PNAEQ and Labquality Preanalytical Schemes in 2023

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Introduction

According to ISO 15189:2012[1], laboratory shall participate in external quality assessment (EQA) programme and implement corrective actions when necessary. These EQA programs should have the effect of checking entire examination process, as well as evaluate laboratory staff involved in the process.

In order to evaluate all the clinical process, most EQA organizers distribute preanalytical schemes to participants, in addition to analytical and post-analytical schemes. The Portuguese EQA Programme (PNAEQ), with collaboration of Labquality, offered nine preanalytical schemes in 2023.

Aim

The main objective of this work is to present the diversity of PNAEQ preanalytical schemes and investigate the most participated ones, as well as characterize participants registered in these schemes and calculate the participation rate in relation to the total number of PNAEQ clinical participants. Compliance with the ISO 15189:2012 is also verified.

Methods

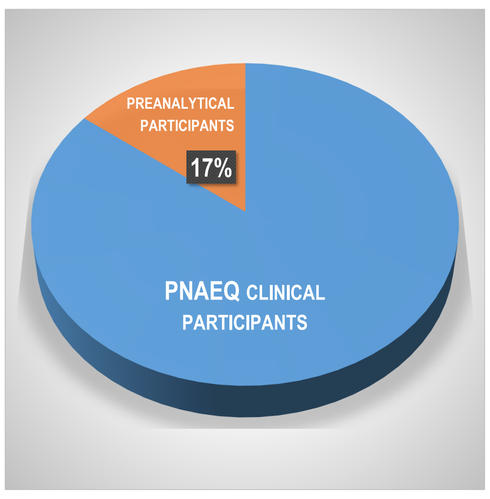
There are three types of preanalytical schemes[2]: procedures registration (I), samples circulation (II) and errors registration (III). PNAEQ schemes covers I and III types. Labquality schemes covers II and III types.

In type I, participants have to collect requested data involving patient (reception, identification, background information), process (registration), sample (request, identification, collection procedure, rejection criteria, transportation), general information for the patient (priorities, prices) and laboratory facilities. In type II, participants have to analyze serum HIL indices (Hemolysis, Icterus and Lipemia) or simulate samples transport. In type III, participants have to identify preanalytical errors (case simulations or audits).

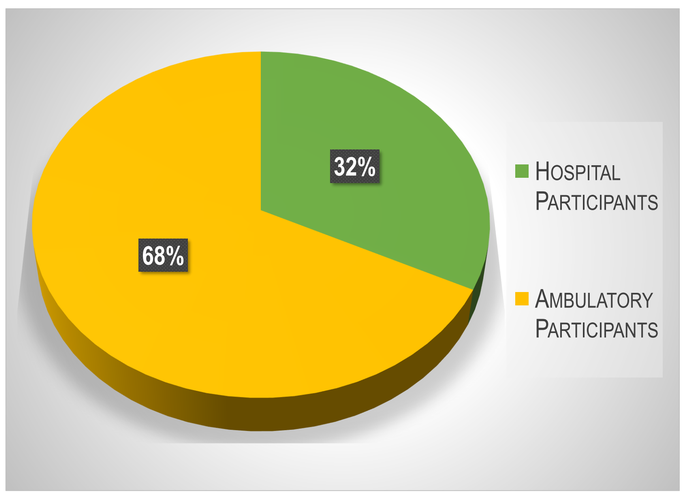
In addition, all laboratory staff involved in preanalytical process can be evaluated (receptionist, lab technician and lab manager).

Results

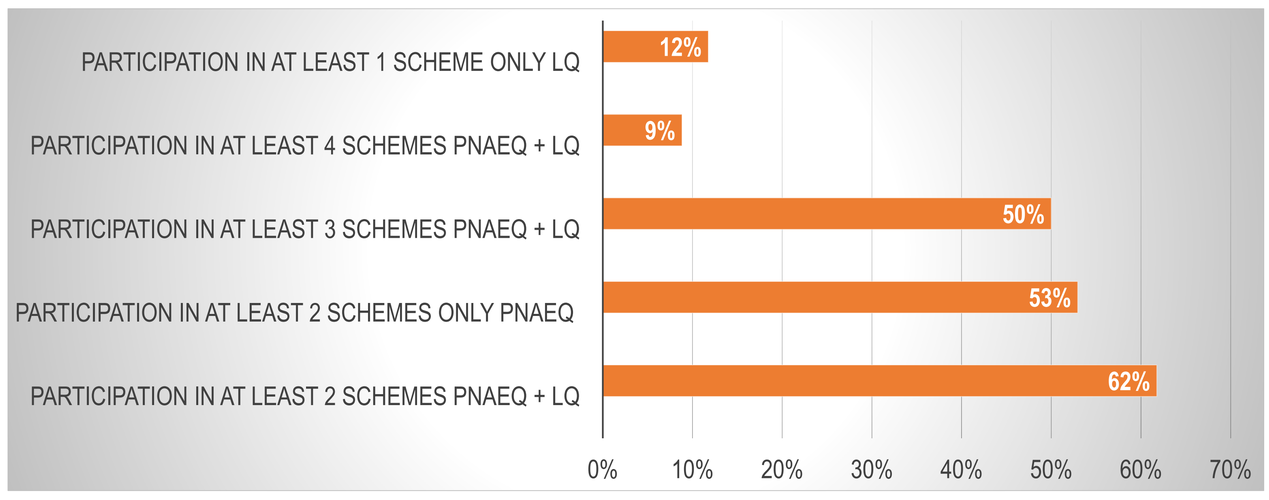
In 2023, 17% of PNAEQ clinical participants (68% private and 32% public) were enrolled in, at least, one preanalytical scheme (N=34). Of these, 62% participated in two or more schemes and 9% in four or more schemes (Graphics 1, 2 and 3).



