

How can the EQA provider encourage the participation in Pre-Analytical schemes

Introduction

Providing a quality sample and ensuring the best laboratory practices should be the aim of Pre-Analytical Phase.

With analytical phase strictly controlled, pre-analytical phase should be the laboratories target for improvement processes. Concerning to this, it is important to have in place a proper system for error detection for this extra-analytical phase and to be able to detect errors that have a significant negative effect on sample quality and patient health. Although laboratory managers are becoming to concern about these issues, the participation rate on the national program on pre-analytical phase is still very low, which means that the EQA provider should have an intervention more active than it has with the analytical phase.

Aim and Objective

In order to contradict this weak participation and to reach the laboratories needs, PNAEQ (*Programa Nacional de Avaliação Externa da Qualidade*) has launched two types of schemes in which laboratories participation depends mainly of the EQA provider. One is the "mystery client", which simulates a real life scenario to verify if the information provided to the patient depends on the laboratory collaborator. The other one is a presential audit, which identify some of the real errors occurred during the blood drawing. The aim of these two types of surveys is to demonstrate that most of the pre-analytical errors are detectable and, more important than that, they can be corrected or eliminated when pre-analytical phase is controlled.

Material and Methods

PNAEQ has a total of 196 laboratories participants in EQA schemes for clinical area in 2017. Of this, only 10% were registered on pre-analytical scheme. Three of them are from developing Portuguese speaking countries. In 2015 PNAEQ has created a Working Group on pre-analytical phase. Since then, all participants are invited to participate on this annual meeting.

The two schemes involving PNAEQ are mystery client and presential audit:

Mystery client: two anonymous telephone calls were made to the laboratories registered in this scheme on 2 different days, one in the morning period and one in the afternoon period. The calls were made based on an interview guide simulating a patient with questions. The simulated required analyses were for Haematology, Clinical Chemistry and Microbiology areas.

Presential audit: In the annual WG meeting was proposed that two PNAEQ elements would perform an audit in two randomly selected laboratories (Lab A and Lab B) among those registered in this scheme. The two auditors observed 5 blood drawings by 3 different technicians, in a total of 15 observations. The items observed focused on three main themes: sample identification, sample quality and safety practices, spread over 10 items. This audit form was previously provided to all registered participants as a tool to be used by laboratories. In addition, it was possible to compare and validate the results obtained by auto evaluation of laboratory (its own auditor) and PNAEQ auditor.

A report concerning these two schemes was sent to each laboratory and it was asked what were the actions implemented to improve good practices in 2017.

Results

The participation rate and performance results for each of the schemes were as follows:

