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Compliance with the clinical laboratory quality protocol in public primary healthcare centres

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Abstract

The clinical and economic relevance of the clinical laboratories procedures in Andalusia (Spain) have led the Regional Department of Health to focus attention on their improvement. A unified laboratory protocol was implemented that consisted of the unification of criteria in the handling and processing of samples, and report of results.

The objective of this study is to describe the degree of compliance with the clinical laboratory protocol in the preanalytical phase, which includes the analytical request and up to the delivery in the laboratory, as well as the influencing factors.

Cross-sectional descriptive study with a sample of 214 healthcare professionals involved in the preanalytical phase of laboratory procedures in primary care. A self-reported questionnaire with 11 items was used for data collection. Each item was assessed separately with a scale from 0 to 10. A 5 points score was considered as the cutoff point. Descriptive analysis was conducted and Mann–Whitney *U* test was used to determine differences between subgroups. Internal consistency of the questionnaire was considered.

The best rated item was verifying the correspondence between the request form and identity of the patient. Each item scored from 3 to 10, and the mean for each item ranged from 6.40 (standard deviation=3.06) to 8.57 (standard deviation=2.00). Values above or equal to 8 were obtained, for 63.6% of them. Statistically significant differences between accredited and nonaccredited centres were found. Differences were not noteworthy regarding centres with a teaching activity or those without it. All the items were measured separately. The compliance with the protocol was adequate among primary healthcare professionals, who have a strategic position in the sample collection and its transport during the preanalytical phase. Being so, standardisation should be a priority to reduce errors and improve clinical safety and results.

Abbreviations: ACSA = agencia de calidad sanitaria de Andalucía – Andalusian health quality agency, PAI = procesos asistenciales integrados – integrated care processes, PC = primary care, SD = standard deviation.

Keywords: error prevention, healthcare management, preanalytical errors, primary care, quality control

1. Introduction

During the last 3 three decades clinical laboratories have undergone a revolutionary change due, among other reasons, to the great technological advancement and the active participation of staff. Thanks to new available resources, laboratory professionals have been able to supply a broader service, including a large variety of tests and increasing the volume of work, without undermining the quality in the results. This has led to a centralized management strategy in which large laboratories provide service to all departments of the healthcare system.[1]

The extensive number of professionals and activities involved in the support process of clinical laboratories requires coordinated action between professionals and levels of care.[2] Since 2000 the Andalusian Regional Department of Health adopted a management model organized by care processes which is proposed as a central part of a strategy to guarantee the quality of services in the public health system.[3] This strategy includes the procesos asistenciales integrados for its acronym in Spanish (PAI) protocols, which describe the itinerary of patients and the set of actions, decisions and sequential activities that must be carried out when dealing with a specific healthcare problem keeping the highest possible quality.[4] The clinical laboratory PAI protocol

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All data generated or analyzed during this study are included in this published article [and its Supplementary information files].

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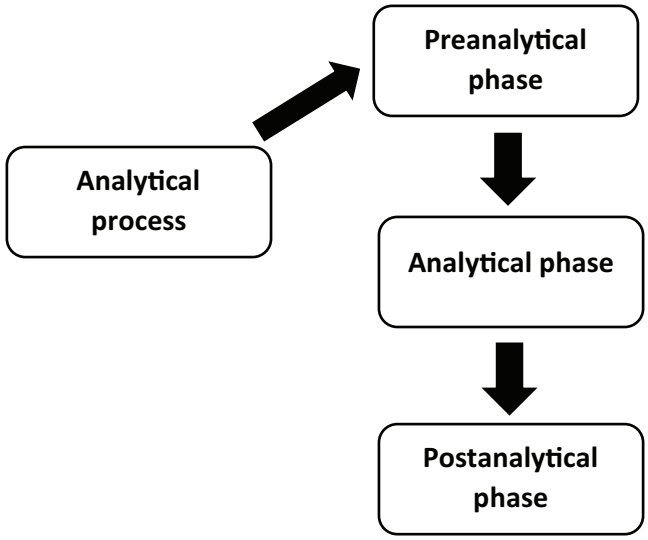

