THE IMPACT OF LEGISLATIVE CHANGES ON QUALITY OF ACTIVITIES IN MEDICAL LABORATORIES

RĂZVAN MIHAI POPA[1]

[1]*Association for Quality in Laboratories (CALILAB), Bucharest*

Keywords: *legislation, legislative changes, external quality control, statistical calculations, coefficients of variation percentages, comparison values*

Abstract: *The goal of this study is to correlate the legislative changes on quality of medical laboratories activities demonstrating the increase of the quality of the service provided by them through comparing the average coefficient of variation of the results reported to the external quality control organized by a national provider in 2008, 2010, 2013 and the round in November 2014, in the fields of biochemistry, hemostasis, hematology for the selected analytes and parameters attended by, between 139 and 233 laboratories in Romania in almost all counties (keeping the confidentiality of the individual results of evaluations of performance in medical laboratories). The methods used are the comparison of articles of legislative texts on the organization and functioning of medical laboratories in the period 2004 – 2015, statistical calculations and comparison of average percentage coefficients of variation as a measure of dispersion values reported by participants for the analytes and parameters included in the study between 2008 – 2014. There was observed a correlation between legislative changes and significant decrease of the mean average coefficients of variation for the analytes and parameters selected from the fields of biochemistry, hematology and hemostasis in the period performing the study. The legislative changes in the period 2004 – 2015 have had a positive impact on the quality of services provided by medical laboratories demonstrated by the significant decrease in the mean average coefficients of variation for the analytes and parameters selected from the fields of biochemistry, hematology and hemostasis in the period 2008-2014*

INTRODUCTION

Romania is one of European Union member countries subject to new challenges in terms of the viability of the national health system.

The main change, which has occurred in the health system in Romania, as a result of political changes from 1989, is the replacement of the centralized health system with a health system whose funds are mainly insured from social health insurances.

Amendments to the provisions on the Methodological Norms for the period 2010 - 2015 Frame - Contract enforcement on the conditions of providing medical assistance in the health insurance systems for medical analysis laboratories.

In this study, we analyzed the legislation with direct impact on the quality of the medical laboratories activity namely, the Implementing Rules, which are approved annually by the common Order of the Minister of Health and Chairman of the National Health Insurance House (CNAS) as an Annex to the Frame - Contract Frame on providing medical assistance within the social health insurance system comparatively analyzed for each of the years 2010 to 2015.

From the comparative analysis, we can see that there has been removed, starting with 2013, the financial criteria that existed in 2011, 2012 from the Criteria for selecting healthcare providers laboratory, the 5% being distributed to Resource evaluation criteria, so that in the years 2013, 2014 and 2015, there were only two assessment criteria for the distribution of funds from the budget of health insurance that we will analyze in this study:

- Resource evaluation criterion with a weighting of 50%;
- The quality criterion with a weighting of 50%.

a. Analysis of changes in provisions on the criterion for assessing the resources (human and technical) highlights the following:

Technical resources - for appliances in all three studied compartments: Biochemistry, Hematology and Hemostasis:

- existence since 2015 of the proof of service contract signed with a provider approved by the Ministry of Health and for the appliances out of warranty, approved by manufacturer as well, and not pointing in 2015 appliances older than 8 years from the date of manufacture;
- changing the score given the for automatic analyzers compared to the semi-automatic ones, taking into account the speed – the number of tests per hour, the number of parameters, as well as the techniques used, the more modern analytical techniques having a higher score;
- scoring of some medical laboratory analysis required to the laboratory and adding them to the score of the equipment in question - electrophoresis, ion urinary biochemistry;

Human resources:

- since 2014, the introduction of the title "medical" for biologists, chemists and biochemists bearing the degree of specialist and primary within medical laboratories;
- since 2014, increase in scoring for human resources and the introduction of scoring for the licensed pharmacists and nurses employed in medical laboratories, of scientific researchers and research assistants in pathology;

b. Analysis of changes in provisions on quality criteria highlights the following:

- annual mentioning in the legal text of the total number of analyzes included in the medical laboratory investigations list to demonstrate that at least 50% the number of analyzes

[1]Corresponding author: Răzvan Popa, Str. J.L. Calderon, Nr. 36, Sc. A, Ap. 7, București, România, E-mail: razvanmihaipopa@gmail.com, Phone: +4021 2313433

