A Critical Evaluation of Critical Value Notification

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Learning Objectives

I. Identify existing recommendations for critical value thresholds

II. Contrast different mechanisms for critical results notification

III. Investigate the origin of the latest ADA hypoglycemic definitions and their impact on the lab

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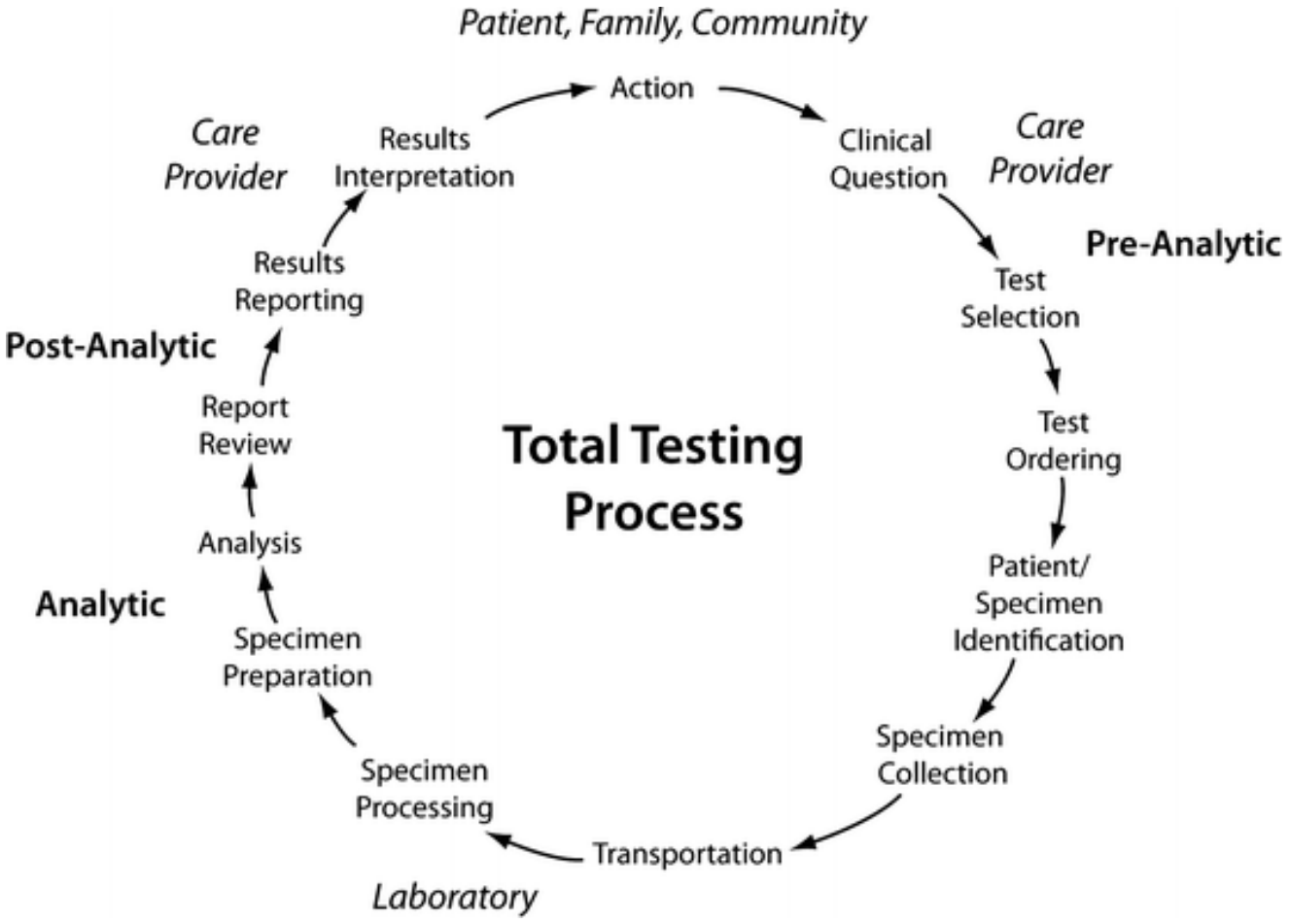
The Total Testing Process: Lifecycle of a Test



