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Reaching consensus on communication of critical laboratory results using a collective intelligence method

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Abstract

Background: There is no consensus in the literature about what analytes or values should be informed as critical results and how they should be communicated. The main aim of this project is to establish consensual standards of critical results for the laboratories participating in the study. Among the project's secondary objectives, establishing consensual procedures for communication can be highlighted.

Methods: Consensus was reached among all participating laboratories establishing the basis for the construction of the initial model put forward for consensus in conjunction with the clinicians. A real-time Delphi, methodology "health consensus" (HC), with motivating and participative questions was applied. The physician was expected to choose a numeric value within a scale designed for each analyte.

Results: The medians of critical results obtained represent the consensus on critical results for outpatient and inpatient care. Both in primary care and in hospital care a high degree of consensus was observed for critical values proposed in the analysis of creatinine, digoxin, phosphorus, glucose, international normalized ratio (INR), leukocytes, magnesium, neutrophils, chloride, sodium, calcium and lithium. For the rest of critical results the degree of consensus obtained was "medium high". The results obtained showed that in 72% of cases the consensual critical value coincided with the medians initially proposed by the laboratories.

Conclusions: The real-time Delphi has allowed obtaining consensual standards for communication of critical results among the laboratories participating in the study, which can serve as a basis for other organizations.

Keywords: benchmarking; clinical laboratory; consensus on critical values; critical results; Delphi; health consensus.

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Introduction

Critical value management is acknowledged by the clinical laboratories as an important contribution to patient safety. A critical result is that reporting a life-threatening pathologic condition of a patient unless corrective action is taken promptly [1]. Critical values are often also called "alarming values" in the literature, although in the present work we opted for "critical values". Lundberg, in his definition of critical value, reflected the importance of the communication of critical results in due time and proper form. Effective critical result communication reduces diagnostic time and/or eases changes in the patient's therapeutic approach. A defined policy of critical results should be considered the right of patients.

Effective and timely communication of critical results is also a requirement for accreditation of clinical laboratories [2, 3].

There is no consensus in the literature about what analytes or values should be informed as critical results, and different terms are used for the same or similar concepts [4–6]. Wide variability is observed between different clinical laboratories regarding the treatment of critical values, revealing the need to harmonize the related procedures [6–10].

This variability can reflect the type of population attended by the laboratory and the different clinical needs in the different medical specialities [4, 11]. The reasons for notification, analytes and limits, should be defined in a way so as not to hinder clinical effectiveness of the notification, improving the patient's care (safety) and minimizing the distraction to the medical team with unnecessary notifications [12].

A guideline for the management of critical results has been published in the last years. It recommends processes and procedures that are compliant with accreditation requirements and consistent with patient safety practices. This guideline has introduced the term "critical-risk results" as the results that require immediate medical attention and action because they indicate a high risk of imminent death or major patient harm [13]. The present work focuses on these category of results.

Communication of critical results needs to be part of a shared policy and should be the laboratory's and the clinicians' responsibility. The cooperation of specialist professionals in defining the critical values is of utmost importance [10], and it is the laboratory's mission to evaluate how physicians understand this concept and how they prioritize their own response to notification for an effective management of the critical result.

The utilization of methods and techniques of collective intelligence, specifically those based on participation by means of the Delphi online methodology, also known as real-time Delphi, have proven to be effective tools for the introduction of professionals' clinical knowledge using strategies that facilitate their effective participation and make decisions more robust from a scientific point of view [14–16]. The platform "health consensus" (HC) is an example of the utilization of this method.

HC is a model that has been successfully applied within the field of health [17, 18], has functionalities to manage professionals' gradual participation and allows real-time exploitation of results.

The main aim of this project is to establish consensual standards (a single relation of magnitudes and values) of critical results for the laboratories participating in the study. Such consensus is to be achieved among a broad collective of clinical and laboratory professionals, using the Delphi methodology. Among the project's secondary objectives, establishing consensual procedures for communication can be highlighted.