Graphic 1: PNAEQ clinical participants (percentage) enrolled in, at least, one Preanalytical scheme, in 2023.



Graphic 2: Participation (percentage) on PNAEQ/Labquality Preanalytical schemes, in 2023.



Graphic 3: Participation (percentage) on PNAEQ/Labquality Preanalytical schemes, in 2023.

The most participated schemes were the ones organized by PNAEQ: “Quality Indicators of Pre and Post-Analytical Phases” (type I) and “Mystery Client and Case-Study of Pre- and Post-Analytical Phases” (type I + III), both with 65%, followed by “Audits of Pre- and Post-Analytical Phases” (type I + III) with 53%. From Labquality offer, type III schemes were the most selected: “Preanalytics, microbiology” (18%), “Preanalytics, clinical chemistry” (12%) and “Preanalytics, urine and blood sample collection” (6%). Also from Labquality, type II schemes had 3% participation each: “HIL-index” and “Preanalytics, pneumatic sample transport” (Figure 1). Figure 2 shows the type of schemes used to evaluate laboratory staff involved in the preanalytical process.

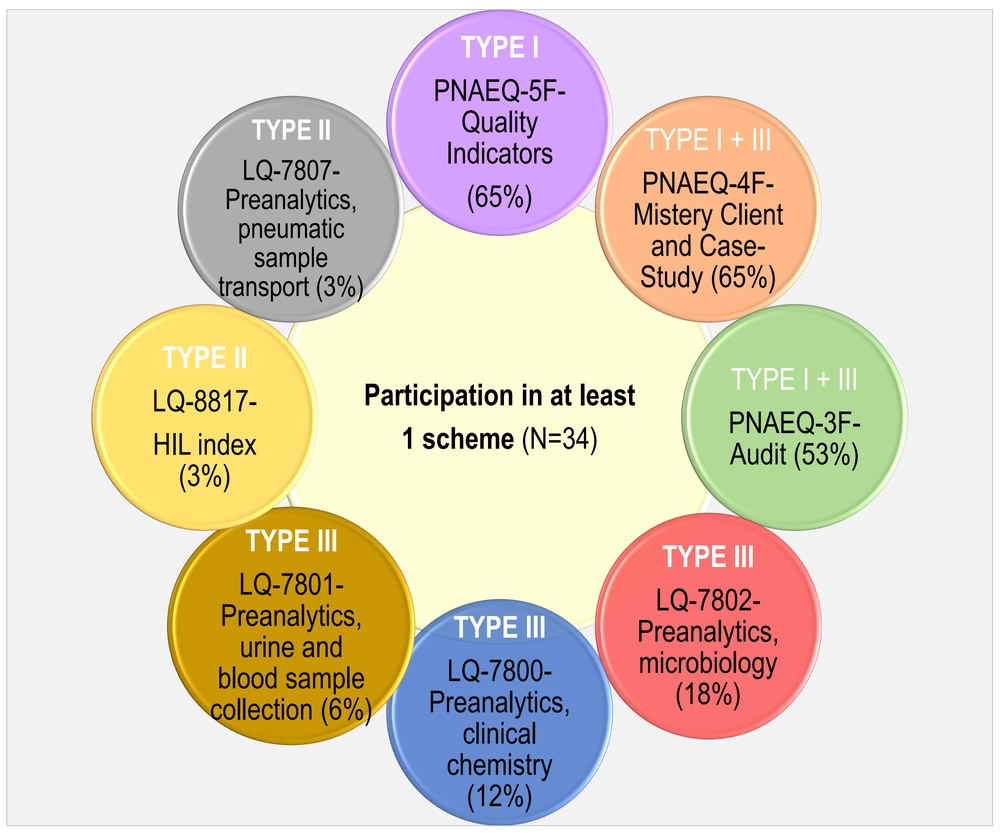


Figure 1: Participation (percentage) for each survey performed on PNAEQ/Labquality Preanalytical schemes, in 2023.

