_Programa Nacional de Avaliação Externa da Qualidade

Portuguese EQAS vision *versus* experience on Pre-Analytical Phase (2007-2011)

EQALM SYMPOSIUM 2011

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Pre-Analytical Phase EQA Program

Objective:

The main objective of this program is to evaluate the performance of participants in order to improve the performance of clinical laboratories nationwide in pre-analytical phase.

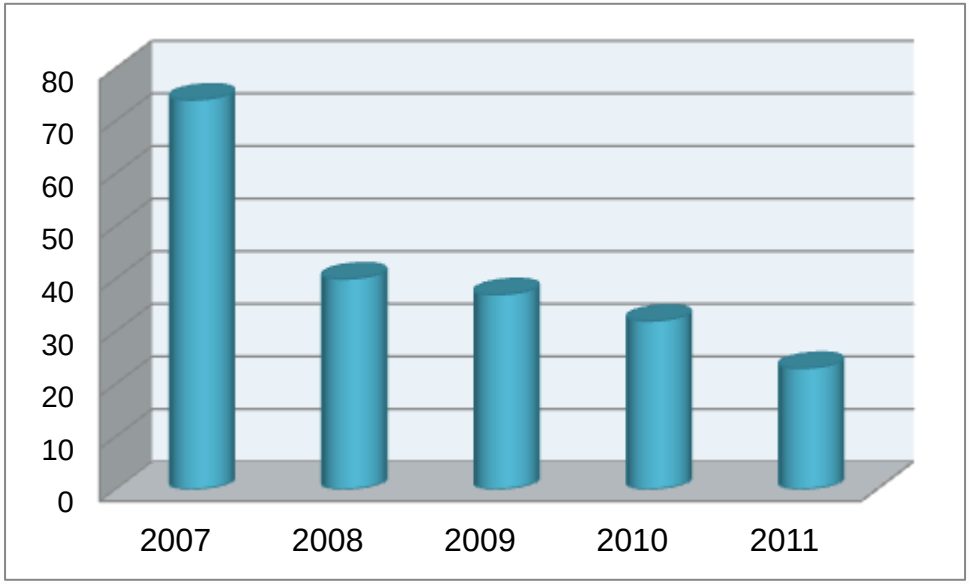
This study evaluated the results obtained in 9 surveys by laboratories participating in the PNAEQ

Pre-Analytical Phase EQA Program

In 2007 the Evaluation of Pre-Analytic Phase was implemented, now part of the 77 existing Clinical Programs in the National External Quality Assessment of the National Institute of Health, Portugal.

2 surveys per year.

Number of participating labs/year



-Although there has been a good first year, there was a decrease in the number of laboratories enrolled over the years (in 2011 less than 1/3 compared to 2007), but with a tendency to an increase active participation in surveys that included sample analysis and case study.

Year	2007		2008		2009		2010		2011	
Number of participating labs	74		40		37		32		23	
% answers	28	27	**65**	43	**63**	49	44	18	**61**	
Average answers/year (%)	28 %		**54%**		**56%**		31%		**61%**	

Results

- The results were statistically analyzed.

  frequency charts performed, according with clients answers.

- In each survey a joint report was prepared with the overall results and pertinent comments.
- It was always proposed that the laboratory staff members jointly reviewed the report card, so that they can draw conclusions and make the self-evaluation.

2007- Questionnaire :

Laboratories were asked to count and classify errors:

- With **no consequence** for the patient
- With **moderate consequence** (need for repeat sampling and timely resolution of the error)
- with **serious consequences** (without timely resolution of the error).

Formulas

The method of calculation of **% error** (number of errors detected / total number of patients during the study period) * 100

Method of calculating percentage of **consequence** (number of moderate or severe consequence / number of errors detected * 100)

2007 – Results (1)

% of errors with moderate consequence found after completing two questionnaires distributed in the first trial of pre analytical phase in the Laboratory and sampling station.

		CL1	CL2	SS1	SS2
Sampling (1)	Incorrect primary sample collection	70	71,4	60	71,4
	Insufficient amount of primary sample	62,5	75	66,7	71,4
	Lack of collection for the requested	60	85,7	75	62,5

CL – laboratory SS – Sampling station

Sampling Station (SS)

Collection

Transport

Central Laboratory (CL)

Collection and analysis

2007 – Results (2)

% of errors with moderate consequence found after completing two questionnaires distributed in the first trial of pre analytical phase in the CL and SS.

		CL1	CL2	SS1	SS2
Sampling(2)	Sample collection without confirmation of requirements	28,6	33,3	-	50,0
	Incorrect labeling of sample tubes	33,3	62,5	-	-
	Use of expired sample material	25,0	-	-	-

CL– laboratory; SS – Sampling station

2007 – Results (3)

% of errors with moderate consequence found in CC1,2 and SS1,2.

		CL1	CL2	SS1	SS2
Adminsitrative/Documents(3)	Incomplete request form	14,3	-	33,0	-
	Identity of the client not confirmed	33,3	33,3	-	-
	wrong delivery or lack of instructions for preparation of the patient	33,3	-	-	-
	Lack of indication of urgent request	40,0	-	-	-
	Incorrect reading and registration of request	42,9	-	46,7	14,3

CL – laboratory SS – Sampling station

2007 – Results (4)

% of errors with moderate consequence found after completing two questionnaires distributed in the first trial of pre analytical phase in the Laboratory and sampling station.

