Pre-analytical Checklist: a relevant tool for External Quality Assessment (EQA)

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Background

According to ISO 15189:2012, laboratory shall participate in an external quality assessment (EQA) programme and implement the corrective actions when necessary. The EQA programs should have the effect of checking the entire analytical process, including pre- and post-examination procedures. The National Program for External Quality Assessment (PNAEQ) provides since 2007 EQA pre analytical schemes, including a checklist since 2016.

Aim

The aim of this work is to share PNAEQ's checklist for pre-analytical phase, and evaluate trend over time of the results of PNAEQ participants, between 2019-2021.

Material and Methods

Area	Question
Administrative Attendance	**1.** Was the request data correctly entered? **2.** Was the Sample Collection Manual correctly consulted? **3.** Were the instructions for sample collection correctly provided?
Facilities, venipuncture material and documentation	**4.** Is patient privacy guaranteed? **5.** Are the collection tubes within their expiration date? **6.** Is the Sample Collection Manual accessible for consultation? **7.** Does the laboratory have a procedure for home sample collection?
Reception of samples collected by patient	**8.** Stools - Was the sample correctly identified? **9.** Stools - Was verified if the number of samples delivered coincided with the request? **10.** Stools - Was the date of collection recorded on all samples delivered? **11.** Urine - Was the sample correctly identified? **12.** Urine - Was relevant clinical information recorded? **13.** Urine - Was the correct collection procedure performed by the patient confirmed? **14.** Urine - Was the date and time of collection recorded?
Phlebotomy	**15.** Did you confirm the patient's identification? (positive identification) **16.** Did you confirm that the patient meets the conditions for collection? **17.** Did you use gloves and sanitize your hands? **18.** Did you disinfect the site to be punctured? **19.** Did you use a needle with a safety system included? **20.** How long was the tourniquet in place? (seconds) **21.** Did you identify the collection tubes in the presence of the patient? **22.** Did you record the time of phlebotomy? **23.** Did you correctly dispose of the venipuncture material used?

Figure 1: Checklist for pre-analytical phase performed between 2019-2021 in PNAEQ scheme.

A checklist (Figure 1) was distributed to PNAEQ participants (clinical laboratories), included in a pre-analytical EQA scheme, between 2019-2021. The 23 questions belong to four main areas: Administrative attendance; Facilities, venipuncture material and documentation; Reception of samples collected by patient and Phlebotomy.

Participants should select a collaborator with knowledge and training to observe Laboratory collaborators performance, fill the form, and return it until deadline. The exercise took place in central laboratories and blood collection sites/hospital ward.

A descriptive analysis was made and sent to participants for self-assessment regarding compliance with good practices as well as to the remaining participants. Comments and suggestions were included.

A binomial logistic model was applied to data from the 23 questions performed in audits between 2019 and 2021, in order to get its trend. A significance level of 0.05 was considered.

Results

The nº of sites observed varied between 11-27 in all study moments (4 or 5). Results to the The questions nº 10, 14 and 17 showed a p-value>0.05 with a positive trend; results to the questions nº 19 and 22 showed a p-value<0.05 with a negative trend and results to the questions nº 5, 8, 18 and 21 presented a p-value=1.00 with 100% of correct answers. For the remaining 14 questions no significant variations were found (Figure 2 and 3).

