Assessment of patient safety culture in clinical laboratories in the Spanish National Health System

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Abstract

Introduction: There is increasing awareness of the importance of transforming organisational culture in order to raise safety standards. This paper describes the results obtained from an evaluation of patient safety culture in a sample of clinical laboratories in public hospitals in the Spanish National Health System.

Material and methods: A descriptive cross-sectional study was conducted among health workers employed in the clinical laboratories of 27 public hospitals in 2012. The participants were recruited by the heads of service at each of the participating centers. Stratified analyses were performed to assess the mean score, standardized to a base of 100, of the six survey factors, together with the overall patient safety score.

Results: 740 completed questionnaires were received (88% of the 840 issued). The highest standardized scores were obtained in Area 1 (individual, social and cultural) with a mean value of 77 (95%CI: 76-78), and the lowest ones, in Area 3 (equipment and resources), with a mean value of 58 (95%CI: 57-59). In all areas, a greater perception of patient safety was reported by the heads of service than by other staff.

Conclusions: We present the first multicentre study to evaluate the culture of clinical safety in public hospital laboratories in Spain. The results obtained evidence a culture in which high regard is paid to safety, probably due to the pattern of continuous quality improvement. Nevertheless, much remains to be done, as reflected by the weaknesses detected, which identify areas and strategies for improvement.

Key words: patient safety; clinical laboratory services; questionnaires; cross-sectional studies; public hospital; universal safety measures; total quality management

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Introduction

The risks and adverse events related to health care, in varying ways, affect all countries. The problem may initially be perceived as one of human responsibility, but fundamentally it concerns the system. Accordingly, experts have proposed that research in developed countries should be aimed, among other aspects, at promoting and enhancing a safety-oriented culture. It is necessary, therefore, to determine the situation in our field of activity, namely the clinical laboratory, and to derive valid solutions (1,2).

Schein viewed the term "culture" as an integrating concept that is expressed in the organizational climate (3). Guldenmund reviewed the literature in this respect and defined "safety culture" as the aspects of organizational culture expected to impact upon attitudes and behavior related to increasing or decreasing risks (4). In the context of a clinical laboratory, patient safety culture refers to the proactive engagement of its staff (safe systems, behavior management) and the perceived commitment of the organization to patient safety, as expressed through the perceptions, skills and attitudes of its personnel.

Clinical laboratories, which are characterized by their well-defined processes, were pioneers in promoting analytical quality and form an important link in the healthcare chain, as over 70% of medical decisions are based on diagnostic test results (5). Apart from decisions pertaining to the framework of the healthcare organization (independent services or specialties with pyramidal structures, outsourcing, mergers, etc.), it is well known that that the majority of errors, and those which are most critical to patient safety, take place in scenarios outside the laboratory itself (6-10). Such errors often compromise patient safety by negatively affecting the reliability of the analytical report (i.e., the absence of errors) and its utility (i.e., the provision of timely, relevant information). Moreover, due to inadequate training and practice, many staff fail to conduct a systematic analysis of the organizational aspects involved in clinical practice (11), despite the fact that the current healthcare environment requires all involved to focus on clinical safety, that is, to prevent the occurrence of avoidable errors (12,13).

Organizations are becoming increasingly aware of the importance of transforming and improving their safety culture, but to do so it is first necessary to understand it and hence there is a need for an appropriate means of evaluation. Questionnaire-based surveys are commonly used to investigate health-related behavior, and constitute valuable instruments for population studies and for assessing educational interventions (14). Diverse questionnaires have been proposed to assess safety culture, depending on the specific purpose and context, including: a) the Hospital Survey on Patient Safety Culture, issued by the Agency for Healthcare Research and Quality (AHRQ) (15,16) and which has been adapted for use in various European countries, including Spain; b) the Safety Attitudes Questionnaire (17), which has also been adapted to the different contexts in which it has been used, mainly intensive care units; c) the Medical Office Survey on Patient Safety Culture (18), which incorporates the main characteristics of a study conducted in the field of primary health care, and which has also been translated, adapted and validated for use in Spain, and which emphasizes safety and quality in health care; d) Team Strategies and Tools to Enhance Performance and Patient Safety, recently validated, which measures perceptions of work among multidisciplinary teams (19).