The project's ultimate goal is eminently practical, so that the implementation of the findings result in a continuous improvement in patient safety.

Materials and methods

Professionals of the Public Laboratories Group of the Catalan Health Institute (Institut Català de la Salut) (ICS) and specialist physicians of health centers (hospitals and primary health centers) affiliated to the laboratories have participated in this descriptive cross-sectional study.

First, with the aim of knowing the state-of-the-art practice of the different laboratories, we reviewed the biological analytes liable to be communicated when a result is critical, the limits considered and the actions to be taken when these critical results are obtained. After this first approximation, consensus was reached among all participating laboratories, which was the basis for the construction of the initial model put forward for consensus with the clinicians.

A real-time Delphi model was applied for this study, specifically the methodology "HC" [14]. The Delphi method is a process for structuring the communication of a group of experts acting together, to deal with a problem and it is considered an efficient way to collect and synthesize opinions and capture tacit knowledge. Although the method admits a range of designs, it shares a common set of features like that it is an iterative communication process and experts get feedback during the different rounds of participation and also there is a conclusion in the form of statement and its degree of agreement among experts.

A questionnaire with motivating and participative questions was elaborated by the group of participating laboratories for the model. The questionnaire was adapted to the format of the "HC" tool and was delivered to the physicians to assess and identify, according to their own criteria, when a result should be considered critical. Once physicians chose an answer, they could see it in real time within the context of all the answers presented by the rest of participants with statistical values; they could change their vote when they deemed it necessary, and eventually raise the level of consensus. The level of consensus was reflected through a color scale ranging from green to red, indicating more or less consensus, respectively.

The questionnaire started with information on the participants' profile (age, gender, seniority, area of health care and speciality), and continued with the questions that composed the three fundamental parts of the model:

(a) Twenty-seven questions for each physician category (primary and hospital care) related with the critical values of the different analytes from which laboratories should generate a warning. The physician was expected to choose a numeric value within a scale designed for each analyte, and the majority scales consisting of six values (44 6-value scales, eight 7-value scales and two 4-value scales), where the minimum and maximum values corresponded to the extremes of the critical results adjusted to the scale, as established in the different laboratories. The values in the scales were expressed both, in international and

conventional units; therefore, there could be different scales for the same analyte, depending on the health care area (hospital or outpatient). A model basis, the scale in conventional units where participants choose a value, was used for all analytes. Together with the conventional scale, there was the international unit scale to facilitate the participation of the physicians who were familiar with the latter. Primary health physicians assessed the critical results of their area in outpatients only, while hospital physicians, who also perform outpatient visits, could choose values for inpatients and outpatients.

(b) Eighteen questions related with the communication circuit (its adequacy, communication channel, information sender and receiver).

(c) Five questions on their satisfaction with communication procedures of critical results established at present in the laboratories.

Responses to the questions about communication circuits were presented in the questionnaire as a 1-to-6 scale, numerical values to express quantitative preferences, 1 being the lowest value of agreement (I completely disagree) and 6 the highest (I completely agree).

Questions about satisfaction were presented in a 3-value scale (dissatisfied, satisfied and very satisfied), in the form of qualitative opinions.

– Participants answered in two rounds. Numbers and relative % between the two physician categories were established a priori.

The first round sought to validate the initial model and gather experiences about the method. To this end, a limited number of primary health care and hospital physicians were contacted about their experience and accessibility. In this first round, 21 participants answered the questionnaire in the presence of the laboratory physician.

In the second round, a larger number of professionals were invited to participate (500, 50 from each laboratory) and different procedures were used to recruit participants. The questionnaire was, in all cases, sent via e-mail and additionally physicians were contacted by phone as a participant recruiting method. Participation was also encouraged at medical meetings.

