

CONTRIBUTION OF EQA TO IMPROVE PREANALYTICAL PRACTICES BY SYSTEMATIC VERIFICATION OF LABORATORY SERVICES



Ana Cardoso, Catarina Ventura, Silvia Viegas, Ana Paula Faria

National Institute of Health Doutor Ricardo Jorge, Epidemiology Department, External Quality Assessment Unit, Portuguese National External Quality Assessment Programme (PNAEQ)

Corresponding author: ana.cardoso@insa.min-saude.pt

Introduction and Aim

International literature describes the preanalytical phase as the most susceptible to errors due to the numerous non-automated activities it involves. Most EQA organizers offer preanalytical schemes to participants. There are basically three types of surveys: procedures registration, samples circulation and errors registration. The Portuguese EQA Programme (PNAEQ) provides these type of schemes for 13 years, using as a guide the ISO 15189:2012. In order to improve the evaluation of the preanalytical phase, PNAEQ recently launched two other preanalytical EQA schemes, mystery client and presentational audits in 2015 and 2016, respectively.

The aim of the **mystery client survey** is to verify whether the information provided to the patient is constant regardless the day and time or if it is dependent on the collaborator.

The aim of the **presentational audit survey** is to give the participants a tool to verify if the procedures performed daily are in accordance with laboratorial good practices recommendations

Mystery Client

Methodology

Mystery client was firstly performed in 2015. PNAEQ prepares an "interview" guide with questions simulating a patient and makes two anonymous phone calls in different date/time to each laboratory. Figure 1 presents the example performed in 2018 (the 2019 round will be performed in the 4th quarter). The questions are regularly modified so that the participants cannot identify PNAEQ as the client. It is also requested the name of the collaborator replying the phone in order to ascertain whether the two telephone calls are answered by the same operator. Participants who do not answer after three attempts are excluded of the round. Results are presented as a comparison of the answers obtained in the two calls for the validated participants.

