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Patient Safety Indicators in Clinical Laboratories: An Exploratory Survey among Costa Rican Laboratory Professionals

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ABSTRACT

Introduction:
Patient safety indicators (PSIs) focus on the prevention of complications and minimization of unnecessary patient risk. Using the methodology known as SMART, the most suitable indicators may be selected by the evaluation of five essential criteria (i.e., specificity, measurability, attainability, relevance, and timeliness). Therefore, the current study aimed to collect and analyze information regarding PSIs related to clinical laboratories in order to support organizations in the process of indicator selection.

Materials and Methods:
The most widely accepted PSIs for clinical laboratories were identified through a literature review. The indicators were evaluated by conducting a survey on a deliberate sample of 77 laboratory professionals. The answers were analyzed in terms of the frequency of responses for sensitivity, measurability, attainability, relevance, and timeliness. The overall performance of the indicators was assessed using a composite score encompassing the five SMART criteria.

Results:
The indicators with the best overall performance were tests without internal controls, internal controls with unacceptable performance, critical values communicated in time, unacceptable performance in external controls, and requests with errors concerning patient identification. Significant differences were observed among the top-, mid-, and bottom-performing groups of indicators.

Conclusion:
The results of the present study revealed the importance of the active participation of the professional community as an essential activity to determine the most appropriate PSIs. In the case of this study in Costa Rica, this community seems to value quality control processes and pre-analytical requirements as key indicators to monitor patient safety in clinical laboratories.

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Introduction

To evaluate the performance at any level of the healthcare system, indicators are frequently employed, and support services, such as clinical laboratories, are not the exception. The indicators can be defined as specific data allowing the measurement of different aspects of performance (1) and being used for the generation of future review criteria and standards which can lead to process improvement (2).

Quality indicators (QIs) are most frequently used in the healthcare system; these are measures associated with the aspects of this system, such as the outcomes of care, resources required, and others (1). In addition to QIs, patient safety indicators (PSIs) are very useful in healthcare settings. Patient safety is a key aspect of healthcare quality because it attempts to guarantee safe care, by maximizing patient's benefit and minimizing any unnecessary patient risk and/or harm (3). Specifically, PSIs are a set of administrative data-based indicators used to identify potential patient safety events, with a focus on the prevention or reduction of iatrogenic harms resulting from the exposure to the health system (3,4). These indicators have the main purpose of being suitable tools to keep the likelihood of error at a minimum within a laboratory (or any other unit) by recognizing the critical aspects of processes that need to be controlled and intervened (5).

Although QIs and PSIs are often used within clinical laboratories, these are not always validated against a set of criteria that define a good indicator.

Such criteria are determined in accordance with public health policies or through the available literature (state of the art). According to the literature, a good indicator is described as one that is clear, valid, meaningful, sensitive, specific, statistically solid, relatable to other similar indicators, and internationally standardized (6,7). One of the strategies that may be helpful in the process of goal, objective, or indicator validation is the SMART method. The SMART model was described in 1981 by George T. Doran as the five essential criteria that an objective should fulfill in order to be meaningful and effective (8,9).

The technique uses five criteria altogether comprising the SMART acronym as follows: a goal should be Specific because it should be clearly and directly related to an outcome; a goal should be Measurable because change and progress should be easily determined; a goal should be Attainable and Relevant because it should set an appropriate and achievable target level of the indicator, aligned with organizational capabilities and goals; and, finally, a goal should be Time-bound, as the desired time frame should be specified (9,10).

Even though the SMART method was originally described for goal setting, this model can also be applied for the selection and evaluation of the indicators (11); therefore, it is chosen as an assessment tool for the present study. Currently, the use of PSIs in laboratories is still not a common practice in clinical laboratories in Costa Rica where QIs remain mainly focused on analytical performance. In addition to this situation, finding PSIs validated for the operation of clinical laboratories is a difficult task due to the fact that they are not as easily available as those developed for medical or nursing specialties (12).

Although it is true that QIs can be used to decrease the occurrence of safety-related errors and may serve as a base for the creation of PSIs, their purpose, methodology, and focus may differ. The QIs' emphasis lies on ensuring the quality of the different processes of laboratory testing operations; however, PSIs are more patient-centered (13). Therefore, the aim of this study was to collect and analyze information regarding clinical laboratory professionals' perspectives on the suitability of various PSIs related to laboratory processes in order to provide some insights to such organizations that could help in the PSI selection and validation process.

Materials and Methods

Selection of potential PSIs

A literature review was carried out with the purpose of identifying the most widely accepted indicators for clinical laboratories among the scientific community. An article search was conducted in PubMed with key terms, such as "patient safety indicators",

and applying "clinical laboratory" as a filter. Then, a total of 197 results were obtained. After applying the following inclusion criteria, only 31 papers were deemed relevant for the present study: (a) the document is either an original study or a review article; (b) the article's title or abstract makes reference to processes taking place within the clinical laboratory; (c) the article's body contains one or more indicators used for the assessment of quality and/or safety in processes related to clinical laboratories' workflow. The PSIs were extracted from the relevant articles and classified under one of the three stages of the clinical laboratory analysis process according to the brain-to-brain loop turnaround model or as support process indicators (14). Table 1 tabulates the PSIs considered for the construction of the survey.