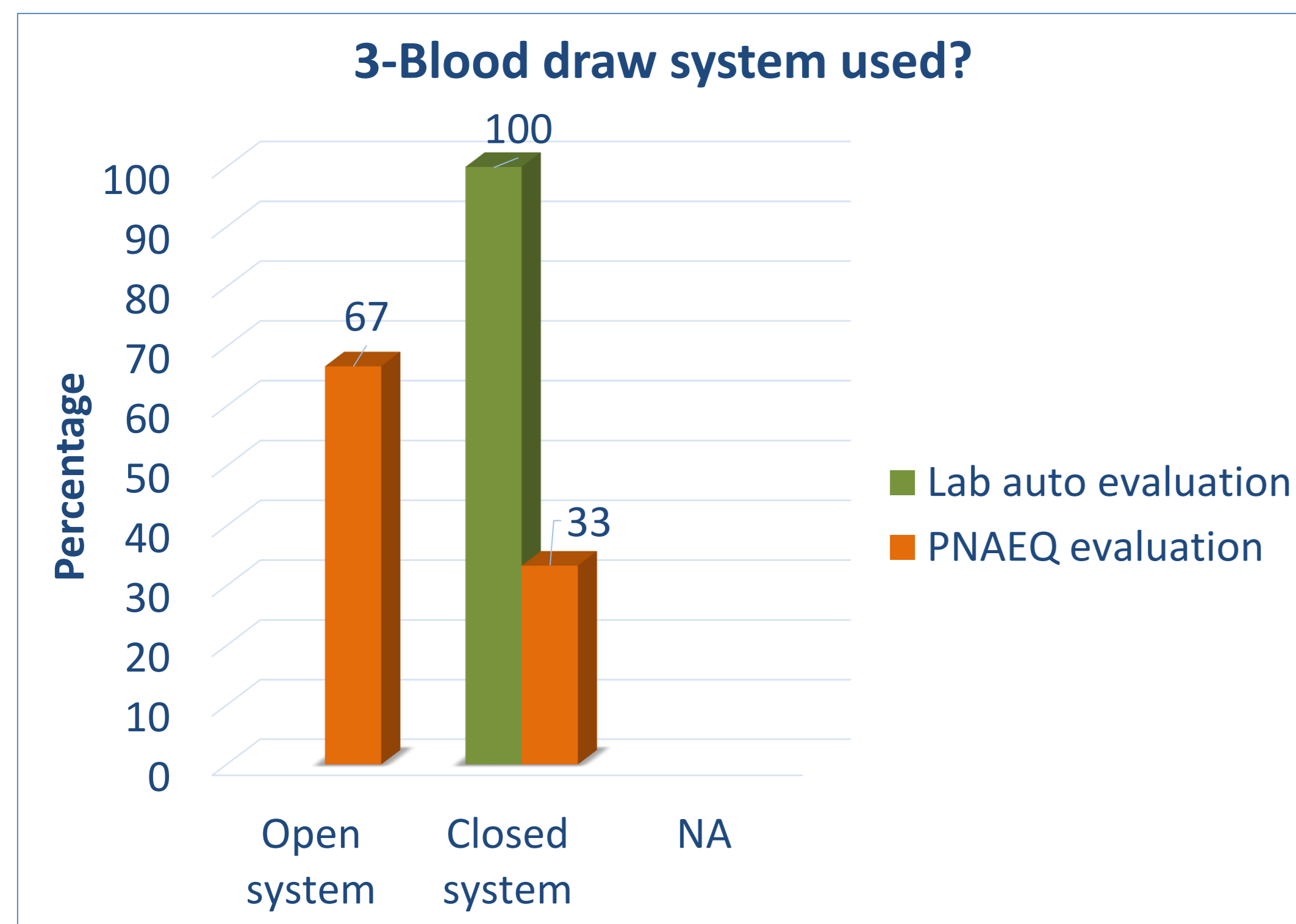
Mystery client: In 2017 were received 19/20 results, corresponding on 95% participation rate. Note that participation rate in other type of schemes which depend only of participants are around 62% in audits and 64% for monitoring indicators. The results show that there was no coherence in the information provided by the collaborators in 40% of the questions raised (Table 1).

Presential audit: For the laboratory A, the PNAEQ audit evidenced non-compliance with good practices in 3 items, when comparing with the laboratory auto evaluation: *3-blood draw system used* (67% of the blood drawings observed by PNAEQ were made with open system, i.e., needle and syringe, in contrast to 0% reported by laboratory), *5-order of draw* (7% of the blood drawings observed by PNAEQ used the incorrect order of draw, according to the CLSI document H3-A6, as opposed to 0% reported by laboratory) and *9-identification of samples in the presence of the patient* (in 53% of the blood drawings observed by PNAEQ, the collectors tubes were not identified during the blood drawing, contrasting with the 0% reported by laboratory) (Graphics 1, 2 and 3).