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Phases of Testing

Pre analytic

- The right test, the right patient, the right time
- Specimen collection
- Transport to the lab

Analytic

- Instrument calibration
- Temperature and humidity
- Specimen sampling

Post Analytic

- Appropriate reference interval
- Reporting the result in the medical record
- Notification of the result to the provider, *result acknowledgement!*

Diagnostic errors in Laboratory Medicine

Diagnostic Error: errors in which diagnosis was unintentionally delayed, wrong, or missed

Year	Type of Error
1950-1990	Analytical Errors
1990s	Errors in Clinical Labs (pre and post) phases
2000s	Errors in the total testing process (pre-pre and post-post analytical phases)
Today	Patient-centered testing related diagnostic errors

Where do the majority of errors occur?

Pre-analytic errors account for 48-62% of total errors in laboratory medicine

Pre-pre analytical errors

- Inappropriate order
- Order entry mistakes
- Patient/Sample misidentification
- Sample collection
- Inappropriate container
- Sample handling, transit, storage

pre-analytical errors

- Aliquot labeling
- Sorting and routing
- Pour-off errors
- Specimen processing (centrifugation, decapping, aliquoting, sampling)

Respective Roles in the Post Analytic Phase

The “Provider”

Diagnostic Decision

The “Lab”

Context for result interpretation

- Reference ranges
- Error identification/specimen quality
- Interpretative comments
- Clinical consultation
- Urgency of decision (*critical values*)

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The origin story of critical (panic) values

***WHEN TO PANIC OVER ABNORMAL VALUES*. LUNDBERG G. MED LAB OBSERVER 1972; 4:47-54**

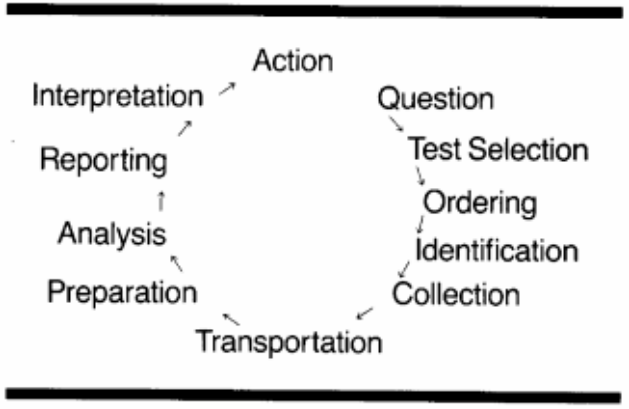
Critical (Panic) Value Notification: An Established Laboratory Practice Policy (Parameter)

A laboratory test begins when a clinician (or patient) asks a question that requires a laboratory result to answer. It ends with an appropriate action being taken on the patient's behalf based on that result. There are at least 11 steps in the performance of that test (Figure). We have called that sequence the "brain-to-brain loop."[1] A chain is known to be only as strong as its weakest link. Thus, anything that interferes with the complete closing of this loop for every laboratory test requested produces at the least, a waste, and at the most, a tragedy.

See also p 704.

Historically, most laboratory personnel have concentrated on the analytic portion of the loop. However, modern quality assurance requires that laboratory personnel consider all steps, actively participating in preanalytic and postanalytic

Brain-to-brain loop



The 11 steps in the performance of a laboratory test.

JAMA. Feb 2 1990 Vol 263 No 5

The definition of a critical value

George Lundberg, MD. University of Southern California Med Center JAMA Feb 1990

- We defined a *critical (panic) value* as one that represents a pathophysiological state at such variance with normal as to be life threatening unless something is done promptly and for which some corrective action could be taken

- A *vital value* represents a pathophysiological state at such variance with normal as to be life threatening and for which a corrective action can be taken but for which rapid action is not as crucial (examples: positive TB, cyto smear for squamous cell carcinoma)

JAMA. Feb 2 1990 Vol 263 No 5

First aggregate of critical values (1990)