Figure 1. Scheme of the analytical process included in the clinical laboratory protocol.

coordinates the interaction between professionals and levels of care and sets the tasks that must be performed starting with the requested laboratory test and until the applicant receives the results report. Minimum criteria are also included for each phase of the process, which try to guarantee that all tasks are carried out in the best way and in the most coordinated way possible, with the ultimate intention of the process to achieve quality results that satisfy the needs and demands of users.[5]

The presence of errors during the clinical laboratory procedures is relatively common, ranging from 1 error per 164 results to 1 per 8300.[6] Previous studies have shown that errors occur in between 0.01% and 0.5% of samples.[7,8] The preanalytical phase, which comprises actions taken from the test request to the delivery of the sample to the laboratory (Fig. 1), has been identified as the period when errors are more frequently found.[7] Up to 70% of the total laboratory errors have been detected during the preanalytical phase, and most occur during the sampling process (up to 60%).[9] The consequences that these errors have on patient care are not negligible, as the information provided by clinical laboratories affects up to 60% to 70% of clinical decisions.[10]

At present, concern about the analysis of preanalytical errors is considered a priority, as research has focused on this issue worldwide.[11,12] In this sense, the samples obtained in primary care (PC) settings are of particular interest, addressing issues such as errors detection and control or strategies to get a deeper knowledge of the problem.[7,13–16] Likewise, the clinical and economic relevance of the procedures carried out in clinical laboratories have led the Andalusian Department of Health to focus attention on their improvement.

For this purpose, the clinical laboratory PAI protocol was designed and implemented throughout the Andalusian healthcare system. This protocol provides the necessary steps to standardise the clinical laboratory procedures, specifying the role of the different healthcare professionals and quality indicators. The enhancement of these procedures is especially related to the quality control in the preanalytical phase, as the largest number of errors with samples in our environment comes from PC.[17] Furthermore, the regional agency for healthcare quality, agencia de calidad sanitaria de Andalucía (ACSA, for its acronym in Spanish), requires laboratories to apply these standards to be accredited centres.[17] ACSA aims to improve the quality of the services provided by health and social services organisations and professionals. This constitutes a challenge that ACSA faces by fostering its own quality certification model, always striving for excellence within health care and social welfare, as well as fostering a culture of continuous improvement. In order to do so, it has been designated as a quality certification body for health and social services organisations, as well as for its professionals, the training they receive and the web pages with health content. Therefore, health centres accredited by ACSA are assumed to have a good adherence to the Clinical Laboratory PAI protocol.[18]

The aim of this study is to describe the degree of compliance with the Clinical Laboratory PAI protocol in the preanalytical phase and the influencing factors.

2. Methods

2.1. Design

A cross-sectional descriptive designed study was conducted, through an online questionnaire designed ad hoc.

2.2. Variables

The present study analysed the compliance with the clinical laboratory PAI protocol as dependent variable. As independent variables, sociodemographic variables such as sex, age, profession (nurse, general practitioner, physician, other healthcare professionals), and type of health centre (accredited by ACSA or not and teaching centre or not) were studied. A health centre was considered to be accredited by ACSA when it has obtained a quality certificate issued by this agency. ACSA standards establish that accredited centres must have a high degree of implementation of the clinical laboratory PAI after an evaluation on all the items.[2] The health centre that participated in the education of future health professionals and received students for practical training was considered as a teaching centre.

2.3. Instrument

An "ad hoc" questionnaire was designed for dependent and independent variables. Regarding the compliance to the PAI protocol, a group of experts was convened including a specialist in clinical analysis, an expert in PAI protocol evaluation, an expert in clinical quality and safety, a general practitioner, and a PC nurse. They took as a starting point the objectives and quality standards described in the clinical laboratory PAI during the preanalytical phase and designed 11 items which reflected the level of compliance by consensus (Table 1). The original version was assessed by an expert panel searching for validity. After the content analysis, triangulation and expert panel consensus, a pilot experience was conducted with a sample of 48 healthcare professionals. The final version was a self-reported questionnaire with 11 items. Each item stated a standard of practice and participants were asked to assess their level of compliance in a scale from 0 to 10. The internal consistency was assessed by Cronbach α coefficient (0.954). Rates were categorized as very poor (0–2), poor (3–4), good (5–6), very good (7–8), and excellent (9–10). A 5 points score was considered as the cutoff point, which means that the participants declared to be compliant with the standard of practice stated in the items that obtained 5 or above.