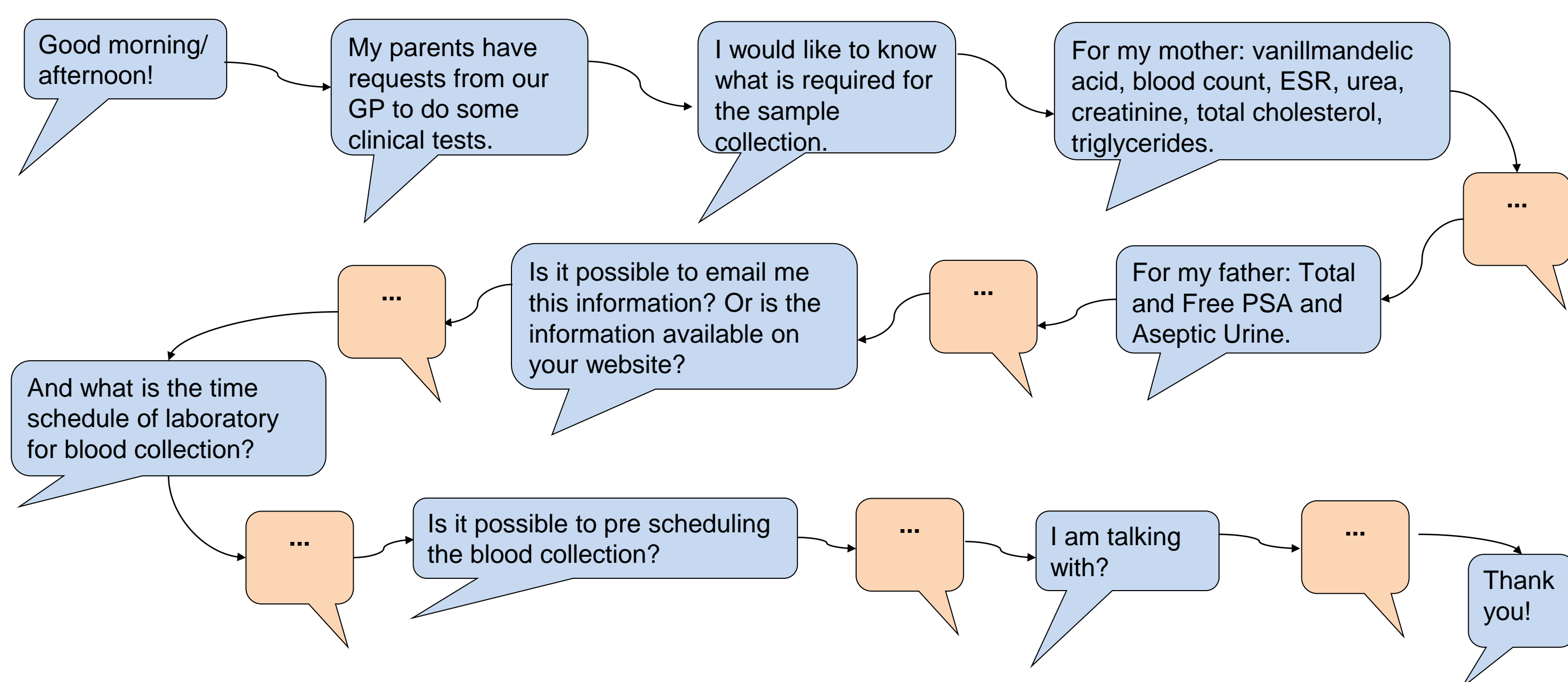
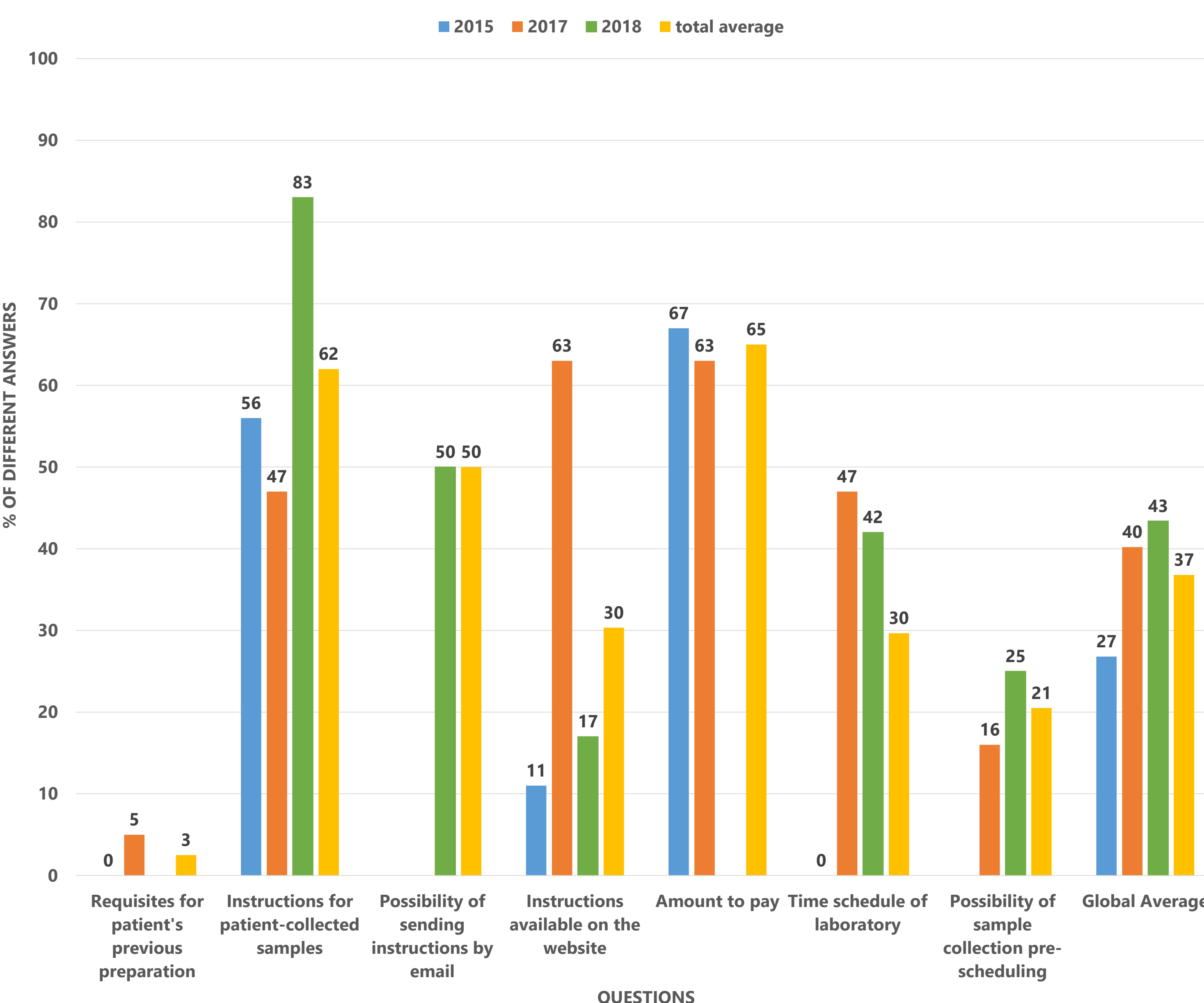


