Introduction

The National External Quality Assessment Program (PNAEQ) is included in the Department of Epidemiology of the National Health Institute Doutor Ricardo Jorge, Portugal. The main goal of PNAEQ is to promote, organize and coordinate EQA schemes in 7 areas: Clinical, POCT, Genetics, Pathology and Air, Food and Water Microbiology. In order to enlarge the EQA schemes available, it was established a collaboration protocol with the Finnish company Labquality Oy.

Since 2007, PNAEQ provides a program on preanalytical phase with a transversal evaluation of the laboratory testing process and not only the frequently surveyed analytical phase. In 2014, in collaboration with Labquality Oy, were launched 4 specific schemes in this area: phlebotomy and POCT units, blood gas analysis, clinical chemistry and microbiology.

In international literature, several studies describe preanalytical phase as more prone to errors due to the manually intensive activities like collection, handling, transportation, preparation and storage of specimens. Implementing quality indicators for preanalytical phase allow the laboratories to improve the services quality and patient safety.

Material and Methods

Between 2007 and 2013 laboratories enrolled in the Evaluation in Preanalytic Phase program, organized by PNAEQ, had to respond to 2 surveys/year. In 2014 it was performed 1 single survey. These schemes comprised questionnaires, samples, case studies, medical request simulation and sample handling simulation.

It was performed the evaluation of the results of error monitoring in the surveys sent in 2007 and 2014. The consequences were requested without a significant feedback from the participants.

The goal is to provide a comprehensive view on the appropriateness of the preanalytical phase to the participants.

The results were statistically analyzed and frequency charts were performed. In each survey was prepared a report with the overall results with PNAEQ’s comments.

Results

In 8 years of this program 116 laboratories were enrolled with 40% average of participation. 53% enrolled only once and 16% maintained their registration in 4 or more years. The highest percentage of answers received was in surveys that included shipment of samples with simulated clinical history (61% to 72%) or case studies (44% to 49%). For questions about patient registration and error detection participants submitted their comments on the most appropriate form. For questions about control records and reagent preparation and biosafety situations, we have not had significant response.

It was compared the results of error monitoring on the surveys performed in 2007 and 2013 (with a participation of 27% to 53%, respectively) and the percentage of reported errors is consistent with those described in international literature. The five more representative indicators in the 2 surveys concerned to sample collection are illustrated in the graphic 1. The graphic 2 shows the two indicators evaluated in the both surveys concerned to administrative process.

Conclusion

The first year of the programme implementation had a good reception but the number of inspections decreased 1/7 since 2007 to 2013, with a slight rising in 2014. The ISO 15189: 2012 states that “External quality assessment programs should, as far as possible, provide clinically relevant challenges that mimic patient samples and have the effect of checking the entire examination process, including pre- and post-examination procedures” (item 5.6.4). In addition, it highlights the need to “establish quality indicators to monitor and evaluate performance throughout critical aspects of pre-examination, examination and post-examination processes” (item 4.14.7).

We are working on laboratories sensibilization trying to highlight the importance of recording errors in preanalytical phase and with an important role in formative part. This should warn and encourage the participants to monitor errors that may occur at the beginning of the analytical process, because not reporting errors does not mean their absence. We are trying to work together with our participants in order to have an annual meeting to discuss the indicators monitoring process and implement corrective actions, preventive actions and continual improvement.

The participation on a EQAS pre analytical program can help to compare the results and to improve laboratories performance.

References

- Documento LE nº 121/5. D.B.P.S. n.º 121-08 CE 1062-59S – Estabelece a regime jurídico relativo à prevenção de fendas provocadas por dispositivos médicos e controlo de segurança dos mesmos.