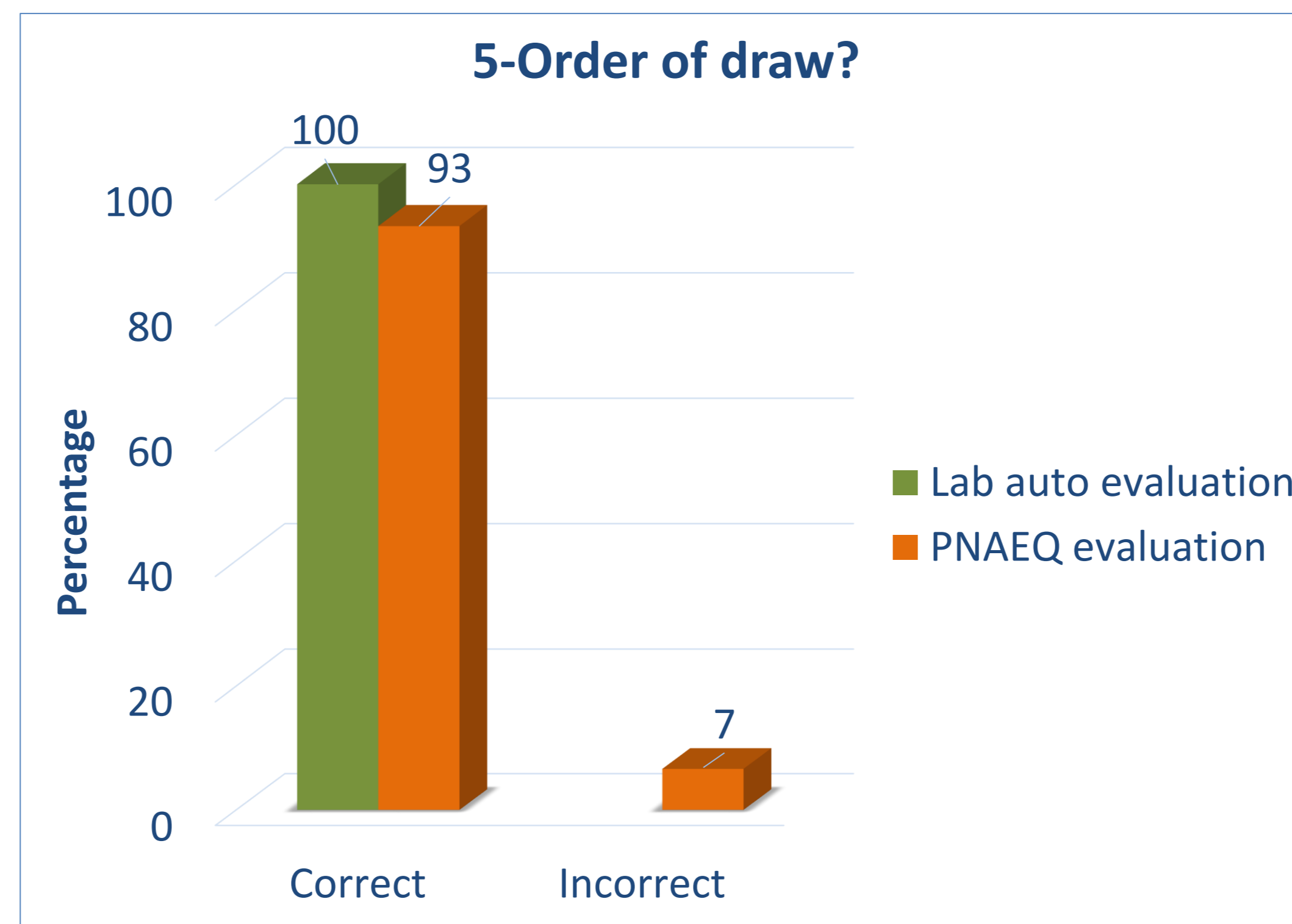
For the laboratory B, the PNAEQ audit confirmed the good practices comparing with the laboratory auto evaluation.

| Questions | 2017 (%) |
|--|-----------|
| Patient preliminary preparation | 5 |
| Instructions provided by laboratory | 47 |
| Information available on laboratory website | 63 |
| Total amount to pay | 63 |
| Laboratory schedule | 47 |
| Possibility of appointment the blood drawing | 16 |
| Average | 40 |

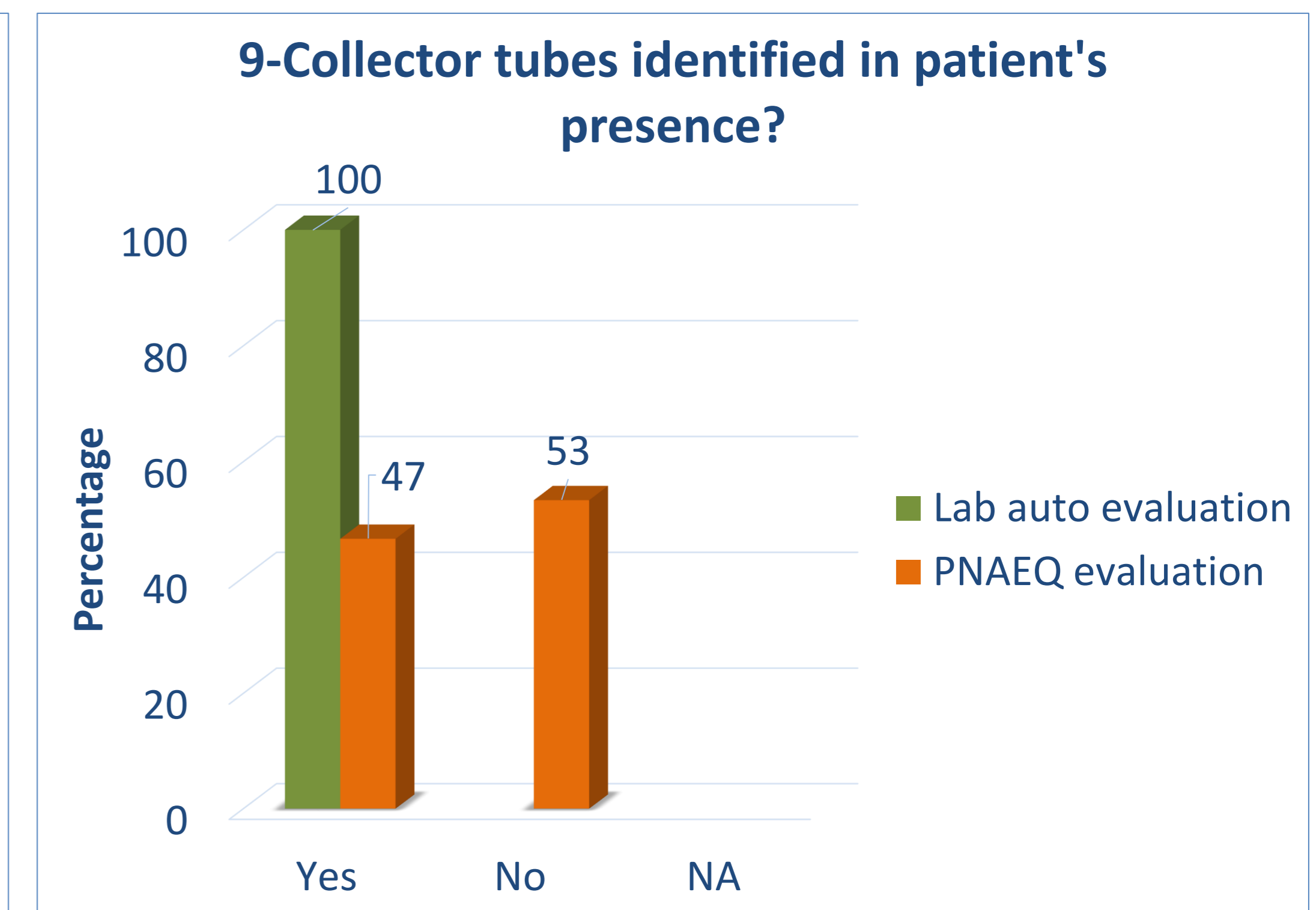
Table 1: Percentage of different answers in the two telephone calls (call 1 versus call 2), made in the morning period or in the afternoon period, for each question.