Figure 1 – Example of the "interview" guide performed in the 2018 round.

Results

Graphic 1 represents the results obtained from Mystery Client surveys distributed in 2015, 2017 and 2018. The 2019 survey will be conducted in the 4th quarter. The annual participation rate was 75% in 2015, 95% in 2017 and 63% in 2018.



Graphic 1 – Distribution of the results obtained in Mystery Client surveys performed in 2015, 2017 and 2018. Note: bars with no data means that the item was not included in the "interview".

Conclusion

- Results from Mystery Client surveys demonstrate the need for written procedures and harmonization of practices for all collaborators, as more than a third of the responses differed in date/time and operator in a global view.
- In the Presentational Audit surveys we highlight as critical points the results regarding questions 3, 5 and 6, as they point to specific problems that occurred during the blood collection procedure, such as operator and patient safety, as well as the quality of the sample collected, suggesting the need to review legal and normative issues and to train collaborators.
- Participants who use systematically these two methodologies are monitoring some of the requirements of ISO 15189:2012, namely 4.1.2.6, 4.3, 4.4.1, 4.14, 5.4.2 (both), 5.4.4.2 (mystery client) and 5.1.2, 5.2.2, 5.2.5, 5.3.2.5, 5.3.2.7, 5.4.4 (presentational audit), contributing to release reliable results for medical decisions.
- For the future, we will extend the questions and items in evaluation in these two surveys to Microbiology area and continuing to offer training in Preanalytical matters.