Table 1: Selection of a pool of potential patient safety indicators from a literature review

Clinical analysis process stage	Code	Indicator	Formula	Periodicity	References		
					Original research articles	Review articles	*Number of references supporting indicator use*
Pre-analytical	01-ReDx%	Requests with clinical questions (possible diagnosis) from general practitioners (%)	$\frac{\textit{Number of test requests with clinical question}}{\textit{Total number of test requests}} \textit{ x } 100$	Monthly	(5, 15, 16, 17, 18, 19)	(20, 21)	*8*
Pre-analytical	02-DrID%	Requests without physician identification (%)	$\frac{\textit{Number of test requests without physician identificaton}}{\textit{Total number of test requests}} \textit{ x } 100$	Monthly	(15, 17)	(20, 21, 22)	*5*
Pre-analytical	03-UnRe%	Unintelligible requests (%)	$\frac{\textit{Number of test requests not understandable}}{\textit{Total number of test requests}} \textit{ x } 100$	Monthly	(5, 15, 16, 17, 19, 23, 24)	(21, 22)	*9*
Pre-analytical	04-PxID%	Requests with errors concerning patient identification (%)	$\frac{\textit{Number of test requests with errors in patient identification}}{\textit{Total number of test requests}} \textit{ x } 100$	Monthly	(5, 15, 16, 17, 18, 19, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33)	(20, 21, 22)	*21*
Pre-analytical	05-TeEr%	Requests with errors concerning input of tests (i.e., missing, added, or misinterpreted) (%)	$\frac{\textit{N° of test requests with missing, added, or misinterpreted tests}}{\textit{Total N° of test requests}} \textit{ x } 100$	Monthly	(5, 15, 16, 17, 19, 23, 24, 29, 30, 32, 33, 34)	(20, 21, 22)	*15*
Pre-analytical	06-InCo%	Samples collected in inappropriate container (%)	$\frac{\textit{N° of samples collected in inappropriate container}}{\textit{Total N° of samples collected}} \textit{ x } 100$	Monthly	(5, 15, 16, 17, 19, 23, 24, 29, 30, 31, 32, 33, 34)	(20, 21, 22)	*16*

Pre-analytical	07-InSa%	Inadequate (e.g., hemolyzed, clotted, and contaminated blood culture) samples (%)	$\frac{\text{N° of inadequate samples received in the laboratory}}{\text{Total N° of samples received by the laboratory}} \times 100$	Monthly	(15, 16, 17, 19, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36)	(20, 21, 22)	*21*
Pre-analytical	08-InVo%	Samples with insufficient volume (%)	$\frac{\text{N° of samples with insufficient volume received by the laboratory}}{\text{Total N° of samples received by the laboratory}} \times 100$	Monthly	(15, 16, 17, 19, 23, 24, 25, 27, 29, 30, 32, 33, 34, 35, 36)	(20, 21)	*17*
Pre-analytical	09-ImLa%	Samples improperly labelled (%)	$\frac{\text{N° of samples with inadequate identification or labelling received by the laboratory}}{\text{Total N° of samples received by the laboratory}} \times 100$	Monthly	(5, 15, 16, 17, 19, 24, 25, 27, 29, 30, 32, 33)	(20, 21, 22)	*15*
Pre-analytical	10-ID<2%	Samples labeled with fewer than two identifiers (e.g., patient name, patient ID, birthdate, and lab internal ID) (%)	$\frac{\text{Number of samples with less than two identifiers received by the laboratory}}{\text{Total number of samples received by the laboratory}} \times 10$	Monthly	(5, 24, 25)	-	*3*
Pre-analytical	11-ImST(%)	Samples improperly stored or transported (%)	$\frac{\text{Number of samples improperly stored or transported to the laboratory}}{\text{Total number of samples received by the laboratory}} \times 100$	Monthly	(5, 15, 16, 17, 19, 24, 27, 29, 30, 31, 32, 33, 34, 37)	(20, 21, 22)	*17*
Pre-analytical	12-NoSa%	Samples lost/not received (%)	$\frac{\text{Number of test requests for which samples were not received by the laboratory}}{\text{Total number of test requests}} \times 100$	Monthly	(5, 15, 16, 17, 19, 23, 25, 27, 29, 30, 31, 32, 33, 35, 36)	(20, 21, 22)	*18*
Pre-analytical	13-InTi%	Samples collected at inappropriate time (%)	$\frac{\text{Number of samples collected at inappropriate time}}{\text{Total number of samples collected}} \times 100$	Monthly	(5, 16, 17, 19, 24, 37)	-	*6*
Analytical	14-NoEQ%	Tests without EQAP (%)	$\frac{\text{Number of tests without an EQAP}}{\text{Total number of tests offered by the laboratory}} \times 100$	Yearly	(5, 19, 23, 24)	-	*4*
Analytical	15-UnEQ%	Unacceptable performances in EQAPs (%)	$\frac{\text{Number of EQAP reports with an unacceptable performance}}{\text{Total number of EQAP reports}} \times 100$	Yearly	(5, 15, 23, 24, 27, 28)	(20, 21, 22)	*9*