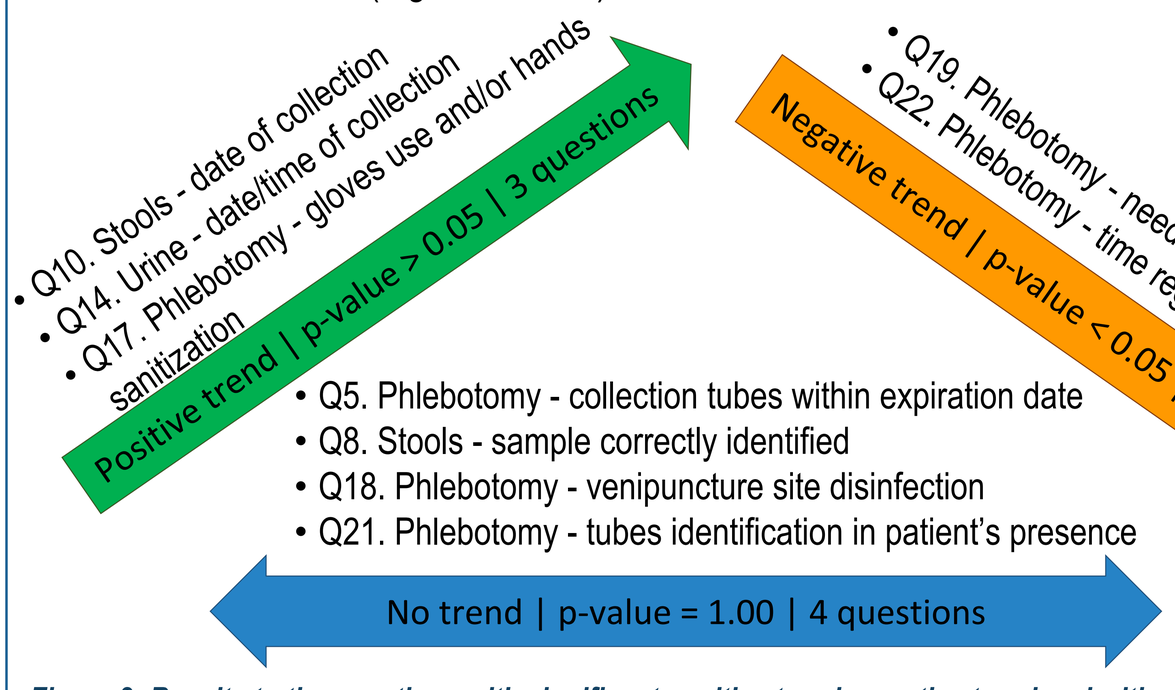

Figure 2: Results to the questions with significant positive trend, negative trend and with no trend between 2019-2021.

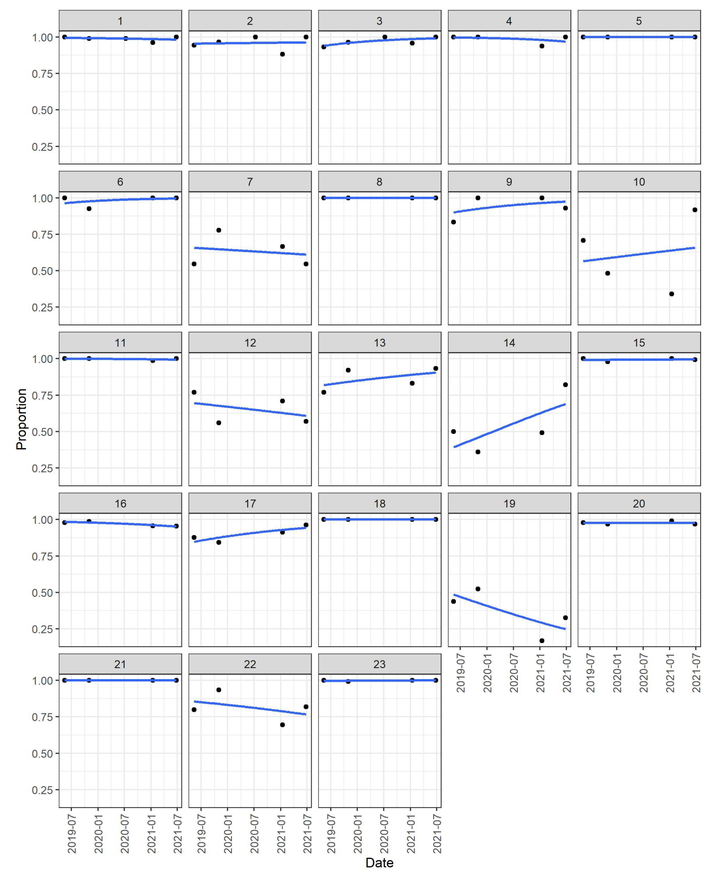

Figure 3: Trend of results for the 23 questions performed between 2019-2021.

Conclusion

From 23 questions of the checklist, 3 shows an improvement in practices, 2 shows a worse performance and 4 maintained a good practice over time. The remaining questions (14) shows no significant variations.

The results obtained demonstrate the need for training and for elaboration of written procedures, as well as the need to review legal matters.

PNAEQ will continue to monitor the process within the participants, identifying critical activities and implementing the necessary tools so they can detect, monitor, reduce and eliminate errors in pre-analytical phase.