The aim of the present study is to evaluate the patient safety culture in clinical laboratories in public hospitals in Spain, to describe the variability among different groups of workers in these laboratories and to analyze the strengths and weaknesses of the system, in order to establish measures by which it can be improved.

Materials and methods

Study design

A descriptive cross-sectional study was performed from September to December 2012. The study was conducted among health workers employed in the clinical laboratories of 27 public hospitals in 15 Spanish regions (Autonomous Communities) and in the (Autonomous) town of Ceuta (Spain) (Table 1).

Used questionnaire was one that had been previously validated to assess patient safety in clinical laboratories (20). It contained the following sections: A) demographic and professional data (seven items); B) questionnaire on patient safety, encompassing six areas (B1: individual, social and cultural factors; B2: factors related to the activity; B3: factors related to equipment and resources; B4: factors related to working conditions; B5: educational and training factors, B6: factors related to

Table 1. Spanish National Health System hospitals participating in the study.

Hospital	Region	Surveys (N = 740)
Hospital Universitario Puerta del Mar de Cádiz	Andalusia	30
Hospital Universitario San Cecilio, Granada	Andalusia	32
Hosp.Clínico Univ. Lozano Blesa, Zaragoza	Aragón	28
Hospital Royo Villanova, Zaragoza	Aragón	17
Hospital Universitario Central de Asturias	Asturias	30
Hospital Sierrallana, Torrelavega	Cantabria	17
Hospital Virgen de la Salud, Toledo	Castilla la Mancha	30
Hosp. Universitario de Salamanca	Castilla y León	31
Hospital del Bierzo, Ponferrada (León)	Castilla y León	30
UDIAT Centre Diagnòstic. Corporació Sanitària Parc Tauli, Sabadell.	Catalonia	31
H. Arnau de Vilanova, Lérida	Catalonia	47
Hospital Vall d´Hebron, Barcelona	Catalonia	19
Hospital Universitario de Ceuta	Ceuta	13
Hospital de Mérida	Extremadura	22
Complejo Hospitalario Universitario Santiago Compostela	Galicia	35
Hospital Arquitecto Marcide - Ferrol	Galicia	42
Hospital de Manacor	Balearic Isles	31
Hospital Son LLatzer, Palma de Mallorca	Balearic Isles	30
Complejo Hospitalario Ntra. Sra. Candelaria - Tenerife	Canary Isles	30
Hosp. Universitario Principe de Asturias, Alcalá de Henares	Madrid	30
Hospital Universitario La Paz, Madrid	Madrid	24
Hospital Clínico Universitario de Navarra (Pamplona)	Navarre	28
Hospital Reina Sofía de Tudela	Navarre	30
Hospital Santiago Apostol de Vitoria	Basque Country	11
Hospital Universitario Araba (Txagorritxu)	Basque Country	8
Hosp. Clínico Universitario de Valencia	Valencia	30
Hospital Dr. Peset	Valencia	34

communication); C) A score on a scale from 0-10 for patient safety in the work unit.

For each factor in the questionnaire, a standardization of scores to a base of 100 was calculated based on the number of items of each factor (on this scale, 0 indicates a minimal perception of patient safety and 100, the highest possible level). Any item for which values were missing or which was coded as "not known - no answer" was recoded as the mean value for the item in question (2.5):

Area 1: Individual, social and cultural factors (Scores Base 100)

area1_p100 *=[item11 + item12 + item13 + item14 + item15 + item16 + item17 + item18 + item19]/* 45*100

Area 2: Factors related to the activity (Scores Base 100)

area2_p100 *=[(item21 + item22 + item23 + item24 + item25 + (5-item26) + item27 + item28 + item29 + item210 + item211 + item212 + item213 + (5-item214) + item215 + item216 + (5-item217)]/85*100*

Area 3: Factors related to fixtures and resources (Scores Base 100)

area3_p100 = [*item31 + (5-item32) + item33 + item34 + item35 + (5-item36) + (5-item37) + item38 + item39 + item 310]/* 50*100

Area 4: Factors related to working conditions (Scores Base 100)

area4_p100 = [*item41 + item42 + item43 + item44 + item45 + item46]/* 30*100

Area 5: Factors related to education and training (Scores Base 100)

area5_p100 = [*item51+ item52 + item53 + item54 + item55 + item56 + item57 + item58 + item59+ (5-item510)]/* 50*100

Area 6: Factors related to communication (Scores Base 100)

Area6_p100 = *[item61 + item62 + item63 + item64 + item65 + item66 + (5-item67) + item68 + item69 +* item610*]/* 50*100

Subjects

The participants were recruited by the heads of service at each of the participating centers, after being informed of the purpose of the survey. All data compiled in this project were recorded anonymously, in strict accordance with the Biomedical Research law currently in force in Spain (Act 14/2007 of 3 July) (21).