Article received on 28.09.2015 and accepted for publication on 26.11.2015
ACTA MEDICA TRANSILVANICA December 2015;20(4):30-34

included in the list of contracted investigations, for each of the laboratories / laboratories organized as workstations to be included in the contract, to provide medical laboratory services – medical laboratory analyses throughout the entire duration of the contract concluded with the health insurance fund, there is proof that quality criteria, both sub-criteria a) "The implementation of quality management system" as well as sub-criteria b) "Participation in proficiency testing schemes for medical laboratories for medical analysis laboratories notified by the Ministry of Health" are met;

- annual specification of the minimum 4 annual mandatory participations in the external quality control (or stated in the previous year), and in 2015, it is also mentioned the maximum number of participations in the external quality control, CNAS settled, respectively 12 participations in the previous year;
- detailed explanation of the requirements relating to the participation in inter-laboratory schemes in the years 2014, 2015.

MATERIALS AND METHODS

The introduction, starting with 2015, of the compulsoriness of submitting by the contracting supplier, respectively during the contract for the supply of medical services, the documents whereby the manufacturer of laboratory equipment, reagents and consumables, certifies the compliance with EN ISO 13485: 2003 for all instruments, reagents and consumables laboratory used for medical services which make the object of the contract signed with the health insurance house.

Evaluation of performance of medical laboratories in Romania

The performance of medical laboratories in Romania is a critical factor for obtaining quality medical services since over 70% of medical diagnoses are set on medical tests.

This study analyzes the values of the coefficient of variation or variability as one of the scattering indicators around central tendency represented by mean, dispersion and standard deviation and one of the statistical calculations used to assess participants' performance.

In this study, we have selected the use of the analysis of variance percentage coefficient values because it is an indicator of scattering which takes into account all the values reported by participants in the external quality control and the scattering of each value around the mean of all reported values.

The percentage representation of the variation coefficient is preferred, which is noted by CV% and it is named the coefficient of variation or variability that represents the percentage of standard deviation (S) or mean (M):

$$CV=\frac{S}{M}=\frac{S*100}{M}\%=CV\%$$

The overall analysis of the results reported by participants in the external quality control round in November 2014 compared to the results reported by participants at external quality control rounds in the years 2013, 2010 and 2008

The overall analysis of the results reported by participants in external quality control organized by a national supplier of external quality control is carried out maintaining the confidentiality of performance assessment results of individual medical laboratories participating in the proficiency testing scheme rounds.

The domains of the medical analysis laboratory the study was performed for are:

- *serum-biochemistry* - for analytes/proficiency tests: glucose, creatinine, cholesterol, iron, urea, uric acid transaminase - TGO, magnesium;
- *hematology* - blood count for three parameters: the number of white blood cells, red blood cells and haemoglobin;
- *haemostasis* - Quick time and serum fibrinogen;

The study consisted in the analysis of the average values of the coefficients of variation of the results obtained after having measured the objects submitted to proficiency tests for the relevant medical tests mentioned above within the field of proficiency testing schemes - biochemistry, hematology and haemostasis performed by medical laboratories in Romania, participating in the external quality assurance schemes, organized by a national provider of external quality control in 2014, compared with the average values of the coefficients of variation of the corresponding results achieved in the years 2013, 2010 and 2008.

RESULTS AND DISCUSSIONS

The study was performed for analyzes in the field of biochemistry, quantitative determinations of serum: glucose, creatinine, cholesterol, iron, urea, uric acid transaminase - TGO, magnesium (table no. 1), analyzes in the field of hematology - blood count for three parameters: number of leukocytes, erythrocytes number and hemoglobin (table no. 2) and analyzes in the field of haemostasis - Quick time and fibrinogen levels (table no. 3) using as a research instrument the values of the variation coefficients - one of the indicators of the quality of services provided by medical analysis laboratories.

Biochemistry quantitative determinations of serum: glucose, creatinine, cholesterol, iron, urea, uric acid, transaminase - TGO, magnesium

The average coefficients of variation for the results obtained after measuring the competency test of the analytes in the field of serum quantitative determinations – biochemistry: glucose, creatinine, cholesterol, iron, urea, uric acid transaminase - TGO, magnesium, each of three years-2008, 2010 and 2013 and in round from the month of November 2014 is highlighted in table no. 2 preceded by table no. 1 that presents the average values of the coefficients of variation obtained for the eight analytes studied both annually and in each quarter of 2008 and 2010.

It is noted that the average value of the coefficient of variation in 2013 is lower than the average value registered in 2010, respectively in 2008 for all the eight medical analyses in the field of serum quantitative determinations - biochemistry, in the three years studied.