2.4. Study population and sample

The study population were healthcare professionals involved in the preanalytical phase of clinical laboratory procedures in the province of Huelva, Andalusia (Spain).

In this paper, authors were interested in focusing on the preanalytical phase, which comprises actions starting from the test request to the delivery of the sample to the laboratory, as it has been identified as the period with more frequently found errors.

Table 1

Description of the items included in the questionnaire.

1	Professionals responsible for the extraction and sampling shall have a manual for the extraction, sampling, and transport of samples.
2	Professionals responsible for the extraction and sampling shall have the appropriate containers in perfect conditions as are necessary for the laboratory's service portfolio.
3	In each centre, there must be a sample extraction and collection schedule according to their characteristics.
4	All centres shall have safety standards for the disposal of containers and potentially hazardous items.
5	All centres shall have working rules ensuring the safety of the worker.
6	The staff of the centres shall be legally empowered and demonstrate their capacities and competencies for the taking and reception of samples.
7	The correspondence between the request and the identity of the patient shall always be verified.
8	The application document shall be verified whether it contains all the identification data.
9	Applications that are not completed with all the essential patient identification, episode, and testing data, and which cannot be solved at the time of extraction, shall be rejected.
10	The identifying data of the person carrying out the specimen, the time, and date thereof, as well as the complications which may have arisen, shall be recorded.
11	Containers shall be identified at the time of obtaining the specimen, in accordance with the basic rules laid down in the specimen collection manual.

Hence, participation of nonlaboratory professionals was considered more relevant

The sample selection was carried out by nonprobability sampling, estimating an optimal size of 231 participants with a 95% confidence level, 7% precision and 15% adjustment for loss, calculated with online samples calculator Question Pro. Finally, after filtering, the sample size was 214, for which there was a loss of 7.36%.

2.5. Data collection

The PC health centres coordinators were contacted via email. They were invited to distribute the questionnaire among the professionals involved in the clinical laboratory procedures. An email reminder was sent 1 week later and another one 2 weeks later. Also, the researchers visited the health centres for on-site recruitment of participants, as facilitators in the spreading of questionnaires. During these visits, the researchers reminded the health professionals of the invitation to participate. In addition, they resolved possible doubts that appeared when filling out the questionnaire and concerns related to the investigation. Each participant completed the online questionnaire with their own perception of compliance, in an informed and voluntary manner. The answers were automatically recorded anonymously in an online database. To guarantee confidentiality, only the researchers had access to this online database. After collecting the data, the researchers refined the database, verifying that all the records were valid and eliminating those filled in erroneously, as was the case for those with a double answer for an item, for example.

2.6. Statistical analysis

Central trend (mean and median) and dispersion measures (standard deviation) were identified. The normal distribution of the data was checked with the Kolmogorov–Smirnoff test, rejecting the normality hypothesis (P<.001), so the data were analysed with nonparametric tests. Mann–Whitney U test was used to determine differences between subgroups. The questionnaire internal consistency was assessed by the Cronbach α coefficient. The data analysis was calculated with the statistical package for social sciences (SPSS) v.22 (IBM, Armonk, NY).

2.7. Ethical aspects

Healthcare professionals participated completely voluntary, always guaranteeing their anonymity, as identification was codified. Likewise, the participants signed an informed consent form in which they were provided with information about the study, complying with the legal regulations in force. The research related to human use has complied with all the relevant national regulations, institutional policies, and in accordance with the tenets of the Helsinki Declaration. This study has been authorised by the Ethics Committee of Huelva in Andalusia, Spain, in January 25, 2015 (PI 008/15).