A convenience sample (non-probabilistic) was selected of hospitals operating within the Spanish National Health System (SNHS), extracted from the 2011 National Catalogue of Hospitals. Within each laboratory, as well as the director or head of service, the survey was addressed to representatives of the different areas of work within the laboratory, both technical and administrative. For a theoretical population of 25,000 healthcare professionals working in public-sector hospitals in Spain, and to determine the result variability, a standard deviation of 0.2 was assumed; therefore, to obtain an accuracy of 2%, a confidence level of 95% and a design effect of 2, 758 surveys were required, and this figure was increased by 10% to offset possible losses, thus producing a final sample size of 840.

Statistical analysis

A descriptive analysis was performed of all the study variables compiled, using measures of central tendency and dispersion for the quantitative variables and of frequency distribution for the qualitative ones. In accordance with the evaluation criteria of the AHRQ (15), we assessed each of the items related to the questionnaire by grouping the positive extreme values (scores of 4 and 5, or of 0 and 1 for the inverse items), establishing a cut-off point to determine strengths (> 75%) and another for weaknesses or areas in need of improvement (< 50%), and using the same criteria for the overall assessment of the six specific areas of the survey. Stratified analyses were performed to assess the mean score, standardized to a base of 100, of the six survey areas, together with the overall patient safety score, after verifying the normal distribution of the sample (Kolmogorov-Smirnov test), using the parametric ANOVA test (for the job title variable) and the student T-test for the dichotomous variables (gender, age and professional experience). The level of statistical significance was set at 0.05. Statistical analysis was performed using SPSS 15.0.1 software (SPSS Science, Chicago, IL).

Results

Of the 40 laboratories initially invited to participate in the study, 27 (67.5%) agreed to do so; and of the 840 surveys sent out, 740 (88.1%) completed questionnaires were received, which comprised the study sample for analysis. Among the sample population, the median age was 46 years and 80.6% were female. Regarding their experience, 66.6% had been working in clinical laboratories for over ten years, and 49.9% for over ten years in the same laboratory. By job description, the largest group (51.4%) was composed of technicians and nurses (312 technicians and 27 nurses), followed by physicians (34.2% – 175 specialists and 51 residents). In relation to the workplace specialty, among the respondents, 69.2% worked in clinical or biochemical units (Table 2).

Table 2. Demographic data and occupational characteristics of the respondents.

Variable	N	% overall	% valid surveys
Gender			
Male	133	18.0	19.4
Female	552	74.6	80.6
Missing data	55	7.4	
Age			
≤ 45	309	41.8	48.4
>45	329	44.5	51.6
Missing data	102	13.8	
Years of lab experience			
≤ 10	220	29.7	33.4
>10	438	59.2	66.6
Missing data	82	11.1	
Years employed in current post			
≤ 10	325	43.9	50.1
>10	324	43.8	49.9
Missing data	91	12.3	
Job description			
Head of service or section	35	4.7	5.3
Physician	226	30.5	34.2
Technician / Nurse	339	45.8	51.4
Administrative personnel	60	8.1	9.1
Missing data	80	10.8	
Speciality			
Haematology	66	8.9	12.7
Microbiology	61	8.2	11.8
Clinical analysis / Biochemistry	359	48.5	69.2
Anatomical pathology	19	2.6	3.7
Immunology	14	1.9	2.7
Missing data	221	29.9	

% valid surveys – percentage calculated respective to surveys without missing data