Analytical	16-NoIQ%	Tests without internal quality control (%)	$\frac{\textbf{Number of tests without internal quality control}}{\textbf{Total number of tests offered by the laboratory}} \times 100$	Yearly	(19, 23)	-	*2*
Analytical	17-UnIQ%	Unacceptable internal control performance (CV% higher than selected target) (%)	$\frac{\textbf{Number of internal control results with unacceptable performance}}{\textbf{Total number of internal control results}} \times 100$	Monthly	(5, 15, 19, 23, 24, 28)	(20, 21, 22)	*9*
Analytical	18-InFa%	Reports with delayed delivery due to instrumentation failures (%)	$\frac{\textbf{Number of result reports delivered outside specified time due to an instrument failure}}{\textbf{Total number of result reports delivered by the laboratory}} \times 100$	Monthly	(15, 38)	(20, 21, 22)	*5*
Analytical	19-ErTr%	Incorrect results due to erroneous transcription of manual entry of data (%)	$\frac{\textbf{Number of results reports with data transcription errors}}{\textbf{Total number of results reports delivered by the laboratory}} \times 100$	Monthly	(5, 19, 24, 31)	(20, 21)	*6*
Analytical	20-Invg#	Investigations undertaken on possibly biased results due to analytical interference (e.g., biotin) (#)	**Number of investigations on interference related biased results**	Yearly	(39, 40)	-	*2*
Post-analytical	21-OutT%	Reports delivered outside the specified time (%)	$\frac{\textbf{Number of result reports delivered outside the specified time}}{\textbf{Total number of results reports delivered by the laboratory}} \times 100$	Monthly	(5, 13, 15, 19, 24, 27, 28, 31, 41)	(20, 21)	*11*
Post-analytical	22-CCom%	Critical values communicated (%)	$\frac{\textbf{Number of critical values reported to caretakers}}{\textbf{Total number of results within critical value range}} \times 100$	Monthly	(15, 23, 24, 26, 28, 42)	(20)	*7*
Post-analytical	23-CinT%	Critical values communicated in a timely manner (%)	$\frac{\textbf{Number of critical values reported to caretakers within specified time}}{\textbf{Total number of results within critical value range}} \times 100$	Monthly	(13, 15, 19, 24, 28, 31, 42)	(20, 21)	*9*
Post-analytical	24-CRID%	Critical values with notification register stating recipient's identification (%)	$\frac{\textbf{Number of critical values reported where caretaker's identity was registered}}{\textbf{Total number of results within critical value range}} \times 100$	Monthly	(42, 43)	-	*2*

Post-analytical	25-IntR%	Reports with interpretative comments promoting a clinician's response and improving the patient's outcome (%)	$\frac{\textbf{Number of results reports containing interpretative comments promoting a clinician's response which improved the patient's outcome}}{\textbf{Total number of result reports delivered by the laboratory}} \textbf{ x 100}$	Yearly	(5, 15, 19, 24, 42)	(20, 21)	*7*
Post-analytical	26-ReSa%	Patients requiring a sample recollection due to unsuitable samples or incorrect results (%)	$\frac{\textbf{Number of patients requiring a sample recollection due to laboratory errors}}{\textbf{Total number of patients received by the laboratory}} \textbf{ x 100}$	Monthly	(5, 19, 24, 26)	(20, 21, 22)	*7*
Post-analytical	27-CAvTmin	Average turnaround time for critical value results in general (min)	**Average turnaround time (min) for critical value results in general**	Monthly	(5, 13, 19, 23, 24, 26)	(21, 22)	*8*
Post-analytical	28-K+_Tmin	Average turnaround time of potassium at 90th percentile (min)	**Average turnaround time (min) of potassium at 90th percentile**	Monthly	(5, 13, 19, 23, 31)	(20, 21)	*7*
Post-analytical	29-CRPTmin	Average turnaround time of C-reactive protein at 90th percentile (min)	**Average turnaround time (min) of C reactive protein at 90th percentile**	Monthly	(23)	(20, 21)	*3*
Post-analytical	30-WBCTmin	Average turnaround time of white blood cells at 90th percentile (min)	**Average turnaround time (min) of white blood cells at 90th percentile**	Monthly	(5, 13, 19, 23, 31)	(20, 21)	*7*
Post-analytical	31-Tn_Tmin	Average turnaround time of troponin I or troponin T at 90th percentile (min)	**Average turnaround time (min) of troponin I or troponin T at 90th percentile**	Monthly	(5, 13, 19, 23, 31, 41)	(20, 21)	*8*
Post-analytical	32-INRTmin	Average turnaround time of INR value at 90th percentile (min)	**Average turnaround time (min) of INR at 90th percentile**	Monthly	(13, 19, 23, 31)	(20)	*5*
Post-analytical	33-AmRe%	Reports requiring amendments or corrections due to laboratory errors (%)	$\frac{\textbf{Number of result reports requiring corrections due to laboratory errors}}{\textbf{Total number of result reports delivered by the laboratory}} \textbf{ x 100}$	Monthly	(13, 19, 24, 26)	(21)	*5*