3. Results

3.1. Sociodemographic results

The median age of the participants was 44.10 (standard deviation [SD]=9.99) years, with a distribution by sex of 92 men (42.99%) and 122 women (57.01%). In terms of the respondents' occupation, 145 were nurses, 48 physicians, and 21 other healthcare professionals (nurse auxiliary, technician, PC attendant). The 73.4% (n=157) of the professionals did not work in accredited centres, and the 55.1% (n=118) of the participants worked in a teaching centre.

3.2. Descriptive results

The descriptive analysis of the data (Table 2) revealed that the clinical laboratory PAI was implemented in every centre included in the study. Items 1, 2, 3, 4, 5, 8, 9, 10, and 11 did not reach the total (n=214) due to data loss (invalid responses). Each item scored from 3 (items 1 and 10) to 10. The best rated item was the one concerning verifying the correspondence between the request and the identity of the patient, valued with a mean=8.57 (SD=2) by 100% of healthcare professionals. The lowest score was obtained by the item related to the manual for the extraction, sampling, and transport of samples by professionals (mean=6.40; SD=3.06). Scores above or equal to 8 were obtained, in total, for 63.6% of the items. Figures 2 and 3 show the mean values by differentiating whether the centre is accredited or not, and whether it includes teaching activity.

Table 3 summarizes the results of the comparative analysis according to the type of health centre. They were identified statistically significant differences between accredited and nonaccredited centres with respect to: having guidelines for blood extraction, sampling, and transport of samples at the disposition of professionals (P value<.001); arrangement of suitable containers and in perfect conditions (P value .046); the existence of a sample extraction and collection schedule (P value .026); safety standards for the disposal of containers and potentially hazardous elements (P value .08), and availability of labour standards to ensure worker safety (P value .05). These differences were not noteworthy regarding teaching and nonteaching centres, as difference was only found in questioning about the legally qualified staff of the centres and their demonstrated skills and competencies for sampling and reception of samples (P value .038).

4. Discussion

The results of this study revealed that compliance with the clinical laboratory PAI protocol is high overall. The participants

Table 2

Descriptive results from the compliance questionnaire (n=214).

	M (SD)	Very poor % (n)	Poor % (n)	Good % (n)	Very good % (n)	Excellent % (n)
Professionals responsible for the extraction and sampling shall have a manual for the extraction, sampling, and transport of samples	6.40 (3.06)	13.0 (27)	16.8 (35)	13.0 (27)	23.6 (49)	33.7 (70)
Professionals responsible for the extraction and sampling shall have the appropriate containers in perfect conditions as are necessary for the laboratory's service portfolio	7.98 (2.12)	1.4 (3)	6.7 (14)	13.9 (29)	28.4 (59)	49.5 (103)
In each centre, there must be a sample extraction and collection schedule according to their characteristics	8.38 (2.03)	1.5 (3)	6.8 (14)	8.8 (18)	19.0 (39)	63.9 (131)
All centres shall have safety standards for the disposal of containers and potentially hazardous items	8.26 (2.10)	2.9 (6)	4.8 (10)	8.2 (17)	26.9 (56)	57.2 (119)
All centres shall have working rules ensuring the safety of the worker	7.78 (2.20)	2.9 (6)	7.7 (16)	12.5 (26)	30.8 (64)	46.2 (96)
The staff of the centres shall be legally empowered and demonstrate their capacities and competencies for the taking and reception of samples	8.04 (2.01)	2.8 (6)	4.7 (10)	10.3 (22)	33.6 (72)	48.6 (104)
The correspondence between the request and the identity of the patient shall always be verified	8.57 (2.00)	1.4 (3)	6.1 (13)	5.1 (11)	21.0 (45)	66.4 (142)
The application document shall be verified whether it contains all the identification data	8.54 (1.89)	1.5 (3)	6.4 (13)	3.5 (7)	26.7 (54)	61.9 (125)
Applications that are not completed with all the essential patient identification, episode, and testing data, and which cannot be solved at the time of extraction, shall be rejected	8.22 (1.99)	1.4 (3)	6.2 (13)	6.2 (13)	34.1 (72)	52.1 (110)
The identifying data of the person carrying out the specimen, the time, and date thereof, as well as the complications which may have arisen, shall be recorded	6.70 (2.99)	8.8 (8)	15.1 (31)	17.1 (35)	23.9 (49)	35.1 (72)
Containers shall be identified at the time of obtaining the specimen, in accordance with the basic rules laid down in the specimen collection manual	8.00 (2.30)	2.9 (6)	7.8 (16)	6.8 (14)	33.2 (68)	49.3 (101)