The statistical analysis was provided directly by the "HC" platform. The medians and the interquartile range (IQR) as well as the arithmetic mean were measured. To decide whether any particular analyte got consensus or not, the value of the normalized IQR, (IQRn) was considered. This was obtained dividing the corresponding IQR by the difference between two consecutive values of the scale. On a 6-point Likert scale and based on the consideration of median values and IQRs, an IQRn of 1 was considered equivalent to a "high" consensus degree while a value equal to or greater than 3 indicated a "medium low" consensus degree. An IQRn of 2 was equivalent to a "medium high" consensus degree.

The criteria was slightly adapted for the two particular cases of scales of 4 and 7 values. For the case of 7-value scales the same threshold was considered, resulting in a more demanding criteria; for the 4-value scales only IQRn ≤ 1 was considered "high" consensus, and IQRn > 1 was considered low consensus.

Results

The baseline biological analytes, the fruit of a first consensus among all the laboratories involved in the study, both for hospitals and primary health care, are reflected in Table 1. Leukocytes, neutrophils, hemoglobin and pH are analyzed in blood; international normalized ratio (INR) in plasma and the rest of analytes in serum.

Supplemental data, Figures 1 and 2 show examples of scales used in the model, corresponding to primary health care and hospital care, respectively.

The consensual model was delivered to physicians from different specialities within the Laboratories' areas of influence. Out of 500 physicians, 186 started the survey and 86.6% (161) answered some parts of the questionnaire. In the questionnaire participation analysis it can be observed that in the first part or key part of the study (consensus on critical values) 145 physicians gave their opinion on the values of the different analytes, and 111 answered over 80% of the questions in the questionnaire; 23 answered between 50% and 80% and 11 answered less than 50%. In the second part of the questionnaire, (consensus on the appropriate procedure of communication of critical values) participation was observed to be smaller; 72 physicians stated their opinion: 56 answered over 80% of the questions in the questionnaire; 13 answered between 50% and 80%, and three answered less than 50%. The last part of the model in which the clinicians' satisfaction towards the circuits of communication of critical values by the laboratories were assessed, was answered by 143 professionals, of which 139 answered over 80% of the questions and four answered between

Table 1: Analytes included in the study.

Analytes	Low critical limit	High critical limit
Bilirubin		*
Calcium (II)	*	*
Chloride	*	*
Creatinine		*
Digoxin		*
Phosphorus	*	*
Glucose	*	*
Hemoglobin	*	
International normalized ratio (INR)		*
Leukocyte	*	*
Lithium		*
Magnesium	*	*
Neutrophils	*	
pH	*	*
Platelets	*	*
Potassium	*	*
Sodium	*	*
Thyroxine (free)		*
Urea		*

50% and 80% of the questions. Most participants completed the consensus model by themselves (126) while some others (35) answered the survey in the presence of a laboratory physician.

The distribution of the participant professionals by gender was similar (51% men and 49% women) and most of them were aged between 45 and 64 years (67%), 31% were aged between 25 and 44 years, and 2% were aged over 64 years.

Table 2: Number of participants classified by medical departments.

Medical specialty	n
Primary Health Care	80
Internal medicine	19
Endocrinology	9
Neurology	9
Hematology	7
Hepatology	5
Oncology	6
Nephrology	4
Urology	4
Cardiology	3
Obstetrics and Gynecology	3
Allergy	2
Anesthesiology	2
Other	8

Regarding their seniority, 10% had less than 10 years' experience, 35% between 10 and 20 years, 35% between 20 and 30 years, and 20% over 30 years. The speciality of the participants in the study is displayed in Table 2.

Tables 3 and 4 show the critical value medians obtained from the different analytes in conventional units (medians in international units can be found in the annex [Supplemental data, Tables S1 and S2]) for primary health and hospital care, respectively, as well as the degree of consensus reflected in the IQR and the limits of the intervals of the scales of values corresponding to the possibilities of response (LL: lower limit; HL: higher limit). In the area of primary health care, a high degree of consensus was observed (IQRn = 1) for critical values proposed in the analysis of creatinine, digoxin, phosphorus, glucose, INR, leukocytes, magnesium, neutrophils; upper limit for communication of critical results of chloride analysis and lower limit for that of sodium. A high degree of consensus was observed in hospital care for critical values proposed for calcium, creatinine, digoxin, INR, lithium, neutrophils, and for the upper limit for sodium and lower limit for magnesium. The degree of consensus obtained for the rest of critical results was "medium high" (IQRn = 2).