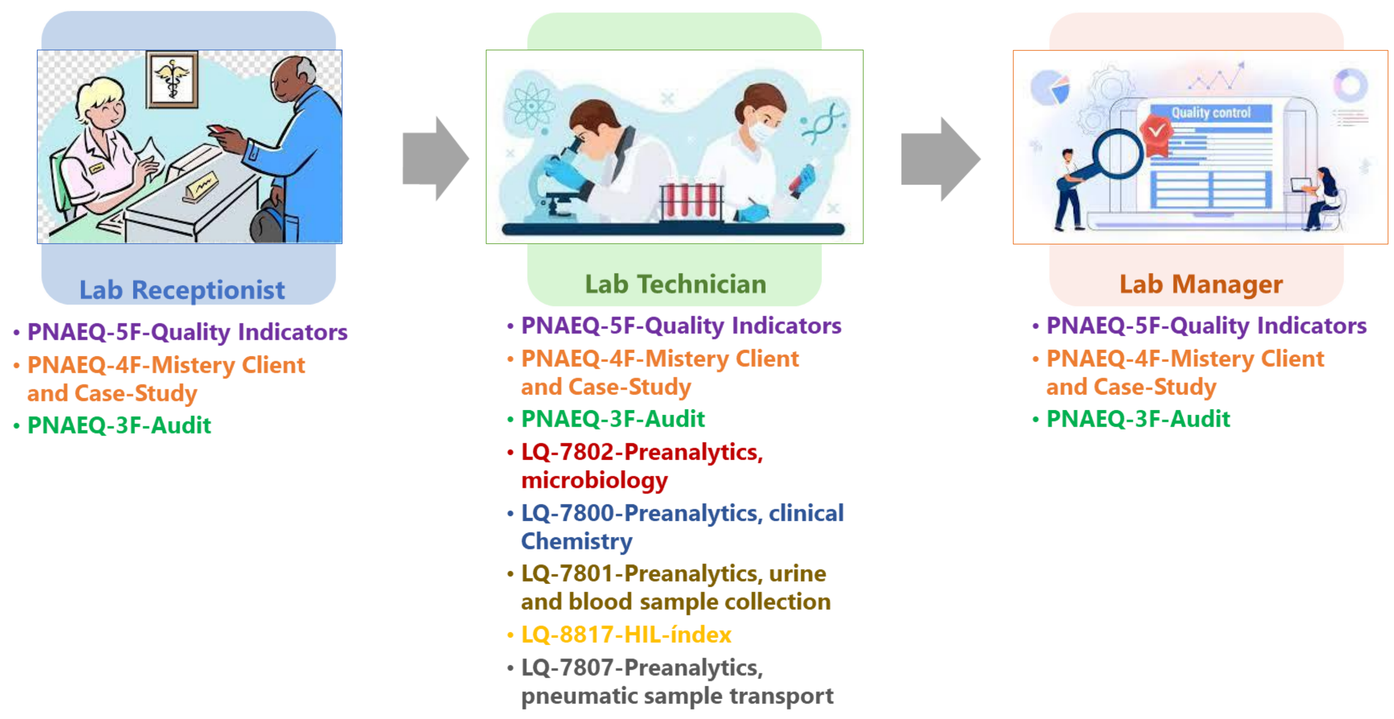


Figure 2: Type of schemes used to evaluate laboratory staff involved in the preanalytical process, in 2023.

Conclusion

- According to ISO 15189:2012, clinical laboratories should identify critical activities and implement tools to detect, monitor, reduce and eliminate errors in preanalytical phase. These tools, when implemented in routine, can be used to verify if collaborators are performing correct and systematic practices in compliance with regulatory[3] and reference requirements, leading to reliable results for medical decisions, as well as to identify their training needs. All these PNAEQ/Labquality schemes can be used in this evaluation, continuously (“Quality Indicators of Pre and Post-Analytical Phases” and “Audits of Pre- and Post-Analytical Phases”) or punctually (all the others). Practically all requirements of ISO 15189:2012 were ensured in these schemes.
- Despite the wide variety of preanalytical schemes offered in 2023, the low rate of PNAEQ clinical participants requires a greater effort from PNAEQ to motivate participation. Some solutions may involve meetings with participants and suppliers, and create tools that can facilitate data collection.
- The requirements of the ISO 15189:2022 will be include in next surveys.

References:
[1] ISO 15189:2012. Specifies requirements for quality and competence in medical laboratories.
[2] G. B.B. Kristensen, K. M. Aakre, A. H. Kristoffersen, S. Sandberg. How to conduct External Quality Assessment Schemes for the preanalytical phase. Biochemia Medica 2014.
[3] Manual de Boas Práticas Laboratoriais de Patologia Clínica ou Análises Clínicas – Despacho 10009/2019, de 5 de Novembro.