When the study areas were analyzed according to a standardized score (base 100), the highest mean scores awarded by the respondents corresponded to area 1 (individual, social and cultural factors) with a mean value of 77.1 (95%CI: 76.0-78.2) and area 6 (factors related to communication) with a mean value of 75.2 (95%CI: 74.2-76.1); in contrast, the lowest scores were for area 3 (factors related to equipment and resources), with a mean value of 58.4 (95%CI: 57.6-59.2) and area 4 (factors related to working conditions), with a mean value of 58.6 (95%CI: 57.2-60.0). Patient safety, assessed overall on a scale from 0 to 10, was given a mean score of 8 points (95%CI: 7.9-8.1). Significant gender differences were found in area 4, where men scored an average of 63.9 points *versus* 57.2 for the female workers ($P < 0.001$); in area 4, too, there were age-related differences ($P = 0.005$) between those aged under 45 years (61.2 points) and those who were older (57 points). For the dichotomized assessment of years of laboratory experience, differences were found ($P = 0.006$) in area 3, with an average of 59.7 points among those with less than ten years' experience of working in the laboratory, compared to 57.4 points among their more experienced colleagues. Similar differences were recorded ($P < 0.001$) for area 4, with a mean score of 62.6 points among those workers with less than ten years' experience, compared to 56.9 points for those who had been employed in laboratories for longer. With respect to differences according to job description, in all areas a greater perception of patient safety was reported by the heads of service or section, followed by the physicians, technicians and nurses, and finally by the administrative staff. In the overall assessment of patient safety, no differences in any of the independent variables were found (Table 3).

Analysis of the ratio and distribution of extreme values for each item showed that in 42 (75.8%) of the 62 items set out in the survey, a positive response rate exceeding 90% was obtained, and only in three items (4.8%) was this rate less than 80%. Item 3.10 obtained the lowest rate (71.8%). According to the respondents, in area 1 (individual, social and cultural factors), three strengths were found; in area 2 (activity-related factors), seven strengths and three weaknesses were identified; in area 3 (factors related to equipment and resources), eight of the ten items were identified as weaknesses; in area 4 (factors related to working conditions), four of the six items were considered weak-

TABLE 3. Mean scores, overall and by patient safety factors.

		Factor 1: Individual. social and cultural factors			Factor 2: Factors related to the activity			Factor 3: Factors related to equipment and resources			Factor 4: Factors related to working conditions		
	N	**Mean**	**CI95%**	**P**	**Mean**	**CI95%**	**P**	**Mean**	**CI95%**	**P**	**Mean**	**CI95%**	**P**
Total	740	77.1	76.0-78.2		73.8	73.0-74.6		58.4	57.6-59.2		58.6	57.2-60.0	
Gender													
Male	133	77.1	74.5-79.7	0.912	74.6	72.7-76.4	0.375	59.3	57.4-61.2	0.144	63.9	61.0-66.8	<0.001
Female	552	76.9	75.6-78.2		73.6	72.7-74.5		57.8	57.0-58.7		57.2	55.6-58.9	
Age													
≤ 45	309	78.4	76.9-79.9	0.162	74.3	73.1-75.5	0.954	59.1	57.9-60.2	0.084	61.2	59.2-63.2	0.005
>45	329	76.8	74.9-78.6		74.3	73.0-75.5		57.6	56.4-58.8		57.0	54.7-59.2	
Years of lab experience													
≤ 10	220	78.0	76.2-79.8	0.240	74.4	73.0-75.8	0.528	59.7	58.5-61.0	0.006	62.6	60.3-64.7	<0.001
>10	438	76.6	75.1-78.1		73.9	72.8-74.9		57.4	56.4-58.4		56.9	54.9-58.7	
Years in current post													
≤ 10	325	77.8	76.3-79.3	0.127	74.1	73.0-75.2	0.730	58.5	57.4-59.7	0.397	60.5	58.5-62.4	0.012
>10	324	76.0	74.2-77.8		73.8	72.5-75.1		57.8	56.7-59.0		56.7	54.4-58.9	
Job description													
Head of service or section	35	85.1	81.5-88.6		80.3	77.2-83.3		63.5	60-67.0		68.3	62.9-73.8	
Physician	226	78.2	76.4-80.1	<0.001	74.8	73.4-76.1	<0.001	58.1	56.7-59.5	0.018	61.3	58.9-63.7	<0.001
Technician / Nurse	339	75.8	74.1-77.5		72.7	71.6-73.9		57.8	56.6-59.0		56.4	54.2-59.0	
Administrative personnel	60	71.2	67.3-75.2		71.2	68.2-74.3		57.0	54.7-59.2		55.4	50.4-60.3	

Table 3. Mean scores, overall and by patient safety factors.