Support processes	34-Trng#	Training events organized for laboratory staff (#)	$\boldsymbol{Number\ of\ training\ events\ organized\ for\ lab\ staff}$	Yearly	(5, 19, 24, 38)	(21)	*5*
Support processes	35-DrSt%	Physician satisfaction with laboratory services (%)	$\frac{\sum \boldsymbol{points\ scored\ by\ the\ lab\ in\ all\ physician\ satisfaction\ surveys}}{(\boldsymbol{maximum\ possible\ score\ in\ satisfaction\ survey} \times \boldsymbol{number\ of\ respondents})} \boldsymbol{x\ 100}$	Yearly	(5, 19, 24, 26, 38)	-	*5*
Support processes	36-PxSt%	Patient satisfaction with laboratory services (%)	$\frac{\sum \boldsymbol{points\ scored\ by\ the\ lab\ in\ all\ patient\ satisfaction\ surveys}}{(\boldsymbol{maximum\ possible\ score\ in\ satisfaction\ survey} \times \boldsymbol{number\ of\ respondents})} \boldsymbol{x100}$	Yearly	(5, 19, 24, 26, 38)	-	*5*
Support processes	37-LISd#	LIS unplanned downtime episodes	$\boldsymbol{Number\ of\ unplanned\ LIS\ downtime\ episodes}$	Yearly	(5, 19, 24)	(21, 22)	*5*
Support processes	38-AdEv#	Incidents/Adverse events occurred in laboratories concerning the health and safety of laboratory staff (#)	$\boldsymbol{Number\ of\ adverse\ events\ concerning\ health\ or\ safety\ of\ laboratory\ staff}$	Yearly	(19, 28, 38)	-	*3*
Support processes	39-NeIn%	Needlestick injuries in laboratory personnel	$\frac{\boldsymbol{Number\ of\ needlestick\ injurires\ suffered\ by\ lab\ staff\ as\ part\ of\ phlebotomy\ procedure}}{\boldsymbol{Total\ number\ of\ venipunctures\ performed\ by\ laboratory\ personnel}} \boldsymbol{x\ 10}$	Yearly	(19, 28, 37)	(22)	*4*

EQAP: External quality assessment program, INR: International normalized ratio, LIS: Laboratory information system

Sample selection

A total of 77 laboratory professionals were selected by deliberate sampling for the evaluation of the indicators under study. These medical laboratory scientists are in charge of the technical and administrative direction of different clinical laboratories in Costa Rica and active members of the College of Microbiologists and Clinical Chemists of Costa Rica.

This sample consisted of 14 employees from national and specialized hospitals, 15 employees from regional public hospitals, 29 employees from public clinics, and 19 employees from private healthcare centers.

Questionnaire design

Ten versions of an online-based questionnaire were prepared, each containing a Likert scale for participants to rate 10 PSIs in terms of specificity, measurability, attainability, relevance, and timeliness (i.e., SMART criteria).

The questionnaire versions were carefully arranged to include PSIs from each of the four areas shown in Table 1 and in such a way that each PSI appeared in at least two versions.

Table 2 tabulates the distribution of PSIs across and within questionnaire items.

Table 2: Codes of potential patient safety indicators comprising each of the 10 questionnaire versions

Version (last digit of professional code)	Item 1	Item 2	Item 3	Item 4	Item 5	Item 6	Item 7	Item 8	Item 9	Item 10
0	01-ReDx%	03-UnRe%	08-InVo%	14-NoEQ%	20-Invg#	21-OutT%	26-ReSa%	32-INRTmin	34-Trng#	38-AdEv#
1	02-DrID%	12-NoSa%	04-PxID%	18-InFa%	15-UnEQ%	33-AmRe%	22-CCom%	27-CAvTmin	39-NeIn%	34-DrSt%
2	09-ImLa%	06-InCo%	12-NoSa%	17-UnIQ%	16-NoIQ%	21-OutT%	28-K+_Tmin	23-CinT%	36-PxSt%	34-Trng#
3	05-TeEr%	13-InTi%	07-InSa%	17-UnIQ%	18-InFa%	29-CRPTmin	31-Tn_Tmin	22-CCom%	35-DrSt%	37-LISd#
4	09-ImLa%	05-TeEr%	13-InTi%	14-NoEQ%	19-ErTr%	25-IntR%	30-WBCTmin	23-CinT%	38-AdEv#	36-PxSt%
5	10-ID<2%	06-InCo%	12-NoSa%	05-TeEr%	14-NoEQ%	20-Invg#	24-CRID%	26-ReSa%	28-K+_Tmin	39-NeIn%
6	10-ID<2%	03-UnRe%	01-ReDx%	11-ImST%	19-ErTr%	15-UnEQ%	33-AmRe%	25-IntR%	29-CRPTmin	34-Trng#
7	02-DrID%	08-InVo%	13-InTi%	04-PxID%	20-Invg#	16-NoIQ%	27-CAvTmin	32-INRTmin	26-ReSa%	35-DrSt%
8	11-ImST%	01-ReDx%	10-ID<2%	07-InSa%	17-UnIQ%	18-InFa%	25-IntR%	27-CAvTmin	30-WBCTmin	36-PxSt%
9	07-InSa%	03-UnRe%	09-ImLa%	02-DrID%	19-ErTr%	15-UnEQ%	31-Tn_Tmin	29-CRPTmin	24-CRID%	37-LISd#