M = mean, SD = standard deviation.

declared they were very good in verifying the correspondence between the request and the identity of the patient. However, they declared that the availability of guidance about the extraction, sampling, and transport of samples was very poor. When comparing the results according to the type of health centre, it was identified that accredited centres performed more in compliance with the clinical laboratory PAI protocol. Regarding teaching or nonteaching centres, no significant differences were found. Therefore, our results highlight the usefulness of the clinical laboratory protocol and its level of acceptance among health professionals.

More than a half of the participants did not work in accredited centres. This may be explained by the fact that accreditation is only voluntary, health centres are not required to obtain accreditation in the Spanish health system. Accreditations are generally linked to the accomplishment of the community healthcare objectives of the healthcare centre. This was supported by results obtained for the item *professionals responsible for the extraction and sampling shall have the appropriate containers in perfect conditions as are necessary for the laboratory's service portfolio,* which 49.5% of participants rated as excellent; or item *in each centre, there must be a schedule for sample drawing and collection according to the centre's characteristics*, which 63.9% of participants rated as excellent. Item *Professionals in charge of blood drawing and sampling must have a manual for extraction, sampling, and transport of samples* revealed the

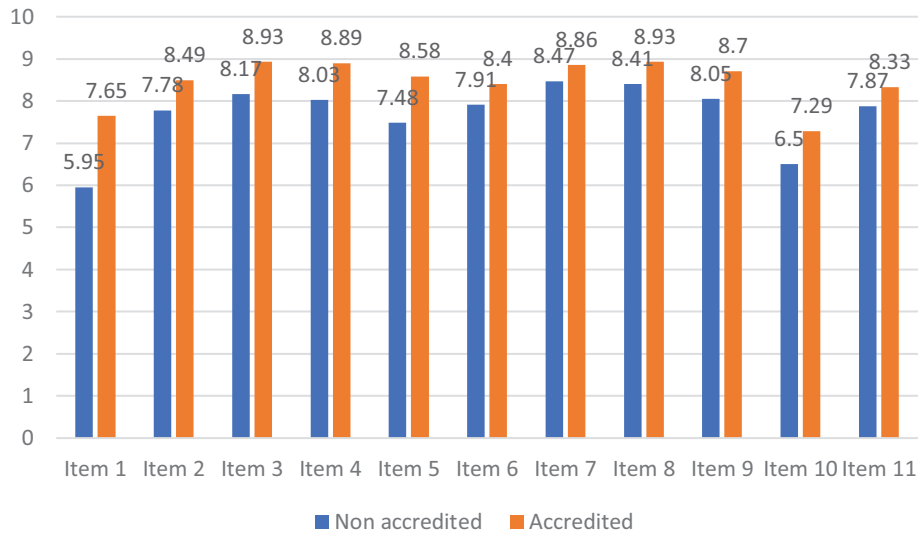

Figure 2. Differences between means according to the type of health centre.