The round of external quality control in November 2014 notes:

- A decrease in the value of the coefficients of variation for the analytes: glucose, creatinine, cholesterol, transaminase TGO and magnesium compared to the corresponding values of the previous years (2013, 2010, 2008);
- A slight increase in the value of the coefficients of variation for the analytes: serum iron, urea and uric acid, compared to their respective values in 2013.

Common comparison groups of the results with quantitative data reported by medical laboratories participating in the study were made by:

- Measurement methods, identical or technically equivalent - in serum biochemistry
- Measuring equipment, identical or technically equivalent in the fields of hematology and hemostasis.

The objects submitted to proficiency test distributed to participants were measured by them using a number of 27 kinds of measuring equipment found in the medical laboratories in Romania to perform medical tests for patients (table no. 2).

Table no. 1. Biochemistry - Comparison of the mean value of coefficients of variation obtained in the years 2008-2013 and the round in November 2014

Biochemistry - Comparison of the mean value of coefficients of variation obtained in the years 2008-2013 and the round in November 2014													
No.	Test	2008					2010					Average annual 2013	The mean value November 2014
		Trim. I	Trim. II	Trim. III	Trim. IV	Average annual 2008	Trim. I	Trim. II	Trim. III	Trim. IV	Average annual 2010		
1	GLUCOSE	± 7,89%	±7,19%	±7,19%	±9,06%	**±7,83%**	± 4,26%	±5,69%	±5,2%	±4,19%	**±4,83%**	**±4,17%**	**±4,08%**
2	CREATININE	±20,64%	±12,47%	±12,47%	±13,28%	**±14,71%**	±10,19%	±16,68%	±14,48%	±9,68%	**±12,76%**	**±10,56%**	**±8,26%**
3	CHOLESTEROL	±8,44%	±9,47%	±8,80%	±8,98%	**±8,92%**	± 5,65%	±4,75%	±4,9%	±6,34%	**±5,41%**	**±4,73%**	**±4,40%**
4	SERUM IRON	±36,34%	±36,97%	±36,17%	±27,96%	**±34,36%**	±16,30%	±10,78%	±9,58%	±13,16%	**±12,45%**	**±10,55%**	**±10,68%**
5	UREA	±27,30%	±12,93%	±12,3%	±14,24%	**±16,69%**	±7,38%	±6,63%	±7,56%	±5,85%	**±6,85%**	**±6,60%**	**±7,09%**
6	URIC ACID	±13,18%	±7,73%	±7,3%	±7,06%	**±8,82%**	±6,26%	±8,12%	±9,26%	±6,13%	**±7,44%**	**±6,08%**	**±6,40%**
7	TRANSAMINASE TGO	±14,53%	±15,73%	±15,3%	±12,11%	**±14,42%**	±9,26%	±9,8%	±8,81%	±7,13%	**±8,75%**	**±7,47%**	**±6,47%**
8	MAGNESIUM	±14,97%	±16,55%	±16,5%	±14,27%	**±15,57%**	±10,81%	±9,48%	±8,56%	±10,04%	**±9,72%**	**±6,90%**	**±5,95%**

Table no. 2. The types of measurement equipment used by medical laboratories participating in the proficiency testing scheme - serum biochemistry in round external quality control in the month November 2014

No.	Name of equipment Biochemistry	No.	Name of equipment Biochemistry
1	Abbott	14	Dimension
2	ABX	15	Dirui
3	Other equipment	16	Easy Lyte (ion analyzer Na / K)
4	Avl	17	Eos Bravo Forte
5	Beckman Coulter	18	Ependorf
6	Biolis	19	Flexor
7	Biolyzer	20	Hitachi
8	Biosystems	21	Humalyzer
9	Biotecnica	22	Humastar
10	BT Targa	23	Ilab
11	Chemwell	24	Konelab
12	Cobas	25	Mindray
13	Cyan	26	Selectra
		27	Vitros – dry chemistry

Haematology - blood counts - three parameters: number of leukocytes, erythrocytes and hemoglobin number

The average value of the coefficients of variation for the results obtained from the measurement of the object submitted to the competence test of parameters in the field of hematology - blood count - number of white blood cells, red blood cells and hemoglobin in the round made in the month of November 2014, compared with the mean value of the variation coefficients obtained in each of the three years, 2008, 2010 and 2013 is highlighted in the table no. 4, which presents the average values of the coefficients of variation obtained for the three studied parameters of blood count, both annually and in each quarter of 2008 and 2010.

The round of external quality control in November 2014 notes: a slight decrease of the coefficients of variation for all the three parameters as against the values obtained in the previous years (2013, 2010, 2008).