Table 5 shows the results of the change in the degree of consensus (IQRn) of critical values caused by the vote modification of participants, considering the initial and final responses in the 2 study areas.

Table 3: Results obtained for outpatients.

Analytes	Units	Median		IQRn		n	
		Low critical limit (LL-HL)	High critical limit (LL-HL)	LCL	HCL	LCL	HCL
Bilirubin	mg/dL		11 (10–15)		2		135
Calcium (II)	mg/dL	6.9 (6–75)	12.3 (12–13.5)	2	3 (2)[a]	134	134(78)[a]
Chloride	mmol/L	79 (75–85)	124 (120–130)	2	1	108	109
Creatinine	mg/dL		3.8 (2.8–7.8)		1		134
Digoxin	ng/mL		2.6 (1.8–3.8)		1		122
Phosphorus	mg/dL	1.05 (0.75–1.50)	8 (7.5–10)	1	1	108	108
Glucose	mg/dL	45 (30–55)	400 (250–500)	2	1	135	136
Hemoglobin	g/dL	7 (6–8.5)		2		136	
International normalized ratio (INR)			5 (3.5–6.5)		1		131
Leukocyte	×10E3/µL	1.3 (0.9–1.9)	30 (20–50)	2	1	137	136
Lithium	mmol/L		1.8 (1.4–2.4)		2		111
Magnesium	mg/dL	0.9 (0.6–1.1)	5 (4–6.5)	2	1	108	106
Neutrophils	×10E3/µL	0.5 (0.25–1)		1		132	
Platelets	×10E3/µL	40 (10–60)	800 (600–1100)	2	2	136	130
Potassium	mmol/L	2.8 (2.5–3)	6.1 (5.9–7.1)	2	2	137	137
Sodium	mmol/L	120 (114–129)	154 (150–160)	1	2	133	135
Thyroxine (free)	ng/dL		4.6 (2.6–7.6)		2		127
Urea	mg/dL		175 (125–250)		2		125

LCL, low critical limit; HCL, high critical limit; LL, lower limit of the scale of values; HL, higher limit of the scale of values; IQRn, normalized interquartile range; n, number of participants. [a]Considering only the answers of general practitioners.

Table 6 reflects the percentage of professionals who modified their initial answer once they visualized the rest of answers, for each limit and analyte.

Supplemental data, Figure 3 shows an example of the evolution in the degree of consensus in the case of the upper critical value proposed for INR. Considerable changes can be appreciated in the median (black line) and in the degree of consensus (IQRn) (dark green shaded area) throughout the two participation rounds.

Medians obtained for questions regarding communication circuits and the degree of consensus reflected in the IQR can be seen as a summary in Table 7.

In the consensus on communication circuits (Supplemental data, Figure 4), professionals expressed agreement in that the laboratory should communicate a critical result despite it being similar to a result obtained previously, or if the patient presented a diagnostic orientation compatible with the result (medium to high degree of consensus [IQRn = 2]). The telephone-call was the most valued means or circuit for the notification of critical results with a high degree of consensus (IQRn = 1). SMS-type text messaging and fax were not considered as adequate means with a medium high degree of consensus (IQRn = 2). No consensus was reached on communication via e-mail. Regarding the person who should carry out the notification, the degree of consensus obtained was medium high for all items (IQRn = 2) among the surveyed population that it had to be medical, not administrative staff in the laboratory, but showed indifference when asked whether it should be technical staff who communicated critical results. Regarding the person appointed to receive notification, the degree of consensus obtained was high or medium high in all items (IQRn = 1 or 2). Physicians considered that the best recipient was the physician requesting the test followed by the physician on duty or primary health care center coordinator, or the physician in charge. On the other hand, participants showed indifference as to whether it was a member of the nursing staff or medical staff in the service/ward/primary health care center receiving the communication. With a high degree of consensus, participants agreed that administrative staff should not receive the notification. Regarding the option that the laboratory contacted the patient, responses showed some indifference. The analysis of the evaluation of professionals' satisfaction showed that over 82% of surveyed participants were "satisfied" or "very satisfied" with the existing notification procedure and the delivery time of critical values of each laboratory. Participants who carry out their practice in primary health care showed greater satisfaction than those in hospital care regarding the present procedures and response time.