Graphic 1: Percentage of blood drawings observed relative to question 3-Blood draw system used?, reported by laboratory and by PNAEQ, for laboratory A. (Legend: NA – No Answer)



Graphic 2: Percentage of blood drawings observed relative to question 5-Order of draw?, reported by laboratory and by PNAEQ, for laboratory A. (Legend: NA – No Answer)



Graphic 3: Percentage of blood drawings observed relative to question 9-Collector tubes identified in patient's presence?, reported by laboratory and by PNAEQ, for laboratory A. (Legend: NA – No Answer)

Conclusion

- These tools were created to facilitate the detection, monitoring, evaluation and correction or elimination of pre-analytical errors when regularly used by laboratories. This is possible while participants can use these real situations to compare their practices with other laboratories and within the laboratory comparing collaborators practices. The approach of these types of surveys is especially educational.
- These two type of schemes will be repeated in the 4th trimester of 2017 so we can verify if laboratories have implemented preventive/corrective actions to improve good practices in pre-analytical routine.
- The cooperation between PNAEQ and participants will be maintained in future rounds of Pre-Analytical Phase. This cooperation allows to clarify laboratories difficulties in data collection and to share national and international guidelines and recommendations, which should improve samples quality and ensure the best laboratory practices.
- In the Working Group annual meetings on Pre-Analytical Phase, there will be discussed the selected indicators and the tools most adapted to the participants collection data, based on national and international results.
- In addition, PNAEQ will continue to promote training actions for implementing the best laboratory practices in Pre-Analytical Phase.
- PNAEQ will continue to work with other European EQA providers, especially in the distribution of online surveys to Portuguese laboratories.

References

- Clinical and Laboratory Standards Institute (CLSI) – Procedures for the collection of diagnostic blood specimens by venipuncture; Approved Standard. Sixth Edition. CLSI document H3-A6 (2007).
 Clinical and Laboratory Standards Institute (CLSI) – Procedures for the Handling and Processing of Blood Specimens; Approved Guideline— Third Edition. CLSI document H18-A3 (2010).
 Decreto-Lei nº 121/13. D.R. Iª Série-A. 161 (22-08-2013) 5052-5055 – Estabelece o regime jurídico relativo à prevenção de feridas provocadas por dispositivos médicos corto-perfurantes que constituam equipamentos de trabalho nos setores hospitalar e da prestação de cuidados de saúde.
 Despacho nº 8835/01. D. R. IIª Série. 98 (27-04-2001) 7383-7396 – Aprova o Manual de Boas Práticas Laboratoriais.
 Direção Geral da Saúde – Norma 013/14: Uso e gestão de luvas nas unidades de saúde (2014).
 ISO 15189:2012. Medical laboratories – Particular requirements for quality and competence.
 World Health Organization – WHO guidelines on drawing blood: best practices in phlebotomy (2010).