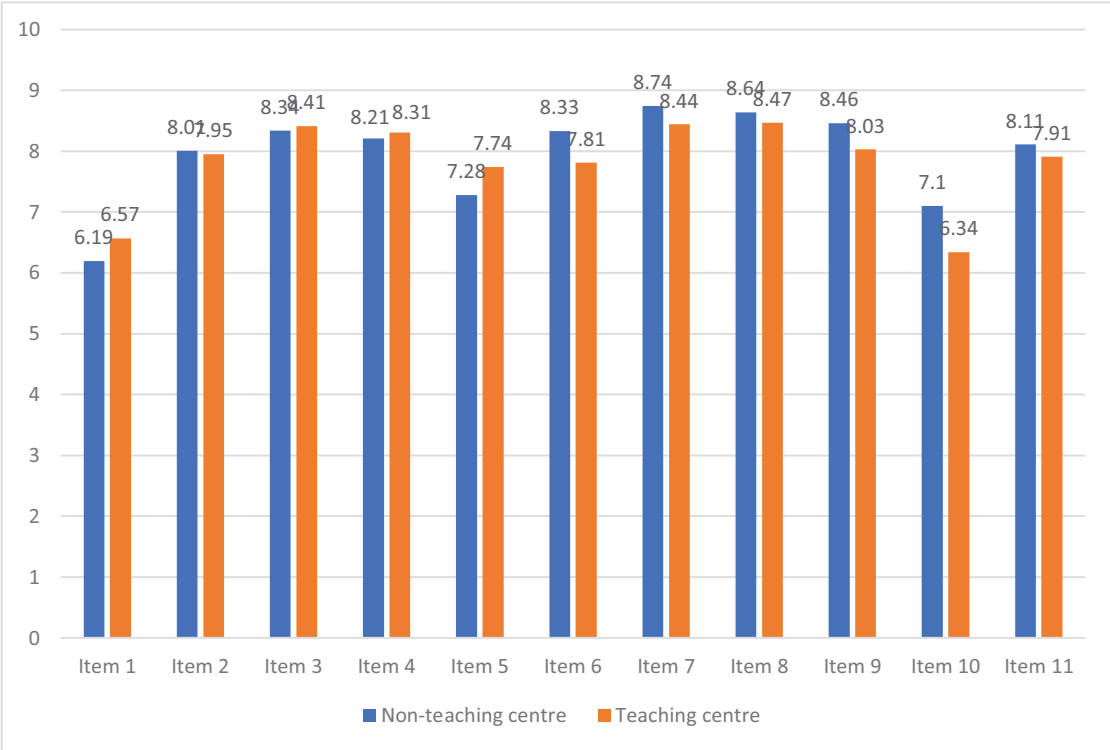

Figure 3. Compliance with the protocol by the teaching activity of the health centre.

existence of adequate protocolised documents, which was congruent with results obtained for items related to identification such as the correspondence between the request and the identity of the patient shall always be checked (147 excellent scores, 65.9%) or *Checking data on the request* (130 excellent scores, 61.6%) (Table 2).

The best rated item in the descriptive analysis was *correspondence between the request and the identity of the patient*. This may lead to better performance in the preanalytical process as lost sample or missed sample has been identified as one of the most frequent errors together with haemolysed sample error.[19,20] Verifying those identifications are checked could help to control the presence of this type of error (Table 2).

By incorporating the perspective of the professionals involved in the laboratory process, knowledge on the process has been enriched. Previously, we carried out several analyses that affected this. The qualitative approach has provided reliable and valuable information that has been supplemented with the weaknesses, threats, strengths and opportunities analysis.[19–25]

Standardisation should be a priority since primary healthcare centres function as integrated units in the regional health system.[26] In our health system, the clinical laboratory PAI protocol has been implemented for more than 10 years, with an irregular distribution at the beginning, but reaching all the regional public health centres in recent times. This study assessed the implementation and has been designed with the opinion of all the involved professionals, not only laboratory workers, but also PC healthcare professionals, who are the suppliers of most of the samples.[20–24] This wider approach may significantly increase the quantity and quality of data regarding the measures to be implemented for the improvement of the process.[24]

The opinion of PC healthcare professionals on the degree of compliance with the protocol was exceptionally positive, with a large majority of excellent scores (9–10 points). This shows an adequate knowledge of the protocol which is of key relevance. Their strategic position in the sample collection and transport and its relationship with preanalytical errors has been previously reported.[20]

As limitations of the present study, first, we did not reach the minimum sample, although we think we have enough data for processing the data analysis. In addition, (r3), the limited geographical area of data collection must be acknowledged, which conditions the generalization of the results. Also, the irregular distribution of the sample, mostly nursing professionals, could influence the interpretation of the results.