01-ReDx%: Requests with clinical questions (possible diagnosis) from general practitioners, **02-DrID%:** Requests without physician identification, **03-UnRe%:** Unintelligible requests, **04-PxID%:** Requests with errors concerning patient identification, **05-TeEr%:** Requests with errors concerning input of tests (i.e., missing, added, or misinterpreted), **06-InCo%:** Samples collected in inappropriate container, **07-InSa%:** Inadequate (e.g., hemolyzed, clotted, and contaminated blood culture) samples, **08-InVo%:** Samples with insufficient volume, **09-ImLa%:** Samples improperly labelled, **10-ID<2%:** Samples labeled with fewer than two identifiers (e.g., patient name, patient ID, birthdate, and lab internal ID), **11-ImST%:** Samples improperly stored or transported, **12-NoSa%:** Samples lost/not received, **13-InTi%:** Samples collected at inappropriate time, **14-NoEQ%:** Tests without EQAP, **15-UnEQ%:** Unacceptable performances in EQAPs, **16-NoIQ%:** Tests without internal quality control, **17-UnIQ%:** Unacceptable internal control performance (CV% higher than selected target), **18-InFa%:** Reports with delayed delivery due to instrumentation failures, **19-ErTr%:** Incorrect results due to erroneous transcription of manual entry of data, **20-Invg#:** Investigations undertaken on possibly biased results due to analytical interferences (e.g., biotin), **21-OutT%:** Reports delivered outside the specified time, **22-CCom%:** Critical values communicated, **23-CinT%:** Critical values communicated in a timely manner, **24-CRID%:** Critical values with notification register stating recipient's identification, **25-IntR%:** Reports with interpretative comments promoting a clinician's response and improving the patient's outcome, **26-ReSa%:** Patients requiring a sample recollection due to unsuitable samples or incorrect results, **27-CAvTmin:** Average turnaround time for critical value results in general, **28-K+_Tmin:** Average turnaround time of potassium at 90th percentile, **29-CRPTmin:** Average turnaround time of C-reactive protein at 90th percentile, **30-WBCTmin:** Average turnaround time of white blood cells at 90th percentile, **31-Tn_Tmin:** Average turnaround time of troponin I or troponin T at 90th percentile, **32-INRTmin:** Average turnaround time of INR value at 90th percentile, **33-AmRe%:** Reports requiring amendments or corrections due to laboratory errors, **34-Trng#:** Training events organized for laboratory staff, **35-DrSt%:** Physician satisfaction with laboratory services, **36-PxSt%:** Patient satisfaction with laboratory services, **37-LISd#:** LIS unplanned downtime episodes, **38-AdEv#:** Incidents/Adverse events occurred in laboratories concerning the health and safety of laboratory staff, **39-NeIn%:** Needlestick injuries in laboratory personnel.

Survey administration and data collection

The questionnaire was administered in Spanish, the official language of Costa Rica. All the participants in the sample were provided with a Google® Forms link which, at the time of access, firstly asked for the participant's informed consent.

After granting consent, the participants were taken to a sorting section where they were asked to select the last digit (0-9) of their professional registration code in the College of Microbiologists and Clinical Chemists of Costa Rica. This step had the sole purpose of assigning the participant to one of the 10 questionnaire versions.

Subsequently, the participants were presented with a 5-point Likert scale for each of the potential PSIs of the corresponding version. The answers were arranged in a spreadsheet containing each participant's 0 to 5 score in specificity, measurability, attainability, relevance, and timeliness for each potential PSI asked in their respective questionnaire version.

Data analysis

The participants' answers were analyzed in terms of frequency and overall performance. For the frequency analysis, the percentage of the participants considering each criterion as strong (answers 4: "very" and 5: "completely") was determined. The indicators were then organized in descending order according to their performance in each criterion. The overall performance of each PSI was assessed using "a SMART composite score"; accordingly, the participants' answers for each of the five criteria were added to obtain an indicator's SMART score, with a value within the range of 5 (participant assigned a score of 1: "not

at all" to all five criteria) to 25 (participant assigned a score of 5: "completely" to all five criteria).

The average SMART score was obtained for the 39 potential PSIs, which were then sorted in descending order to visualize the overall performance of each indicator. According to this ranking, the indicators were classified under three ranking groups, namely Top 5 (i.e., the five potential PSIs with the highest average SMART score), Bottom 5 (i.e., lowest average SMART score), and Mid-range (i.e., the remaining 19 indicators between the top and bottom groups) groups.

To determine whether the differences between groups' SMART scores were statistically significant, the analysis of variance (ANOVA) was carried out using SPSS software (version 20) with ranking groups and analytical stage as independent variables and SMART score as the dependent variable.

In cases with statistically significant differences, a post hoc Tukey's test was performed in order to determine the origin of such difference in variance.

Results

All 39 PSIs were assessed in terms of good performance for each SMART criterion. According to the sample of the present study, the most specific PSIs were the percentage of tests without internal quality control (16-NoIQ%), average turnaround time of troponin at 90th percentile (31-Tn_Tmin), average turnaround time of international normalized ratio (INR) value at 90th percentile (32-INRTmin), percentage of samples improperly labeled (09-ImLa%), and percentage of unacceptable performance in external quality assessment programs (EQAPs) (15-UnEQ%) by 94.1%, 92.3%, 92.3%, 91.3%, and 81.5% of the respondents considering them as "completely" or "very" specific, respectively (Figure 1A).