Table 1.—Clinical Chemistry Critical Limits

Test	Listing Frequency, %	Units	Low (SD)	Range	High (SD)	Range
Glucose	100	mmol/L	2.6 (0.4)	1.7-3.9	26.9 (8.0)	6.1-55.5
		mg/dL	46 (7)	30-70	484 (144)	110-1000
Potassium	100	mmol/L	2.8 (0.3)	2.5-3.6	6.2 (0.4) 8.0 (Hemolyzed)	5.0-8.0
Calcium	100	mmol/L	1.65 (0.17)	1.25-2.15	3.22 (0.22)	2.62-3.49
		mg/dL	6.6 (0.7)	5.0-8.6	12.9 (0.9)	10.5-14.0
Sodium	100	mmol/L	120 (5)	110-137	158 (6)	145-170
CO_2 content	75	mmol/L	11 (2)	5-20	40 (3)	35-50
Magnesium	33	mmol/L	0.41 (0.16)	0.21-0.74	2.02 (0.82)	1.03-5.02
		mg/dL	1.0 (0.4)	0.5-1.8	4.9 (2.0)	2.5-12.2
Phosphorus	33	mmol/L	0.39 (0.10)	0.26-0.65	2.87 (0.48)	2.26-3.23
		mg/dL	1.2 (0.3)	0.8-2.0	8.9 (1.5)	7.0-10.0
Bilirubin	25	µmol/L	...	...	257 (86)	86-513
		mg/dL	...	...	15 (5)	5-30
Chloride	20	mmol/L	75 (8)	60-90	126 (12)	115-156
Osmolality	20	mmol/kg	250 (13)	230-280	326 (18)	295-375
Urea nitrogen	20	mmol/L	...	...	37.1 (21.1)	14.3-107.1
		mg/dL	...	...	104 (59)	40-300
Uric acid	20	µmol/L	...	...	773 (119)	595-892
		mg/dL	...	...	13 (2)	10-15
Cerebrospinal fluid glucose	16	mmol/L	2.1 (0.6)	1.1-2.8	24.3 (11.4)	13.9-38.9
		mg/dL	37 (10)	20-50	438 (206)	250-700
Creatinine	10	µmol/L	...	...	654 (380)	177-1326
		mg/dL	...	...	7.4 (4.3)	2.0-15.0
Free calcium	7	mmol/L	0.78 (0.05)	0.75-0.88	1.58 (0.25)	1.50-1.63
		mg/dL	3.13 (0.20)	3.01-3.53	6.33 (1.00)	6.01-6.53
Lactate	5	mmol/L	...	...	3.4 (1.3)	2.3-5.0
		mg/dL	...	...	30.6 (11.7)	20.7-45.0

- National survey of 92 institutions
  - 20 trauma centers
- Low and High Critical Limits were self reported by labs
- For each critical limit, the mean, and SD, and range were determined
- Chemistry, hematology, qualitative tests (slide review, microbiology, urinalysis, blood bank) and newborn critical values included

JAMA. Feb 2 1990 Vol 263 No 5

Glucose Critical Values

- Mean Glucose Lower Limit CV: 46 mg/dL
- Mean Glucose Upper Limit CV: 484 mg/dL
- Range of Low CV: 30-70 mg/dL
- Range of High CV: 110-1000 mg/dL

two qualitative tests. Glucose and potassium levels were the most important tests. The glucose mean low critical limit is associated with symptomatic hypoglycemia and significant counter-regulatory hormonal response.[10] The mean glucose critical limits are more conservative than former ad hoc values.[3,5] The importance of potassium critical limits is obvious in view of the risks of cardiac arrhythmias. Critical limits for new-