Common comparison groups were performed by the specialists of the national provider of external quality control for a number of 15 kinds of measuring equipment and a group with measuring equipment, technically equivalent called "other equipment" located in the departments of hematology and used by the medical laboratories in Romania to conduct medical analyzes for patients (table no. 4).

Hemostasis - Quick time and serum fibrinogen

The average coefficients of variation for the results obtained after the testing competency measurement of analytes in the field of haemostasis - Quick time and serum fibrinogen in the round of external quality control in the month November 2014, compared with the average variation coefficients obtained in each of three years, 2008, 2010 and 2013 are shown in table no. 5, which presents the average values of coefficients of variation obtained for the two analytes studied, both annually and in each quarter of 2008 and 2010.

Table no. 3. Hematology - blood count - Comparison of the mean value of the coefficients of variation obtained in the years 2008-2013 and the round in November 2014

Hematology - blood count - Comparison of the mean value of coefficients of variation obtained in the years 2008-2013 and round in November 2014													
No.	Test	2008					2010					Annual average 2013	The mean value November 2014
		Trim. I	Trim. II	Trim. III	Trim. IV	**Annual average 2008**	Trim. I	Trim. II	Trim. III	Trim. IV	**Annual average 2010**		
1	Leukocytes WBC	±23,0 %	±14,89 %	±14,8%	±8,64%	**±15,33%**	± 8,99%	±4,94 %	± 5,72%	±4,73%	**±6,10%**	**±5,09%**	**±4,33%**
2	Erythrocytes	±3,5%	±3,82%	±3,2%	±4,85%	**±3,84%**	± 3,38%	± 3,54%	± 2,95%	± 2,78%	**±3,16%**	**±2,70%**	**±2,23%**
3	Hemoglobin	±8,5%	±4,52%	±4,2%	±5,16%	**±5,60%**	±4,03 %	± 3,21%	± 3,43%	± 3,21%	**±3,47%**	**±3,50%**	**±2,19%**

Table no. 4. The types of measurement equipment used by medical laboratories participating in the proficiency testing scheme in the area - Hematology in the round of external quality control in the month November 2014

No.	Name of equipment Hematology
1	ABACUS
2	ABX
3	Other equipment
4	BECKMAN COULTER
5	CELLDYN
6	CELLTAC
7	DREW EXCELL - 2280
8	MINDRAY
9	MINDRAY - BC 3000 PLUS
10	MINDRAY - BC 5300
11	MINDRAY - BC 5800
12	MINDRAY - BC-2800
13	MS - MELET SCHLOESING
14	MYTHIC
15	RAYTO
16	SYSMEX

The round of external quality control in November 2014 notes: an increase in the value of the coefficients of variation for both studied parameters compared to their values from previous years (2013, 2010, 2008), when it was observed a constant annual reduction of the coefficients of variation.

Common comparison groups were made by the specialists of the national provider of external quality control for a number of 11 kinds of measuring equipment and a group with technically equivalent measuring equipment called "other equipment" found in the hemostasis equipment departments and used by the medical laboratories in Romania to perform medical tests for patients (table no. 6).

Table no. 6. The types of measurement equipment used by medical laboratories participating in the proficiency testing scheme - Haemostasis in the round of external quality control in the month November 2014

No.	Name of Equipment Haemostasis
1	ACL
2	Other equipment
3	AMELUNG
4	BFT
5	COADATA
6	COATRON
7	DIA TIMER
8	RAYTO
9	START
10	SYSMEX
11	THROMBOLYZER
12	THROMBOTIMER

Table no. 5. Haematology-Haemostasis - Comparison of the mean value of coefficients of variation obtained in the years 2008-2013 and round in November 2014

Haematology-Haemostasis - Comparison of the mean value of coefficients of variation obtained in the years 2008-2013 and round in November 2014													
No.	Test	2008					2010					Annual average 2013	The mean value November 2014
		Trim. I	Trim. II	Trim. III	Trim. IV	Annual average 2008	Trim. I	Trim. II	Trim. III	Trim. IV	Annual average 2010		
1	Quick time	±22,2 %	±23,1%	±23,1%	±22,0%	**±17,60%**	±11,0 %	±15,2%	±10,6%	±11,0%	**±11,95%**	**±12,36%**	**±17,33%**
2	Serum fibrinogen	±27,7 %	±20,5%	±20,5%	±26,2%	**±23,73%**	±13,7 %	±20,4%	±13,4%	±12,2%	**±14,93%**	**±11,77%**	**±17,81%**

CONCLUSIONS

This study presents the values of coefficients of variation of the results reported to the external quality control organized by a national supplier in 2008, 2010, 2013 and the round in November 2014 in the fields of biochemistry, hemostasis, hematology for the selected analytes and parameters.