		CL1	CL2	SS1	SS2
Others (4)	Incorrect sample conservation	20,0	-	-	-
	Icteric, coagulated, hemolysed samples	46,0	-	-	-
	Broken tubes in centrifuge	33,3	75,0	-	50,0

CL – laboratory SS – Sampling station

Not reporting errors,
does not mean their absence.

Conclusion of these two first surveys

- It was in the **sampling** area where was reported a higher % of error (moderated).

- **Handling** of samples and interpretation of the **requests** also deserves special attention.

- It was in the Central laboratories and in the 1st survey we have got a higher % of responses.

- Taking advantage of the lifting of the current situation with the analysis of responses sent, we organized the surveys of the following years based on the % and classification of the errors found.

2008 ➡ 2011 we distributed :

- samples with case studies
- medical request simulation
- sample handling simulation
- emergency situations,
- cases of drugs interference.

We made considerations of

- Demanding of the National legislation and guidelines of the General Directorate of Health;

- contents of collection manual;

- different conditions for special collection;

- collections in sampling stations;

- biosafety considerations;

- equipment and sample material;

- criteria for sample rejection;

- control and reagent preparation;

- record of traceability of the pre-analytical process.

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Requisição de Análises

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INFORMAÇÃO DE ANÁLISE

DATA DA COLHEITA 18.12.2008

ANALISES A EFECTUAR

Prova de Tolerância á glucose
PCR Hepatite C
Colesterol
Triglicéridos
PSA total
Exsudado ocular

INFORMAÇÃO DO MÉDICO

MEDICO REQUISITANTE Dra Francisca Menezes **TELEFONE** 21 751 9350

Lisboa, 17 de Dezembro de 2008

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Requisição de Análises

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INFORMAÇÃO DE ANÁLISE

ANALISES A EFECTUAR

Acido Úrico
Bilirrubina total
Glicose
Ureia
Creatinina
Colesterol total
Triglicéridos
Urina II

INFORMAÇÃO DO MÉDICO

MEDICO REQUISITANTE Dr. José Ribeiro **TELEFONE** 21 751 9350

Lisboa, 11 de Junho de 2009

Summary (1)

Documentary / Administrative

	Questionnaire	Evaluated in	%
Incomplete request form	14,3% and 33,0%	2008 and 2009	40%
Identity of client not confirmed	33,30%	2008 and 2009	40%
Lack of indication of urgent request	40%	2008, 2009, 2010 and 2011	33%
Incorrect reading and registration of request	42,9%, 46,7% and 14,3%	2008, 2009, 2010 and 2011	40%

Summary (2)

Sample collection

	Questionnaire	Evaluated in	%
Incorrect primary sample collection	70%, 71,4%, 60% and 71,4%	2008, 2009, 2010 and 2011	-
Insuficient amount of primary sample	62,5% 75% 66,7% 71,4%	2008	-
Lack of collection for the requested	60% 85,7% 75% 62,5%	2008	-
Sample collection without confirmation of requirement	28,6% 33,3% 50%	2008, 2009, 2010 and 2011	-

Summary (3)

Other

	Questionnaire	Evaluated in	%
Incorrect sample conservation	20%	2009 and 2010	-
Broken tubes in centrifuge	33,3% 75,0% 50%	2008 and 2011	-
Use of expired sample material	25%	2008, 2009 and 2011	-

Conclusion (1)

-The highest percentage of answers received was in surveys that included shipment of **samples** with simulated clinical history (44 to 65%) or case studies (63%).
In these surveys we considered some incomplete comments.

- In **patient registration** and error detection in simulated medical **request**, participants submitted their comments on an appropriate and complete way.

-For questions asked on control records and reagent preparation, questionnaires with accounting errors and biosafety situations, we have not had significant response.

-We consider we are still in the **sensibilization process** of laboratories, trying to highlight the importance of the participation in this program.
In the report cards, information is sent on critical points inherent in this phase.

Conclusion (2)

-We believe that the **formative** part of this program may warn, encourage and sensitize the participants to errors that may occur at the beginning of the analytical process.

- Laboratories that had an assiduous involvement in 4/ 5 years, have the **quality management system** implemented, (a facilitating tool for a response to the program), demonstrating a practice of procedures with records for detection and quantification of errors in different phases of the analytical process.

Conclusion (3)

According to recent bibliography it's in the pre-analytical phase that a predominance of errors is observed (32 to 75%), that are not noticed, or are overlooked in assessment procedures or result interpretation.
It became, therefore, important to monitor its use, as well as the absolute necessity to compare and standardize procedures.

Although with an average participation in the first survey of only 27%, the percentage of reported errors is consistent with those described in the literature.
In the itens that we were able to quantify, the % found in the questionnaire and over the next 4 years were similar.

Not reporting errors, does not mean their absence.

2012….

-We'll distribute another **questionnaire** to record errors and their classification.

- We´ll try to develop **simpler tests** to facilitate the processing of information.

--We'll **increase the frequency** to three times a year.

-We'll try to provide tools to facilitate implementation of quality **indicators** that will cover the entire pre analytical phase.

-As main purpose, we want to study the evaluation of the **impact of errors** in future trials.

Portuguese PNAEQ Team

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Helena Correia	Cristina B. Correia	Raquel Rodrigues

Administrative Services

Cristina Brito | Paula Melo | Nazaré Ventura | Helena Jorge

"If you are working on something exciting that you really care about,

you don't have to be pushed.

The vision pulls you "

Steve Jobs

Thanks ☺

"Portuguese EQAS vision
versus
experience on Pre-Analytical Phase
(2007-2011)"

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