JAMA. Feb 2 1990 Vol 263 No 5

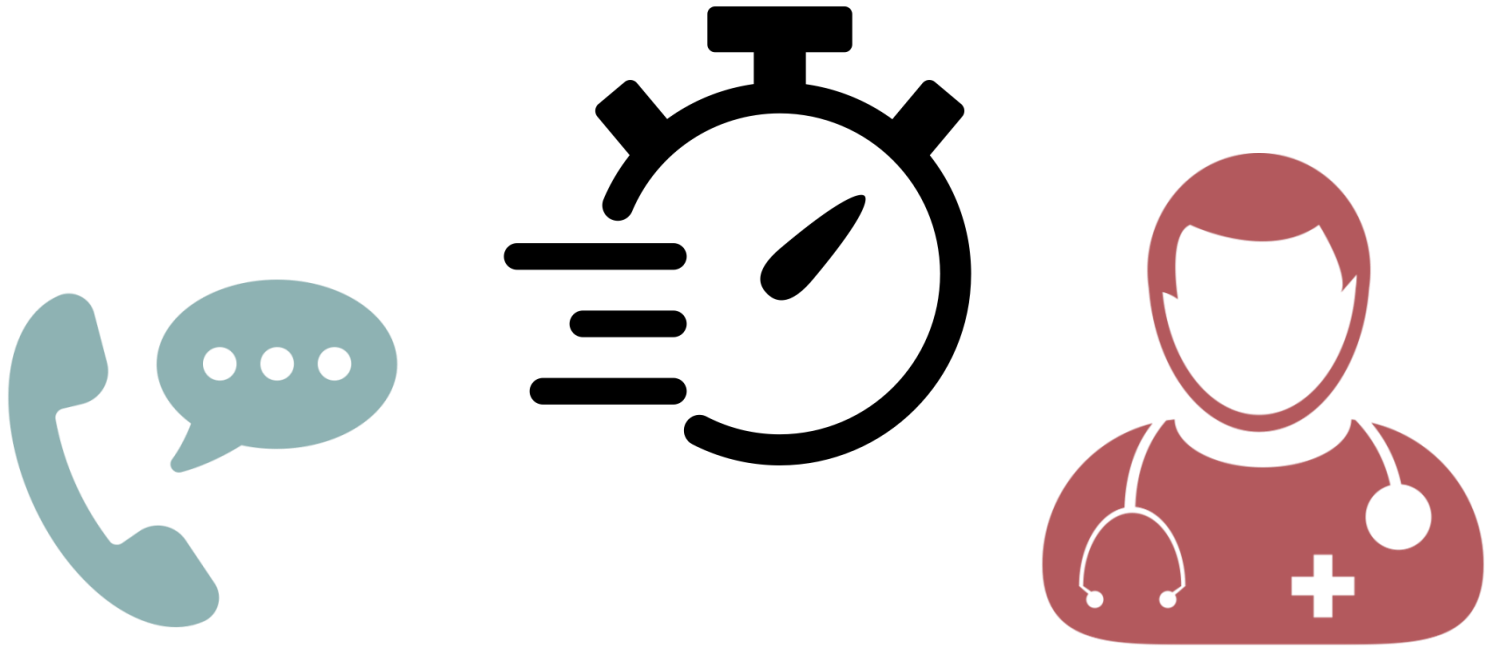
Q-Probes: 2002 (and 1992)

- College of American Pathologists sponsored survey
- Voluntary submission of critical Values for labs participating in Q-probes.
- Q-probes are short term external studies that provide a one-time assessment of quality processes.—Not graded
- Published in Archives of Pathology & Laboratory Medicine.

Laboratory Critical Values Policies and Procedures

A College of American Pathologists Q-Probes Study in 623 Institutions

Peter J. Howanitz, MD; Steven J. Steindel, PhD; Nan V. Heard, MD



6. Steindel SJ, Heard NV. *Critical Values: Q-Probes 92-04*. Northfield, Ill: College of American Pathologists; 1992.

Chemistry Critical Values

Table 1. Analytes From Supplied List Used on Participants' Critical Values Lists*