Of the participating physicians, 86% scored the method of consensus used in this study as satisfactory.

Table 4: Results obtained for inpatients.

Analytes	Units	Median		IQRn		n	
		Low critical limit (LL-HL)	High critical limit (LL-HL)	LCL	HCL	LCL	HCL
Bilirubin	mg/dL		12 (10–15)		2		65
Calcium (II)	mg/dL	6 (5–7.5)	13 (12.7–14.2)	1	1	69	67
Chloride	mmol/L	79 (75–85)		2		55	
Creatinine	mg/dL		6 (6–7.5)		1		68
Digoxin	ng/mL		2.9 (2.1–4.1)		1		55
Phosphorus	mg/dL	0.93 (0.75–1.20)	8.8 (8.5–10)	2	2	59	59
Glucose	mg/dL	45 (30–55)	450 (400–525)	2	2	69	67
Hemoglobin	g/dL	6.5 (5–7.5)		2		70	
International normalized ratio (INR)			5 (4–10)		1		66
Leukocyte	×10E3/μL	1.1 (0.9–1.9)	35 (25–55)	2	2	70	68
Lithium	mmol/L		2 (1.6–2.6)		1		46
Magnesium	mg/dL	0.9 (0.6–1.1)	5 (4–6.5)	1	2	57	55
Neutrophils	×10E3/μL	0.5 (0.25–1)		1		67	
Platelets	×10E3/μL	30 (10–60)	800 (600–1100)	2	2	67	64
Potassium	mmol/L	2.6 (2.5–3)	6.3 (5.9–7.1)	3 (2)[a]	2	69(17)[a]	69
Sodium	mmol/L	120 (110–120)	158.5 (154–169)	2	1	68	68
Thyroxine (free)	ng/dL		3.5 (2.7–3.9)		3 (2)[a]		55(17)[a]
pH		7.2 (7–7.30)	7.6 (7.58–7.63)	2	2	65	65

LCL, low critical limit; HCL, high critical limit; LL, lower limit of the scale of values; HL, higher limit of the scale of values; IQRn, normalized interquartile range; n, number of participants. [a]Considering only the answers of internal medicine specialists.

Table 5: Change in the degree of consensus over the study. Initial and final IQRn.

Analytes	CL	Outpatients IQRn		Inpatients IQRn		Scale[a]
		Initial	Final	Initial	Final	
Bilirubin						
	High	3	2	3	2	6
Calcium (II)						
	Low	3	2	1	1	6
	High	3	3	1	1	6
Chloride						
	Low	3	2	2	2	6
	High	2	1			
Creatinine						
	High	2	1	2	1	6
Digoxin						
	High	2	1	1	1	6
Phosphorus						
	Low	2	1	1	2	6
	High	2	1	2	2	6
Glucose						
	Low	2	2	2	2	6
	High	1	1	3	2	6
Hemoglobin						
	Low	2	2	2	2	6
International normalized ratio (INR)						
	High	4	1	2	1	7
Leukocyte						
	Low	4	2	3	2	6
	High	3	1	2	2	7
Lithium						
	High	2	2	1	1	6
Magnesium						
	Low	2	2	2	1	6
	High	2	1	2	2	6
Neutrophils						
	Low	1	1	2	1	4
pH						
	Low			3	2	7
	High			3	2	6
Platelets						
	Low	3	2	2	2	6
	High	2	2	3	2	6
Potassium						
	Low	3	2	4	3	6
	High	2	2	2	2	7
Sodium						
	Low	2	1	3	2	6
	High	2	2	2	1	6/7
Thyroxine (free)						
	High	2	2	4	3	6
Urea						
	High	2	2			6

CL, critical limit. [a]Scale: number of points included in the rating scale for each analyte.