Presentational Audit

Methodology

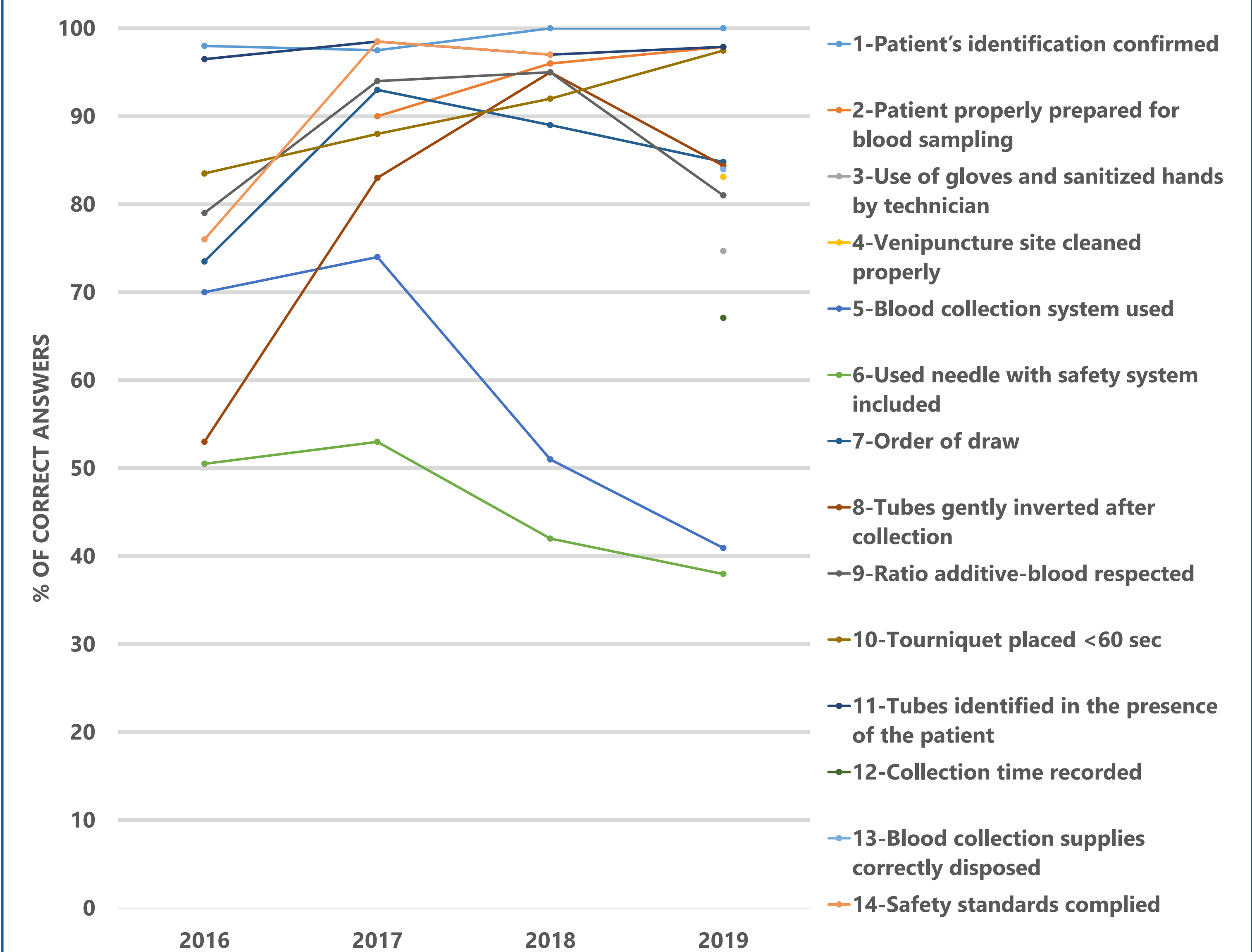
The first checklist for presentational audits was launched in 2016. The checklist (Figure 2) was updated four times based on observed difficulties and incomplete or inconsistent results obtained. The audits are performed in two rounds (except in 2018, only with one round) by a laboratory collaborator with competence and training in these matters. In each round, the auditor should attend to the collection of five blood samples by eight technicians (when possible). Audits should be performed within no more than two weeks to ensure that there are no changes to the procedures. The audits should be performed in two different sites: blood collection sites/outpatient consultation depending on it is a private or public laboratory and in central laboratory. Some questions about the technician basic education, career time, length of service and place of work are also requested. Between the two rounds, participants should provide education to the technicians in order to improve critical points.