Analytes	Low Critical Value Percentile			High Critical Value Percentile			% Appearing on Stat List (N)
	10th	50th (Median)	90th	10th	50th (Median)	90th	
Chemistry							
Ammonia, µmol/L	**0.0**	**4.4**	**22.2**	**19.4**	**43.3**	**110.8**	46.4 (289)
Arterial pH	7.2	7.2	7.3	7.5	7.6	7.6	45.9 (286)
Arterial P_{CO_2}, kPa	2.5	2.7	4	6.7	9.3	9.3	45.3 (282)
Arterial P_{O_2}, kPa	5.3	5.3	8.0	**7.3**	**14.8**	**33.3**	44.4 (279)
Bilirubin (neonatal), µmol/L	**0.0**	**0.0**	**17.1**	206.2	256.5	307.8	66.1 (412)
Calcium (ionized), mmol/L	**0.22**	**0.75**	**1.50**	**0.35**	**1.58**	**1.75**	17.3 (108)
Calcium (total), mmol/L	1.50	1.50	1.75	3.0	3.25	3.50	82.5 (514)
Carbon dioxide, mmol/L	10	10	15	40	40	45	82.5 (514)
Chloride, mmol/L	*70*	*80*	*90*	*115*	*120*	*130*	73.4 (457)
Creatinine, µmol/L	**0**	**18**	**44**	265	442	884	60.5 (377)
Glucose (cerebrospinal fluid), mmol/L	*1.10*	*2.15*	*2.31*	*4.13*	*11.00*	*27.50*	63.7 (397)
Glucose (serum), mmol/L	2.20	2.20	2.75	16.50	24.75	38.50	57.6 (359)
Lactic acid, mmol/L	**0.00**	**0.06**	**0.33**	**0.27**	**0.44**	**3.40**	86.4 (538)
Lecithin/sphingomyelin (L/S) ratio	**1.0**	**1.5**	**2.0**	**2.0**	**2.0**	**3.0**	35.5 (221)
Magnesium, mmol/L	0.39	0.41	0.57	1.23	1.91	2.50	9.3 (58)
Phosphorus, mmol/L	0.32	0.32	0.65	1.78	2.58	3.23	57.9 (361)
Potassium, mmol/L	2.5	2.8	3.0	6.0	6.2	6.5	49.3 (307)
Osmolality, mOsmol/kg	*219*	*250*	*270*	*300*	*323*	*350*	86.2 (537)
Sodium, mmol/L	110	120	125	150	160	170	43.0 (268)
Urea nitrogen, mmol/L	**0.0**	**1.1**	**2.1**	17.9	28.6	35.7	85.9 (535)
Uric acid, mmol/L	**0.0000**	**0.0590**	**0.1180**	**0.5990**	**0.7611**	**0.8850**	65.2 (406)

	Median glucose mg/dL
Low	40
High	446

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Microbiology Critical Values

Table 2. Participants (%) Reporting Microbiology Results as Critical Values

Microbiology Result	Participants, %
Positive blood cultures	95.0
Positive CSF cultures	91.2
Positive AFB smear or culture	71.9
Positive Gram stains of sterile body fluids	66.8
Initial stool isolates of *Salmonella, Shigella, Campylobacter,* and *Yersinia*	59.7
Positive latex agglutination and/or antigen detection test	50.7
Positive CSF VDRL	25.7
Other microbiology critical values	44.8

* CSF indicates cerebrospinal fluid; AFB, acid-fast bacilli; and VDRL, Venereal Disease Research Laboratory test.

Illicit or TDM Critical Values

Table 3. Participants' Reporting Practices	
Drug Results	**Participants, %**
Drugs of abuse	
Telephone all positive results	25.2
Do not telephone all positive results	52.8
Not applicable	22.0
Therapeutic drugs	
Telephone all toxic values	96.3
Do not telephone all toxic values	2.9
Not applicable	0.8

Beat the clock….

Table 4. Time Spent to Complete or Abandon a Critical Value Call

No. of Beds	Mean Time to Complete Call, min (No. of Participants)				Mean Time to Abandon Call, min (No. of Participants)			
	Inpatient			Outpatient, All Shifts	Inpatient			Outpatient, All Shifts
	Night	Evening	Day		Night	Evening	Day	
Unknown	6.8 (8)	12.6 (9)	6.9 (9)	16.5 (8)	. . .	5.0 (1)	. . .	. . .
0	. . .	. . .	. . .	11.2 (2)	. . .	. . .	. . .	. . .
1–150	7.0 (110)	10.1 (127)	8.3 (136)	13.2 (123)	9.8 (4)	46.6 (8)	54.8 (9)	23.4 (14)
151–300	5.7 (190)	5.8 (196)	5.9 (203)	11.4 (185)	3.5 (8)	7.3 (8)	7.5 (8)	27.2 (26)
301–450	5.4 (124)	6.0 (128)	7.5 (131)	21.2 (123)	15.7 (4)	36.4 (5)	6.4 (4)	108.6 (15)
451–600	2.9 (63)	3.4 (65)	4.0 (66)	9.5 (60)	0.8 (1)	0.5 (1)	6.1 (3)	28.3 (3)
>600	3.1 (51)	4.7 (53)	3.3 (54)	9.3 (49)	15.0 (2)	13.3 (3)	0.0 (1)	34.2 (5)
All	5.3 (546)	6.5 (578)	6.4 (599)	13.7 (550)	8.5 (19)	25.3 (26)	23.9 (25)	46.3 (63)

Who receives your critical value calls?