		Factor 5: Factors related to education and training			Factor 6: Factors related to communication			Patient safety - Overall		
	N	**Mean**	**CI95%**	**P**	**Mean**	**CI95%**	**P**	**Mean**	**CI95%**	**P**
Total	740	74.1	73.2-75.0		75.2	74.2-76.1		8.0	7.9-8.1	
Gender										
Male	133	74.0	71.6-76.3	0.864	74.3	72.0-76.6	0.488	7.9	7.7-8.2	0.595
Female	552	74.2	73.1-75.3		75.2	74.1-76.3		8.0	7.9-8.1	
Age										
≤ 45	309	75.4	74.0-76.7	0.171	75.8	74.5-77.2	0.577	8.1	7.9-8.2	0.858
>45	329	74.0	72.5-75.5		75.3	73.8-76.8		8.0	7.9-8.2	
Years of lab experience										
≤ 10	220	74.3	72.6-76.0	0.998	75.7	74.2-77.3	0.535	8.1	7.9-8.2	0.317
>10	438	74.3	73.1-75.5		75.1	73.8-76.3		8.0	7.8-8.1	
Years in current post										
≤ 10	325	74.4	73.1-75.8	0.723	75.1	73.8-76.4	0.881	8.0	7.9-8.2	0.573
>10	324	74.1	72.6-75.6		75.2	73.7-76.8		8.0	7.8-8.1	
Job description										
Head of service or section	35	80.4	76.4-84.4		82.3	78.6-85.9		8.1	7.9-8.4	
Physician	226	76.5	75-78.1	<0.001	75.6	74.0-77.2	<0.001	7.9	7.7-8.0	0.344
Technician / Nurse	339	73.1	71.7-74.4		74.7	73.3-76.1		8.1	7.9-8.2	
Administrative personnel	60	66.6	62.6-70.5		70.3	66.8-73.7		8.0	7.6-8.3	

nesses; in area 5 (factors related to education and training), four items were cited as strengths and three as weaknesses; and in area 6 (factors related to communication), there were five strengths and one weakness (Table 4).

Table 4. Response rate and distribution of extreme values

AREAS Items	Response Rate	% Minimal (0-1)	% Maximal (4-5)
Area 1: Individual, social and cultural factors			
1 I like my work	99.6	0.0	90.0
2 I am satisfied with the work I do	99.9	0.8	80.9
3 The staff are treated with respect	99.6	1.9	76.5
4 There is a good atmosphere in the workplace	99.7	2.6	65.4
5 My superiors provide good management and support	98.5	7.3	58.4
6 I am proud to form part of the work team	98.5	3.3	68.6
7 I am aware of the mission, the viewpoint and the goals of my Unit	98.9	4.6	73.6
8 I have my own identity within the organisation	98.6	3.8	68.1
9 My suggestions are received sympathetically	96.8	7.1	51.3
Area 2: Factors related to the activity			
1 I am aware of the functions, competences and responsibilities of my job	99.6	0.0	91.2
2 My work routine complies with the procedures and rules	99.3	0.4	86.8
3 The staff in my Unit support each other	98.1	1.9	71.3
4 When there is a lot of work, all the staff work as a team to complete it	98.9	4.0	70.6
5 When the workload increases, the work is carried out appropriately	97.7	3.2	62.9
6 Analytic results are filled out manually	93.1	28.2	28.7
7 Work routines are modified in response to anomalies or mistakes	95.9	6.1	64.9
8 My laboratory has procedures and actions to ensure the correct identification of patients (requests) and samples	97.6	0.8	88.9
9 Mistakes related to obtaining samples are recorded and notified	95.8	3.0	81.4
10 Mistakes related to patient identification are recorded and notified	96.2	2.9	81.5
11 Incidents during the obtaining of samples (haemolysis, coagulated sample, incorrect volume measurement, inadequate container, etc.) are recorded and notified	96.2	1.5	87.1
12 All incidents and errors are monitored and followed up, and an appropriate response made	94.7	5.0	70.9
13 After changes are made to improve patient safety, their effectiveness is evaluated	82.8	6.0	56.6
14 The analytic processes that are performed manually in my Unit may be detrimental to patient safety	91.9	38.8	27.1
15 The different services collaborate to improve patient safety	89.1	8.6	47.6
16 My supervisor/manager ignores problems related patient safety	92.2	5.4	77.0
17 The rate of lost analytic reports is determined and assessed	79.9	58.4	15.1
Area 3: Factors related to equipment and resources			
1 There are sufficient human resources to deal with the workload	97.8	10.9	40.6
2 My Unit has too many staff who are temporary or replacement	97.7	57.5	11.5
3 Replacements are made for staff on sick leave or on holiday	98.6	44.7	19.0
4 In the transport of peripheral samples, the time and temperature are controlled	82.6	13.6	47.6
5 The numbers of patients seen in the sample-taking Unit is appropriate to the human resources available	82.3	7.2	45.5
6 The proportion of analytic requests with patient data filled out by hand is determined	81.6	34.8	16.9