As for measurability, the indicators with the largest proportion of respondents considering them "completely measurable" or "very measurable" were the percentage of tests without internal quality control (16-NoIQ%; 100.0%), average turnaround time of INR value at 90th percentile (32-INRTmin; 92.3%), percentage of internal control determinations with unacceptable internal (17-UnIQ%; 88.5%), percentage of tests without external quality assessment program (14-NoEQ%; 87.5%), and percentage of patients requiring a sample recollection due to unsuitable samples or incorrect results (26-ReSa%; 86.4%)(Figure 1B).

With regard to the third criterion, the indicators considered by most respondents "completely attainable" or "very attainable" (Figure 1C) were the percentage of tests without internal quality control (16-NoIQ%; 100.0%), percentage of critical values communicated in a timely manner (23-CinT%; 94.7%), percentage of samples improperly stored or transported (11-ImST%; 93.3%), percentage of unacceptable performance in EQAPs (15-UnEQ%; 89.5%), and percentage of internal control determinations with unacceptable internal (17-UnIQ%; 88.5%).

Then, Figure 1D depicts the percentage of samples improperly labeled (09-ImLa%), average turnaround time of troponin I or troponin T at 90th percentile (31-Tn_Tmin), average turnaround time of INR value at 90th percentile (32-INRTmin), percentage of critical values communicated in a timely manner (23-CinT%), and percentage of tests without internal quality control (16-NoIQ%) at the top which were considered "completely relevant" or "very relevant" by 100.0%, 100.0%, 100.0%, 94.7%, and 94.1% of the respondents, respectively.

Finally, the indicators with the highest proportion of respondents considering them "completely timely/time-bound" or "very timely/time-bound" are highlighted in Figure 1E, namely the average turnaround time of INR value at 90th percentile (32-INRTmin; 100%), percentage of critical values communicated in a timely manner (23-CinT%; 94.7%), percentage of tests without external quality assessment program (14-NoEQ%; 91.7%), percentage of inadequate samples (07-InSa%; 90.5%), and average turnaround time of potassium at 90th percentile (28-K+_Tmin; 88.9%).