Table 6: Percentage of professionals who modified their initial answer once they visualized the answers of the previous participants.

Analyte	Answer change (%) outpatients		Answer change (%) inpatients	
	LCL	HCL	LCL	HCL
Bilirubin		0[a]		0[a]
Calcium (II)	0[a]	25[a]	0[a]	58[c]
Chloride	0[a]	40[b]	0[a]	
Creatinine		0[a]		68[c]
Digoxin		30[b]		0[a]
Phosphorus	0[a]	20[a]	42[b]	0[a]
Glucose	0[a]	12[a]	0[a]	48[b]
Hemoglobin	0[a]		0[a]	
International normalized ratio (INR)		0[a]		45[b]
Leukocyte	36[b]	0[a]	0[a]	34[b]
Lithium		0[a]		0[a]
Magnesium	31[b]	0[a]	51[c]	0[a]
Neutrophils	21[a]		36[b]	
Platelets	0[a]	22[a]	0[a]	53[c]
Potassium	0[a]	20[a]	0[a]	59[c]
Sodium	0[a]	24[a]	0[a]	44[b]
Thyroxine (free)		0[a]		0[a]
Urea		26[b]		
pH			0[a]	32[b]

LCL, low critical limit; HCL, high critical limit. [a]≤25% of participants modified their answer. [b]26%–50% of participants modified their answer. [c]50% of participants modified their answer.

At the end of the document there are two summary tables (Tables S3 and S4) which show the recommended tests to include in a critical value list and their thresholds in conventional and international units.

Discussion

The design stage of the survey was laborious as it had to comply with the "HC" Model, and at the same time, it had to be personalized to attain the scales for each analyte that was supposed to collect the critical results of all participants, displayed in international system (IS) units and in conventional units. We chose to differentiate the questions addressed to the primary health care area from those to hospital care, and two differentiated questionnaires were designed with the aim of facilitating inclusion or exclusion of some analytes, adequate the critical results proposed and improve participants' understanding of questions.

Recruiting physicians to participate voluntarily in the Delphi survey was the biggest difficulty. Having validated

Table 7: Medians obtained for questions regarding communication circuits and the degree of consensus.

Question		M	IQRn	n
Laboratory should communicate a critical value:	even if similar to previous	5	2	143
	even if compatible with patient's diagnosis	5	2	142
The most appropriate means to communicate a critical value is:	telephone	5	1	141
	SMS	2	2	140
	email	3	3	141
	fax	2	2	139
The professional who communicates a critical value should be:	medical staff	5	2	143
	a laboratory technician	4	2	143
	administrative staff	2	2	142
The professional who should receive notification of a critical value should be:	requesting physician	6	1	143
	doctor on duty	5	2	143
	nurse in care of the patient	4	2	143
	any doctor of the department/primary care center	3	2	143
	administrative staff of the department/primary care center	1	1	142
Regarding outpatients, when none of the professionals mentioned is available, laboratory should contact with:	primary care coordinator	5	1	136
	emergency health center	5	1	137
	doctor on duty (or hospital outpatients)	5	1	140
	patient	3	2	141

Rating scale: 1 (I completely disagree) to 6 (I completely agree). M, median; IQRn, normalized interquartile range; n, number of answers.

the model in the first round, and with the aim of recruiting more participants, we invited physicians from different specialities via e-mail, telephone, medical meetings and by making contact through regional medical administrations. Although the level of participation was sufficiently acceptable to reach a consensus, it was lower than had been expected in spite of participating deadlines being extended several times. The limited participation could be due to several causes. On the one hand, technical difficulties derived from the software in the computers not meeting the necessary requirements to support the Model; on the other hand, the time required by clinicians to answer the questionnaire.