AREAS Items	Response Rate	% Minimal (0-1)	% Maximal (4-5)
7 The proportion of analytic requests that are labelled, but lack a patient-identification barcode (such that there is no automatic data scanning) is determined	81.8	40.0	15.2
8 The proportion of analytic requests that are labelled with a patient-identification barcode (enabling automatic data scanning) is determined	85.3	8.7	64.5
9 Priority is given to ensuring suitable staff are employed in each position	93.5	17.8	32.4
10 There is sufficient privacy in areas for patient attention	71.8	13.9	35.2
Area 4: Factors related to working conditions			
1 There is sufficient lighting in my workspace	99.5	4.5	68.6
2 Temperature and background noise are acceptable	99.6	28.2	17.1
3 The workers have sufficient private space	98.0	21.4	30.2
4 The ergonomics of the workspace fixtures and fittings are sufficient	99.5	21.7	27.2
5 The amount of workspace available is sufficient	99.2	17.7	40.7
6 Sufficient resources are available to comply with codes of good professional practice and to reduce occupational hazards	98.0	8.3	51.3
Area 5: Factors related to education and training			
1 I have received appropriate training to perform my job	98.8	4.1	69.4
2 My acquisition of job skills is evaluated satisfactorily	91.8	9.0	52.9
3 I have been trained in the appropriate use of the information produced	95.9	7.9	57.5
4 Effective activities are implemented to enhance patient safety	83.6	9.0	49.4
5 I have received training or information related to patient safety	89.3	13.3	40.7
6 I am aware that my job performance may generate errors that could prejudice patient safety	98.0	1.0	93.2
7 I am aware of the possible consequences to patients of any errors arising in the laboratory	98.8	0.8	95.1
8 I understand why records concerning patient safety are compiled and kept, in areas such as sample quality, requests, arrival times, identification mistakes, etc.	98.4	0.5	92.3
9 All laboratory errors are analysed, even if they pose no potential harm to the patient	95.0	3.1	78.8
10 The staff feel that their mistakes are used against them	93.0	39.5	17.6
Area 6: Factors related to communication			
1 Laboratory staff communicate the circumstances whenever anything that might affect patient safety is observed	96.8	0.7	83.2
2 All errors and incidents occurring within the Unit are analysed and reported	96.8	1.8	78.4
3 The appropriate channels for reporting errors are clearly understood	97.7	2.9	77.9
4 When a critical error is made, it is discussed with the staff concerned	96.6	1.3	88.8
5 Incidents are reported and recorded at shift changes in the Unit	84.3	5.4	74.2
6 All results related to patient safety are appropriately reported to the staff in other healthcare services	82.7	3.4	72.7
7 When an error is reported, the person involved is held accountable	92.8	41.0	18.3
8 When an error is reported, the problem is investigated	94.9	3.8	67.0
9 The laboratory assesses and implements procedures with other Units to ensure that the patient is correctly prepared	79.1	4.4	56.1
10 Near-critical results are correctly reported and recorded in the Unit in accordance with the procedure for their communication	84.1	1.4	78.3

% Minimal (0-1) – percentage of answers 0 and 1
% Maximal (4-5) – percentage of answers 4 and 5

Discussion

To the best of our knowledge, this is the first study to be conducted on patient safety culture in clinical laboratories belonging to public hospitals within the Spanish National Health System. The results of the demographic data and from the survey respondents show that in these laboratories, 80% of workers are female and that two thirds have over ten years' experience in the laboratory. This latter fact may be a positive factor in terms of safety culture, reflecting these workers' professional stability, shared background and common learning experience (3).

