 year old person has a mean value of 10.6 kPa. All considerations here are done at normobaric conditions. Hypo- and hyperbaric conditions fall outside this presentation. One must also have in mind that changes of pH and pCO_2 are not independent. A change in pCO_2 will also change pH.

EVALUATION OF QUALITY SPECIFICATIONS

As no relevant model is applicable,my proposals for goals in quality in determinations of blood gases (the pure analytical field,given as EA, Error Allowable (4 and 5)) are:

pH: 0.02 units on all levels (expressed as SD).

pCO_2: 1-2 % (CV) depending on respiratory alcalosis,normal situation or respiratory acidosis.

pO_2: 2-4 % (CV) depending on hypoxemia, normoxemia or hyperoxemia.

It is also of great interest the clinical indication for the measurement. (Screening, diagnostic, therapeutic or scientific purposes.)

DESIGN OF CONTROL SYSTEM

a. Internal system. Tonometry is the best way to evaluate the quality of pCO_2 and pO_2. Owing to the continuous change in barometric pressure, one must evaluate the difference between the measured and calculated value. For pH it is necessary to use ampouled control solutions. For all three parameters, pH, pCO_2 and pO_2, it is advisable to also use ampouled solutions. Owing to the bias for the single instrument,

it is necessary to analyze ampoules from the same batch each day for 30 days and determine the mean (target value) and SD for the single instrument and use these values in the following period.

b. External system. It is necessary to use ampouled solutions. See above (characteristics of methods).

DISCUSSION

The resources for better quality in pH and blood gas analyzes must in my opinion be used to improve the preanalytical conditions and also try to improve the bias of the analyzes. When I am asked to day: "Do my blood gas analyzer's results compare with results of other analyzers?". I cannot honestly answer yes. The efforts should especially be used in the analyzes of pCO_2 and pO_2. The analyzes of pH are from the clinical point of view satisfactory. The imprecision, both within series and day to day, has from my point of view reached an acceptable plateau. To improve the preanalytical phase in blood gas analyzes, one must give more information and increase the teaching of all users of this kind of instruments. To reduce the bias it is necessary with more standardisation of the instruments and the QC-procedures.

CONCLUSION

The variation of the measured parameters pH, pCO_2 and pO_2 is caused by preanalytical, analytical and biological factors. We cannot influence the biological factors at all. The Achilles'heel in this field is the preanalytical phase and components of the analytical field.

The proposed quality specifications for the pure analytical variation are given above. It is not possible to give specifications for the total preanalytical field, neither have we specific documentation of the pure biological variation. With the increased development of the in vivo technique for measuring bloodgases, we will in few years have much more exact documentation of the biological variation.

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