The role of the laboratory physician has been key throughout the study, both in the selection of participating physicians, especially during the first stage, and in answering doubts and solving problems of the participating professionals during the survey. It was stated that physicians did not always differentiate between critical and pathological values (results that are found outside the reference values) and to reach a consensus on critical values, this differentiation was crucial.

The medians of critical results obtained represent the consensus on critical results for outpatient and inpatient care. Hospital physicians with outpatient practice in hospital also had the option of answering the primary health care questionnaire, which gave the consensus on outpatient critical results greater participation.

Within the outpatient domain, and taking into account the answers of all participants, the level of consensus obtained was "high" or "medium-high" for the critical results proposed for all the analytes, except for the upper limit of calcium analysis (12.3 mg/dL or 3.075 mmol/L) that presented a "medium-low" consensus. If we analyze the answers of general practitioners only (n = 78) in this critical result for calcium, this coincides with the global group and the level of consensus rises to "medium-high" (Tables 2 and 7). We considered accepting this result as upper limit for communication of critical results of the serum calcium concentration. The higher dispersion and lower consensus on the need to communicate calcium results in outpatients could be due to the inclusion of hospital physicians from very diverse specialities in this group with outpatient practice and with a view more orientated to the diseases they treat in their own speciality. However, this effect was not observed for the rest of analytes.

The level of consensus reached in the hospital environment, that is: consensus on critical results for inpatients, was "high" or "medium-high" for all analytes, except for the lower limit of the results of substance concentration of the potassium ion in serum/plasma (2.6 mmol/L) and the upper limit of substance concentration of free thyroxine (6.3 ng/mL), both with a "medium-low" consensus. If we analyze the responses of internal medicine specialists only (n = 17), as the largest hospital group, the medians of critical results of the two analytes coincide with those

of the global group, and the level of consensus rises to "medium-high" (Tables 3 and S1). We considered accepting these medians as consensual critical results for the analysis of the potassium ion and free thyroxine.

From the comparison of medians of analytes obtained for primary health and hospital care, we can state that primary health care specialists were more conservative in their estimations of upper and lower limit for most analytes (values nearer the reference values), except for the upper level of free thyroxine. They coincided in establishing the lower levels of glucose, magnesium, neutrophils, chloride and sodium, and the upper levels of magnesium, INR and platelets. One of the reasons for this convergence could be that outpatient physicians requested notification of critical values earlier to anticipate any therapeutic decision-making due to outpatient particularities. In addition, inpatients with higher pathologic complexities, are subject to further supervision.

The "HC" tool proved useful in establishing consensus. The evolution of professionals' votes throughout the Delphi process allowed improving the level of consensus. The most considerable increase was observed in leukocytes and INR. However, IQRn was not modified with the evolution of Delphi, in hemoglobin, lithium, urea, the upper limit of potassium, calcium and the lower limit of glucose.

It is worth noting that, although the distribution of the changes of response per analyte is similar in hospital and primary health/outpatient hospital care, the greatest percentage of changes from the initial response are observed within the hospital environment.

The degree of agreement between the critical values obtained from consensus and those proposed initially was assessed in a qualitative manner. On the one hand, the critical result was chosen to be considered as unchanged when the consensual response was some of the central values in the scale (in scales with an even number of values) – as the median was within that interval – or the central value in the scale (in those with an uneven number of values). On the other hand, the critical result was considered to differ from the initial response when after consensus a value in the scale was obtained, which was "slightly different": positions 2 and 5 in the scale in 6-value scales, or 3 and 5 in 7-value scales; "considerably different": consensus was any other value in the scale.