| Blood sampling | 1 st blood collection | 2 nd blood collection | 3 rd blood collection | 4 th blood collection | 5 th blood collection |
|---|--|--|--|--|--|
| 1-Patient's identification confirmed? (positive ID) | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 2-Patient properly prepared for blood sampling? | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 3-Use of gloves and sanitized hands by technician? | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 4-Venipuncture site cleaned properly? | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 5-Blood collection system used? | <input type="checkbox"/> Open system <input type="checkbox"/> Open system <input type="checkbox"/> Open system <input type="checkbox"/> Open system <input type="checkbox"/> Open system | <input type="checkbox"/> Open system <input type="checkbox"/> Open system <input type="checkbox"/> Open system <input type="checkbox"/> Open system <input type="checkbox"/> Open system | <input type="checkbox"/> Open system <input type="checkbox"/> Open system <input type="checkbox"/> Open system <input type="checkbox"/> Open system <input type="checkbox"/> Open system | <input type="checkbox"/> Open system <input type="checkbox"/> Open system <input type="checkbox"/> Open system <input type="checkbox"/> Open system <input type="checkbox"/> Open system | <input type="checkbox"/> Open system <input type="checkbox"/> Open system <input type="checkbox"/> Open system <input type="checkbox"/> Open system <input type="checkbox"/> Open system |
| 6-Used needle with safety system included? | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 7-Order of draw? | (indicate 1 st - 6 th) | (indicate 1 st - 6 th) | (indicate 1 st - 6 th) | (indicate 1 st - 6 th) | (indicate 1 st - 6 th) |
| Blood culture bottle | --- | --- | --- | --- | --- |
| Citrate tube | --- | --- | --- | --- | --- |
| Plain tube or tube with clot activator | --- | --- | --- | --- | --- |
| Heparin tube | --- | --- | --- | --- | --- |
| EDTA tube | --- | --- | --- | --- | --- |
| Glycolysis inhibitor tube | --- | --- | --- | --- | --- |
| 8-Tubes gently inverted after collection? | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Blood culture bottle | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Citrate tube | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Plain tube or tube with clot activator | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Heparin tube | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| EDTA tube | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Glycolysis inhibitor tube | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 9-Ratio additive-blood respected? | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Blood culture bottle | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Citrate tube | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Plain tube or tube with clot activator | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Heparin tube | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| EDTA tube | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Glycolysis inhibitor tube | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 10-How long the tourniquet was placed? | seconds | seconds | seconds | seconds | seconds |
| 11-Tubes identified in the presence of the patient? | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 12-Collection time recorded? | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 13-Blood collection supplies correctly disposed? | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Notes (ex.: difficult venous blood access, etc.) | | | | | |

Figure 2 – Checklist used for the blood collection presentational audit, distributed in 2019 1st round.

Results

The results obtained over time in the presentational audits surveys are shown in Graphic 2. In four years were performed 1617 presentational audits in 11 laboratories (annual average). Of the 52 collaborators audited per year (annual average), most of them were biochemical technicians (79%) working in the central laboratory (71%) for 6 or more years (56%) and with a career time equal or superior than 11 years (57%). The annual participation rate was 53% in 2016, 70% in 2017, 60% in 2018 and 67% in 2019.



Graphic 2 – Percentage (annual average) of the results obtained in accordance with good practice (see References) in the presentational audits surveys carried out in 2016, 2017, 2018 and 2019, respectively. Notes: Question 2 was introduced in 2017; questions 3, 4, 12 and 13 were introduced in 2019; question 14 was reworded in 2019.

References

- Portuguese National Law No. 217/99. D.R. Series I-A. 137 (15-06-99) 3410-3417 - Establishes the legal regime for the licensing and supervision of private healthcare units, with a view to making the State responsible for the operation of these units.
- Portuguese National Law No. 121/13. D.R. Series I-A. 161 (22-08-13) 5052-5055 - Establishes the legal framework for the prevention of wounds caused by medical sharp devices that constitute work equipment in the hospital and healthcare units.
- Portuguese National Order No. 8835/01. D.R. Series II. 98 (27-04-01) 7383-7396 - Approves the Manual of Good Laboratory Practices.
- Portuguese National Order No. 597/02. D.R. Series II. 8 (10-01-02) 515 - Defines who is legal qualified to collect biological specimens.
- International Standard ISO 15189:2012. Medical laboratories – Requirements for quality and competence.
- Portuguese National Standard 013/2014. Use and management of gloves in healthcare units. General Directorate of Health.
- A.-M. Simundic et al. EFLM-COLABIOCLI Recommendation for venous blood sampling. Clin Chem Lab Med 2018; aop.
- G. Kristensen et al. How to conduct External Quality Assessment Schemes for the pre-analytical phase? Biochemia Medica 24(1) (2014) 14–22.
- M. Cornes et al. The role of European Federation of Clinical Chemistry and Laboratory Medicine Working Group for Preanalytical Phase in standardization and harmonization of the preanalytical phase in Europe. Annals of Clinical Biochemistry 53(5) (2016) 539–547.
- M. Plebani et al. Performance specifications for the extra-analytical phases of laboratory testing: Why and how. Clinical Biochemistry 50 (2017) 550–554.