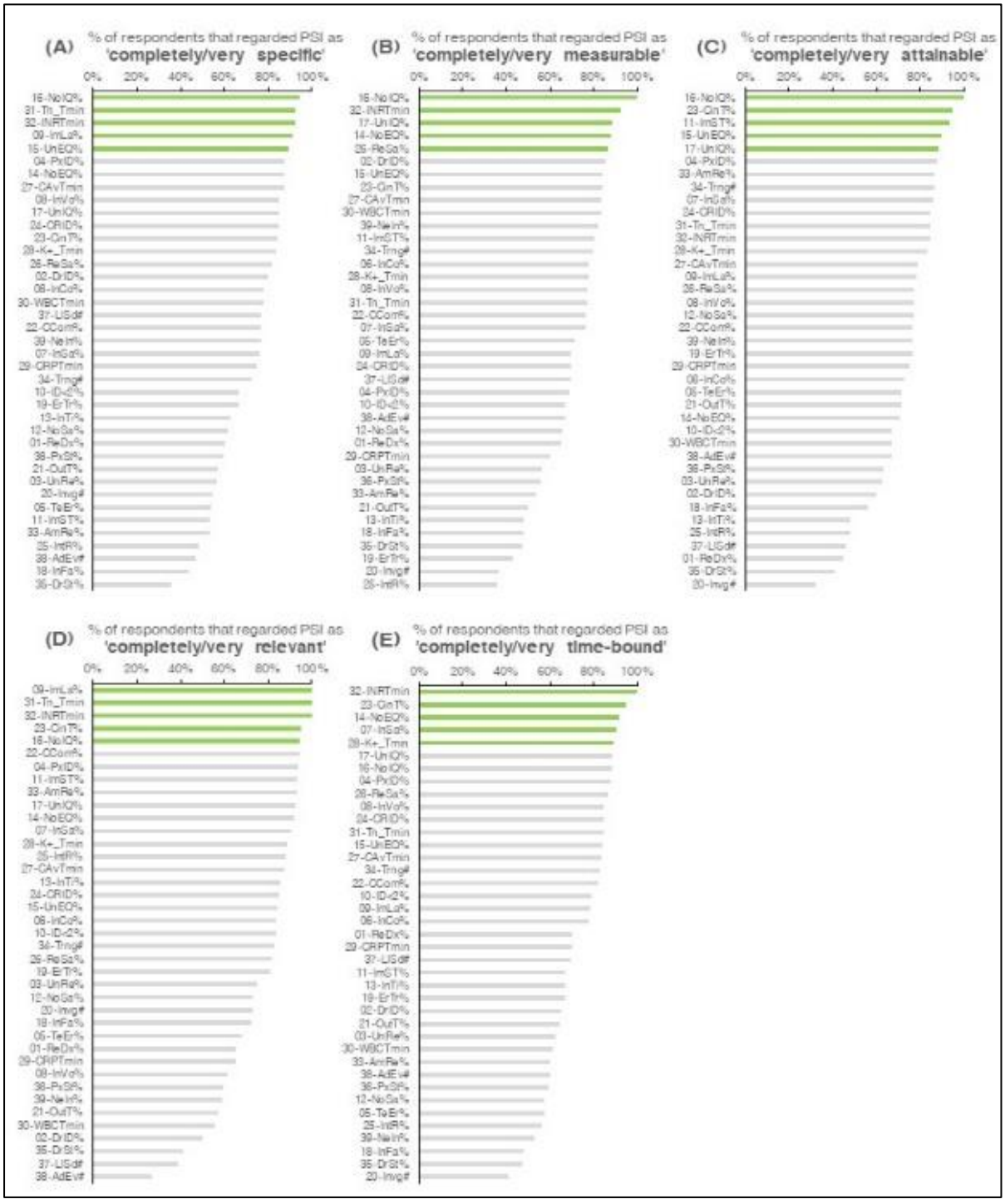

Figure 1: Proportion of respondents assigning a "completely" or "very" answer to each potential PSI in terms of (A) Specificity, (B) Measurability, (C) Attainability, (D) Relevance and (E) Timeliness.

Overall performance analysis

When considering a composite SMART score, the highest results were obtained by the percentage of tests without internal quality control (16-NoIQ%), percentage of internal control determinations with unacceptable performance (17-UnIQ%), percentage of critical values communicated in a timely manner (23-CinT%), percentage of unacceptable performance in EQAPs (15-UnEQ%), and percentage of requests with errors concerning patient identification (04-PxID%). Therefore, these were classified as the Top 5 PSIs (Figure 2; green columns).

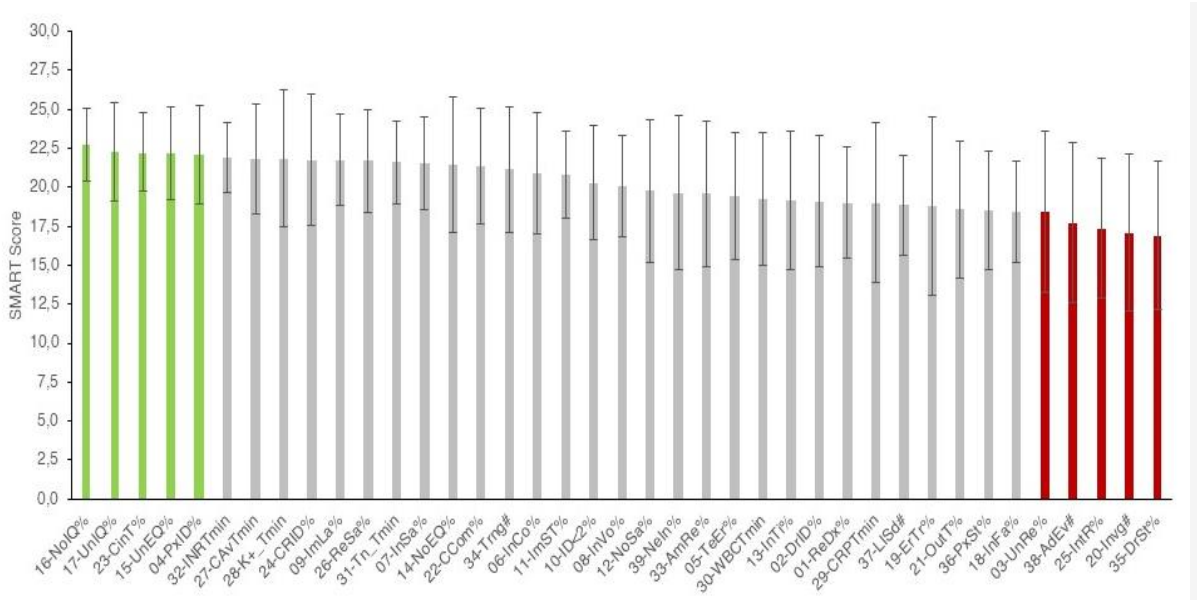

Figure 2: Overall performance of potential PSIs in terms of a composite SMART score. Error bars depict ±1 standard deviation.

The indicators that obtained the lowest scores and considered Bottom 5 PSIs (Figure 2; red columns) were the percentage of physician satisfaction (35-DrSt%), number of investigations undertaken on possibly biased results due to analytical interference (20-Invg#), percentage of reports with interpretative comments promoting a clinician's response and improving the patient's outcome (25-IntR%), number of adverse events on health and safety of laboratory staff (38-AdEv#), and percentage of unintelligible requests (03-UnRe%). The ANOVA showed significant differences between ranking groups ($F=24.321$; $P<0.001$), which were confirmed by a post hoc Tukey's test. The comparison of average SMART scores between Top 5 and Bottom 5 groups yielded a p-value of less than 0.001, and the same was applied for comparisons between Top 5 and Mid-range ($P<0.001$) and Bottom 5 and Mid-range ($P<0.001$) groups. No significant differences were observed between the indicators in the analytical stage.

Discussion

Table 1 shows a list with different indicators grouped by sections forming the total analysis process. Table 1 also shows a count of supporting literature of the different indicators. Some indicators with more support in terms of the number of articles mentioning them can be highlighted; such is the case of the indicators related to the pre-analytical stage with the most diffusion. This variability in the use of indicators reaffirms the importance of determining, on a context-specific basis (i.e., by country or institution), which PSIs are the most needed and generate the strongest impact on patient safety. Regarding the individual assessment according to each of the five SMART criteria, Figure 1 depicts that indicators related to patient- and sample-identification errors, analytical quality assessment, and critical value turnaround time were most frequently associated with high scores in all five criteria. This finding is in accordance with the results of previous studies in which the relevance of correct patient identification and patient-sample concordance has been acknowledged (44,45), thereby reinforcing the key role of this PSI category to maintain adequate surveillance in patient safety and monitor the progress of goal accomplishment in this area of the pre-analytical stage.