5. Conclusions

As shown by the results, the degree of compliance of the clinical laboratory PAI protocol is high and adequate among PC health professionals. Differences were found between accredited and nonaccredited health centres, however, there were no differences between teaching and nonteaching centres. Although the degree of implementation among PC professionals, whose role is key in the sample collection and transport steps of the preanalytical phase, was shown to be excellent, standardisation must be a priority to reduce errors and improve clinical safety and results.

The involvement of the health professionals in assessing their level of compliance would enhance their commitment with the future interventions for improvement.

No previous studies of compliance with our clinical laboratory PAI protocol were found. Being the first could be the main result of our study. For this reason, the proposed methodology opens an important line of research on the valid techniques for the evaluation of the laboratory protocols. These results provided relevant information and knowledge about the protocol, its implementation, weaknesses and areas of improvement, and also reinforces the need to develop this line of research through a deeper analysis of the results and also by incorporating patients' perspective.

Table 3

Differences between the level of compliance according to the type of health centre.

		Accreditation			Teaching act			
		No	Yes	Sig.	No	Yes	Sig.	Total
	N	157	57		96	118		214
	%	73.4%	26.6%		44.9%	55.1%		100%
1. Professionals responsible for the extraction and sampling shall have a manual for the extraction, sampling, and transport of samples	N	153	55		93	115	.367	208
	Mean	5.95	7.65		6.19	6.57		6.40
	Stand. dev.	3.140	2.451		3.167	2.977		3.061
2. Professionals responsible for the extraction and sampling shall have the appropriate containers in perfect conditions as are necessary for the laboratory's service portfolio	N	151	57	.046	91	117	.937	208
	Mean	7.78	8.49		8.01	7.95		7.98
	Stand. dev.	2.230	1.713		2.041	2.189		2.121
3. In each centre, there must be a sample extraction and collection schedule according to their characteristics	N	148	57	.026	88	117	.492	205
	Mean	8.17	8.93		8.34	8.41		8.38
	Stand. dev.	2.177	1.462		1.935	2.106		2.030
4. All centres shall have safety standards for the disposal of containers and potentially hazardous items	N	151	57	.008	91	117	.739	208
	Mean	8.03	8.89		8.21	8.31		8.26
	Stand. dev.	2.268	1.423		2.359	1.891		2.104
5. All centres shall have working rules ensuring the safety of the worker	N	151	57	.005	91	117	.709	208
	Mean	7.48	8.58		7.82	7.74		7.78
	Stand. dev.	2.380	1.388		2.209	2.213		2.207
6. The staff of the centres shall be legally empowered and demonstrate their capacities and competencies for the taking and reception of samples	N	157	57	.399	96	118	.038	214
	Mean	7.91	8.40		8.33	7.81		8.04
	Stand. dev.	2.170	1.450		1.845	2.117		2.012
7. The correspondence between the request and the identity of the patient shall always be verified	N	157	57	.890	96	118	.492	214
	Mean	8.47	8.86		8.74	8.44		8.57
	Stand. dev.	2.188	1.329		1.718	2.202		2.000
8. The application document shall be verified whether it contains all the identification data	N	148	54	.239	87	115	.625	202
	Mean	8.41	8.93		8.64	8.47		8.54
	Stand. dev.	2.043	1.315		1.745	1.993		1.888
9. Applications that are not completed with all the essential patient identification, episode, and testing data, and which cannot be solved at the time of extraction, shall be rejected	N	154	57	.124	93	118	.119	211
	Mean	8.05	8.70		8.46	8.03		8.22
	Stand. dev.	2.173	1.253		1.742	2.148		1.986
10. The identifying data of the person carrying out the specimen, the time, and date thereof, as well as the complications which may have arisen, shall be recorded	N	154	51	.124	96	109	.106	205
	Mean	6.50	7.29		7.10	6.34		6.70
	Stand. dev.	3.079	2.625		2.755	3.145		2.986
11. Containers shall be identified at the time of obtaining the specimen, in accordance with the basic rules laid down in the specimen collection manual	N	148	57	.455	90	115	.344	205
	Mean	7.87	8.33		8.11	7.91		8.00
	Stand. dev.	2.439	1.874		2.344	2.273		2.301

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