The questionnaire results provide an overview of how clinical laboratories are positioned with respect to safety culture. This appears to be fairly homogeneous, with significantly high scores, above 75%, in Areas 1 and 6, both of which are of crucial importance, reflecting laboratory organization and management, and in which some items denote values, feelings and leadership that are essential to a culture of patient safety (20). Also well considered are Areas 2 and 5, for which high scores are recorded for overall perceptions of patient safety, which is indicative of a good organizational culture in this respect. These positive overall results can be attributed to the very nature of this activity, based on well-defined processes, associated with long experience in quality control. On the contrary, Areas 3 and 4 are both close to the cutoff point to be rated as areas in need of improvement. These areas present greater variability, as was to be expected; they generate considerable interest and potential for criticism in the workplace, and most of the items concerned are more dependent on the hierarchy of the healthcare organization itself than on laboratory managers. In addition, problems in these areas can hinder the organizational system and propitiate underlying problems in the workplace affecting productivity and workers' motivation (22,23), and hence clinical safety. In all areas but one, the questionnaire responses obtained are unaffected by gender, age and length of work experience. The exception to this is Area 4 (factors related to working conditions), in which the female workers were found to be more critical than their male counterparts.

The most important finding of this analysis concerns the variable "job description" and the classification by professional type or groups, which reflects significant differences in questionnaire responses depending on the professional category of the staff concerned. Thus, for all areas of analysis, the perception of patient safety increases in line with the respondent's professional category. Heads of service or section report the highest perceptions of patient safety (due to their involvement in the management of quality policies), well above those of the other groups, with the administrative staff located at the opposite end of the scale.

This is an important finding because pre-analytical errors represent 50-75% of all laboratory errors (6,9-10) and it is precisely at this stage that the personnel with the weakest perceptions of patient safety, many of them sub-contracted, are involved (6-10,24). Therefore, it is in these processes (the processing of analytical requests, obtaining specimens, their preparation, transport, aliquoting, etc.), where fail-safe technologies must be enhanced and where training to strengthen patient safety culture must be intensified.

Further valuable information was obtained regarding individual assessments of each of the questionnaire items, which enabled us to identify areas in need of improvement. The questionnaire responses obtained also highlighted the following overall strengths of the system, which are crucial to a culture of patient safety: a) in relation to the work environment ("I like my work, I am satisfied with the work I do and the staff are treated with respect"); b) in aspects that are critical to achieving patient safety ("I am aware of the functions, competences and responsibilities of my job, my work routine complies with the procedures and rules, my laboratory has procedures and actions to ensure the correct identification of patients (requests) and samples, mistakes related to obtaining samples are recorded and notified and mistakes related to patient identification are recorded and notified"; c) aspects related to patient safety culture ("I am aware that my job performance may generate errors that could prejudice patient safety, I am aware of the possible consequences to pa-

tients of any errors arising in the laboratory, I understand why records concerning patient safety are compiled and kept, in areas such as sample quality, requests, arrival times, identification mistakes, etc., and all laboratory errors are analyzed, even if they pose no potential harm to the patient"); d) aspects related to a safety-oriented laboratory climate such as "communication", both verbal and written.

An even more interesting question is that of identifying areas of weakness where improvements should be made. In this respect, nearly a third of the 62 questionnaire items are problematic, and some of these make an evident contribution to critical errors (7-9): "results are entered manually," "requests are filled out by hand" and "requests presented with no barcode labels" – all of which mean that demographic data cannot be scanned in – as well as "manual analytical processes are performed, in which safety is evidently compromised" and "time and temperature in the transport of samples are not controlled".

Four of the five worst-rated items are related to deficiencies in the physical structure of the laboratory; this is a logical outcome, due to the considerable age of some buildings and to the technological evolution of laboratories, but it nevertheless impacts on work conditions and thus on healthcare workers' perceptions of organizational adequacy, job satisfaction and the workplace environment: thus criticisms are directed at "inadequate areas of privacy", "noise and room temperature", "ergonomics of laboratory fittings" and "space" (23,25).