Moreover, external and internal quality assessments have been long recognized as essential components (46,47), but perhaps not sufficient on their own (48), to achieve adequate patient safety standards through the laboratory quality management system. It should be noted that the majority of EQAPs

are focused on the assessment of quality within the analytical stage of the laboratory process; consequently, it should not be surprising that some authors have called for the necessity of incorporating external assessment in pre-analytical and post-analytical procedures, where the majority of laboratory errors are registered (47).

The turnaround time of some of the most critical tests and average time to report critical values correctly have been considered of utmost importance for assuring patient safety and improving potential patient outcomes, particularly in the laboratories of emergency departments (49, 50). Then, it seems reasonable that a considerable number of respondents in the sample of the current study assessed one or more of this type of PSIs as highly sensitive, measurable, attainable, relevant, and time-bound.

With regard to the overall performance analysis on the basis of a SMART composite score, similar trends were observed. Figure 2 prompts that assuring quality in patient results released by the laboratory (15-UnEQ%, 16-NoIQ%, and 17-UnIQ%) is one of the main goals of the current sample of laboratory professionals that in order to minimize the patient's risk of receiving erroneous results compromise their clinical care. The identification and rectification of causes of failure in internal control performances and external assessments are imperative for effective and mature quality system management (51). The results of the present study suggest a strong quality culture where traceability and interpretation of these programs' results are meaningful for laboratory professionals and their laboratory quality objectives (i.e., the standards of acceptability).

Furthermore, the timely notification of critical values (23-CinT %) stands out as a needed measure for supporting accurate clinical decision-making based on laboratory results. Implementing tech-based strategies starting from an up-to-date laboratory information system (LIS) in Costa Rican healthcare centers may optimize some notification-related procedures, reducing time-consumption and missing/false reports likelihood. For instance, an observational study demonstrated that an electronic closed-loop notification system developed within a hospital increased positive indicators, such as timely notification ratio, notification receipt ratio, and timely notification receipt ratio of critical values (42). This type of intervention might also indirectly enhance other PSIs from the mid-range group (22-CCom% and 24-CRID %).

On the other hand, patient misidentification errors (04-PxID %) are regarded as a well-known quality and safety determinant. Just like every other factor involved in the pre-analytical phase, these indicators should be cautiously assessed, given that the percentage of errors occurring in this phase is the highest among all phases of the laboratory processes (33). This implies designing solid educational and training programs for laboratory technicians and medical staff in data collection, transcription, and entry to the LIS and other electronic systems (18).

Regarding the Bottom 5 and other Mid-range group results (Figure 2), these indicators seem to have intrinsic complexities, not contemplated in the workflow design of Costa Rican laboratories-, the adoption of which should be considered since they represent improvement opportunities, such as in-house research, integral surveillance of health services, and communication strategies with other professionals. Some of those indicators that were not regarded as important for patient safety by the sample of respondents in the present study are more related to interprofessional interaction and their performance in this study might have been influenced by educational and organizational barriers among healthcare workers (52).

It should be noted that many of the PSIs regarded as Mid-range or Bottom 5 by the respondents of the current study are considered important in other previous reports. However, it has been proposed that an indicator should be supported by the individuals in charge of its implementation (and not only by scientific evidence) in order to provide useful information (53). This means that experts' opinions about an indicator's validity should be taken into account throughout the indicator selection and implementation process (54).

In other words, pertinence to the local context and support by professionals are essential for the successful adoption of any PSI. As a result, it is suggested to readjust and reassess these indicators in order to transform them into more convenient parameters according to the Costa Rican clinical laboratory-network requirements. Moreover, an additional suggestion would be the evaluation of new strategies to control processes with growing relevance in the field of patient safety, such as the management of information security (e.g., controlling the e-mailing notification of laboratory results and LIS server protection), patient education and empowerment, and antimicrobial stewardship programs, to name a few.

Conclusion

The present study carried out a brief review of the literature regarding PSIs in the clinical laboratory, gathering a total of 39 indicators, which were presented to the local community of laboratory professionals in Costa Rica to be evaluated. The traceability and interpretation of the results of quality control programs are significant for laboratory quality objectives.

This was pointed in this study since several indicators were designated with the highest potential to be good PSIs, namely the percentage of tests without internal quality control, percentage of internal control determinations with unacceptable performance, percentage of critical values communicated in a timely manner, percentage of unacceptable performance in EQAPs, and percentage of requests with errors concerning patient identification.

To the best of our knowledge, this study has been the first investigation within the Costa Rican context to collect data about the healthcare professionals' perspectives on PSIs. This survey reveals the importance of quality control good practices and pre-analytical requirements for laboratory professionals in Costa Rica. The aforementioned items are considered key factors in facilitating the selection of preliminary indicators seeking to promote a patient safety culture in the clinical laboratory.

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