The results obtained showed that in 72% of cases the consensual critical value coincided with the medians initially proposed by the laboratories. That is, notification of these critical values is now being done in accordance to the needs manifested by clinicians.

For the outpatient (primary health/outpatient hospital care), this corresponded to 21 out of 27 values proposed (78%). In six cases (upper limit for communication of critical values for bilirubin, calcium, creatinine, phosphorus, leukocytes and potassium), the consensual result was slightly lower to that proposed by the laboratories, which indicates that clinical physicians require earlier notification.

For hospital patients, 18 out of 27 consensual values (63%) did not differ from the initial agreement between laboratories. However, for six of the results slightly different values were obtained: upper critical value for calcium, phosphorus, leukocytes, potassium and free thyroxine and lower critical value for pH. Except for pH and thyroxine, consensual values were more conservative than those proposed by the laboratories. In addition, the upper critical value for creatinine and INR (prothrombin time) as well as the lower critical value for sodium were considerably modified.

It is worth highlighting that, in all the cases where the laboratories' initial proposal was modified, clinical physicians proposed less extreme values (closer to the interval of reference).

Furthermore, five out of nine analytes in which there has been change from the initial median have coincided in both environments: calcium, creatinine, phosphorus, leukocytes and potassium.

The present study would be classified within the highest quality standard, according to the systematic literature review carried out by Campbell [7], in including collaboration between clinicians and laboratories. Results in Campbell's publication are similar to those obtained in our study. The consensual medians obtained at hospital level coincide in both limits for calcium, glucose, pH, lower limit for sodium and upper limit for magnesium. For the remaining values, in spite of not being coincidental, our results fall within the interval of medians obtained in this review.

Participants' comments presented a great diversity of opinions. Most proposed that limits by medical specialities were established and that analytes were established (glomerular filtrate instead of creatinine) or discarded (chloride, phosphorus, magnesium, bilirubin and urea). Some participants also valued the importance of differentiating the patient's critical situation (acute or chronic state of the pathology) in establishing some critical values (however, globally they wish to be notified even when the patient presents a similar previous result).

The importance of taking into account all the results of critical values by all physicians was also highlighted, and it was suggested that these were included in the

system that manages the computerized clinical reports of patients. The importance of differentiating critical values according to the care area was also highlighted.

Regarding the results of the survey on the communication circuit, the telephone was the most valued method and the most frequently used by most laboratories [5, 19–22]. Text SMS-type messaging was not considered effective although it was one of the alternatives described as successful by other authors [8, 23]. E-mail was not considered a good tool either, coinciding with descriptions in previous studies [23, 24] failing to achieve a high level of consensus. Participants manifested their preference in the laboratory physician as the person notifying, coinciding with the habitual practice in most Spanish laboratories [23]. Equally, medical staff were considered the best recipients of communication, also common practice [19, 22–24], probably valuing direct communication as faster and more efficient, and avoiding possible errors.

The physicians surveyed did not take a position on whether the laboratory should contact the patient directly or not, in spite of the new tendencies in patient safety moving in this direction [25]. Some participants in the study suggested the importance of assessing the content of the notification and the form of communication to avoid unnecessary alarm or undue concern in these cases.

Although the study shows a high level of satisfaction with the circuit of notification of critical results existing in the different laboratories, we propose actions with the aim of increasing communication effectiveness. Such actions would envisage improving the computer systems used for the management of patient medical records and the use of new IT in the communication of results.

Patient safety requires that laboratories have a consensual management system for the timely and effective communication of critical results. Our study entails an added value in the management of these results, since we add the experience of clinicians to the initial consensus of critical values of laboratories.

The real effectiveness of communication of critical results in terms of morbidity and mortality should be studied and could be the point of departure for further studies.

In conclusion, the real-time Delphi has allowed obtaining consensual standards for communication of critical results among the laboratories participating in the study, which can serve as a basis for other organizations.

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