External quality control is a tool that measures the comparability of results of medical tests given to patients by medical laboratories by using statistical calculations.

In our study, we demonstrated the increase of comparability of the results of medical tests by lowering the annual coefficients of variation for the analytes and parameters selected for biochemistry, hemostasis, hematology fields.

The methodological amendments to the Norms for the period 2010-2015 for the implementation of the Frame - Contract on the conditions to grant medical assistance within social health insurance systems for medical analysis laboratories are correlated with the coefficients of variations studied in the period 2008- 2014.

The methodological amendments to the Norms for the period 2010 - 2015 have had positive impact on increasing the quality of medical laboratories activity demonstrated by the decrease of the coefficient of variation or variability as one of the indicators measuring each value scattering around the mean values of all values reported by the participants in the external quality control organized by a Romanian supplier.

Comparability of the results of medical tests offered to patients by medical laboratories is a must regardless of the equipment, qualification and number of specialists employed, laboratories space, reagents, calibrators, internal controls or the measurement methods used by medical laboratories.

External quality control as a medical service is an instrument which measures effectiveness and comparability of measurement methods used to perform analyzes to patients by medical laboratories, such that a patient should not be declared healthy on the basis of a analysis report issued by a laboratory and sick based on a different analysis report issued by the same laboratory or a different laboratory.

The statistical data obtained upon performing the external quality control are useful only together with and closely linked to the medical service provided by medical laboratories

and represented the patients' medical test results.

REFERENCES

1. Dragomirescu L, Drane JW. Biostatistics for beginners. Vol I. Descriptive Biostatistics. 6 revised edition, Publisher CREDIS, ISBN 978-973-734-4618, Bucharest; 2009. p. 207.
2. Order no. 2071 of 16 December 2008 approving the procedure for notification of proficiency testing schemes for medical laboratories issued by the Ministry of Public Health and published in the Official Gazette no. 11 of January 7, 2009;
3. Order no. 1301 of 20 July 2007 approving the Norms on medical analysis laboratories functioning issued by the Ministry of Public Health and published in the Official Gazette no. 617 of 6 September 2007.
4. Standard EN ISO 15189:2012 Medical Laboratories requirements for quality and competence.
5. Standard EN ISO IEC 17043: 2010 General Requirements for Conformity Assessment proficiency tests.
6. Specific rules for accreditation of providers of proficiency testing according to ISO IEC 17043 of 10.24.2014.
7. Government Decision no. 262/2010 approving the Framework Agreement on the conditions of granting medical assistance within the health insurance system for 2010.
8. Order Nr. 265/408 of 1 April 2010 approving the Methodological Norms for the application of the Framework Agreement on the conditions of granting medical assistance within the health insurance system for 2010.
9. Government Decision no. 1389/2010 for the approval of the framework conditions for granting medical assistance within the health insurance system for the years 2011 – 2012.
10. Order no. 864/538 of 31 May 2011 approving the Methodological Norms for the application of the Framework Agreement on the conditions of granting medical assistance within the health insurance system for 2011.
11. Government Decision no. 1389/2010 for the approval of the framework conditions for granting medical assistance within the health insurance system for the years 2011 - 2012;
12. Order no. 1723/950 of 20.12.2011 approving the Methodological Norms for the application of the Framework Agreement on the conditions of granting medical assistance within the health insurance system for 2012.
13. Government Decision no. 117/2013 approving the Framework Agreement on the conditions of granting medical assistance within the health insurance system for the years 2013 – 2014.
14. Order no. 864/538 of 31 May 2011 approving the Methodological Norms for the application of the Framework Agreement on the conditions of granting medical assistance within the health insurance system for 2013.
15. Government Decision no. 400/2014 approving the Framework Agreement on the conditions of granting medical assistance within the health insurance system for the years 2014 – 2015.
16. Order no. 619/360 from 29.05.2014 approving the Methodological Norms for the application of the Framework Agreement on the conditions of granting medical assistance within the health insurance system for 2014.
17. Government Decision no. 400/2014 approving the Framework Agreement on the conditions of granting medical assistance within the health insurance system for the years 2014 – 2015.
18. Order no. 388/186 of 31 May 2015 approving the Methodological Norms for the application of the Framework Agreement on the conditions of granting medical assistance within the health insurance system for 2010.