Organizational climate is known to make a strong impact on workers' motivation and on the results achieved (23,25-28). In this sense, the "inadequacy of human resources for the activity to be performed", the "excessive employment of temporary staff", the "non substitution of personnel on sick leave or on holiday" and "the non-prioritization of ensuring the suitability of the person to the post", are very significant, have a strong impact on the workers and constitute high-risk aspects that should be targeted in order to ensure patient safety.

Finally, weaknesses are present in key dimensions for a safety-oriented culture, namely the "lack of collaboration with other services to improve safety", the "lack of effective activities aimed at enhancing patient safety", the "lack of training and information in safety issues", the fact that "staff feel that their mistakes are used against them" and the fact that "when an error is reported, the impression is that the person is being judged".

In our view, the main virtue of the present study lies in the high representativeness of laboratories of Spanish National Health System. We obtained the wide-ranging participation of laboratories, providing different levels of attention and located in all parts of Spain, with multidisciplinary input from every medical specialty in the field of clinical laboratories, and from all groups and levels of personnel. Nevertheless, the study is subject to the limitation that only 67.5% of the laboratories invited to participate actually did so; this could reflect a certain non-response bias, with some laboratories not wishing to take part in the study, probably influenced by the severe economic crisis currently affecting the country, which has provoked cutbacks in the field of health care. Furthermore, participants for the questionnaire survey were selected *via* heads of service or section; inevitably, issues related to laboratory management and the socio-occupational framework itself will have influenced how the questionnaire was administered and the questions answered. In all areas of work, the same types of personnel tend to participate most actively, and this can give rise to the presence of a social desirability bias, thus impacting on the results obtained; nevertheless, our analysis of the responses by job description (from head of service to administrative staff) did not detect any bias in this sense.

Another possible limitation of the study lies in its use of the construct "culture". We are aware that questionnaire responses alone are unlikely to adequately reflect all the dimensions inherent to this term (3-4). Furthermore, the generalizations derived from the data obtained may be unsound, as both the characteristics and the organizational environment of the healthcare centers taking part in the study, especially with respect to their culture,

may differ considerably. Finally, the use of self-assessment methodology is also a weakness. Nevertheless, our analysis revealed significant differences in results among the groups.

Since the assessment mechanisms are similar, our study could be compared with that performed in 2009 by the Ministry of Health, Social Services and Equality, entitled "Analysis of patient safety culture conducted in Spanish public hospitals" (29). However, the approaches adopted in the two studies are different: in our study, the sample of centers evaluated was somewhat larger (27 *versus* 24), and furthermore, they were stratified according to the different levels of service provided. We obtained a higher overall response rate, from a more comprehensive study population, representing all those involved in the clinical analysis process. We obtained a higher average score, overall, and we identified a significant number of strengths. However, three weaknesses were highlighted in both studies, namely "the provision of human resources", "collaboration with other services/units" and "punitive response to errors".

In future studies, we intend to conduct a benchmarking analysis of the laboratories involved in this work, comparing individual assessments by centre and by hospital. Safety is a dynamic condition and in this sense, the present study was conducted at a crucial moment, due to the healthcare cutbacks being implemented and their impact in terms of technology and human resources. Furthermore, a process of radical change is currently taking place in laboratories' organizational structure. In consequence, after these new organizational models have become clarified and established, it would be interesting to examine whether the interventions and changes made in management practices have effectively improved performance and enhanced the safety culture in clinical laboratories. Finally, if organizational culture is evaluated in order to determine its relationship to performance and quality in the workplace (30), it would be desirable to go a step further and to analyze its effects on the results obtained.

This paper presents the first multicentre study aimed at evaluating clinical safety culture in hospital laboratories within the Spanish national health system. The results obtained reflect the existence of a strong emphasis on patient safety, probably due to the trend toward continuous quality improvement in the system, although much remains to be done, as evidenced by the weaknesses detected. Therefore, the following strategies should be implemented to improve the outlook for patient safety in this environment: 1) greater support from management for fail-safe technology to be incorporated; 2) the promotion of shared responsibility, which is an aspect of great importance in diagnostic support, and an area in which many diverse parties are involved; 3) strengthening a non-punitive culture in response to errors committed in safety matters, providing enhanced training and greater information in this respect.

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Potential conflict of interest

None declared.

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