Table 5. Personnel Involved in Critical Value Calls

	Inpatients, No. (% of Total)	Outpatients, No. (% of Total)
Reporting personnel		
Person performing test	11 587 (91.0)	2308 (77.3)
Section supervisor	330 (2.6)	117 (3.9)
Laboratory clerk	718 (5.6)	515 (17.2)
Other management personnel	96 (0.8)	47 (1.6)
Receiving personnel		
Registered nurse	4775 (37.8)	622 (21.2)
Any staff nurse	2307 (18.3)	393 (13.3)
Unit clerk/office staff	3985 (32.5)	1237 (42.1)
Medical student	21 (0.2)	3 (0.1)
Any physician on call	455 (3.6)	196 (6.7)
Physician ordering test	1090 (8.6)	490 (16.7)

- Lab staff performing the test call most critical values
- Registered nurses take most critical results (inpatient)
- Unit clerk/office staff take most critical results (outpatient)

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Policies around critical values were not unified.

- At the time of the survey, very few labs had considered what to do about repeat critical values
- Some labs (6.8%) allowed for physicians to opt out
- Difficult to gauge impact of the critical value notification
  - Critical Value result or critical value notification?

Table 6. Repeat Critical Value Calls

Policy	Participants, %
No policy on how handled	71.4
Repeat values not called	11.6
Values not called on physician request	6.8
Seed physicians' permission to not call	1.9
Have preset policy on no. of calls	1.8
Seek physicians' permission not to call after preset no. of values	0.3
Use another policy	6.1

Table 7. Use of Critical Values as Indicated by Chart Review and Physician Surveys

Finding	5426 Charts Reviewed	4237 Physicians Surveyed
Critical value anticipated, %	54.3	59.3
Critical value influenced therapy, %	64.9	62.9
Test reordered, %	66.3	43.3
Found in nursing or progress notes, %	75.5	. . .

But is it helpful?—Let's rephrase. Is it perceived as helpful?

Table 8. Perception of Critical Values

Location*	Respondents	% Aware of List	% Think List Is a Valid Indicator	% Feel Calls Are Helpful
Emergency department	575 nursing supervisors	17.3	16.7	19.1 ←
ICU/CCU	576 nursing supervisors	23.6	23.3	27.6
Medicine/surgery	576 nursing supervisors	33.5	33.4	40.8
Other station	574 nursing supervisors	16.0	16.2	20.6
Hospital	514 physicians	76.9	78.6	94.9 ←

* ICU indicates intensive care unit; CCU, critical care unit.

- Very large discrepancy in the perception of value between physicians and nurses
- Somewhat influenced by location
- This is some of the first evidence suggesting CV notification might be a delicate balance
- Most CV limits were set by in-house studies and medical staff consultation

ASCP: Critical Values ASCP Practice Parameter 1997

KENNETH EMANCIPATOR MD

Largely based on Q-probes *1992*

THE CRITICAL VALUES LIST

The diversity among the critical values lists in use by various laboratories is quite remarkable.[6] Apparently, this diversity stems from the need for each individual institution to use a critical values list that is tailored to its own specific mission. Therefore, attempting to implement a uniform list in all laboratories would be counterproductive. In fact, for precisely this reason, the College of American Pathologists (CAP) Q-Probes Committee abandoned its original intent to establish (by consensus) a national standard critical values list.[6] The use of individualized critical values lists clearly benefits patient care.

TABLE 1. GENERIC CRITICAL VALUES LIST*

	Chemistry Tests†
	Critical Values (Conventional units)
Arterial pH	< 7.2 or > 7.6
Arterial pCO_2	< 20 or > 70 mm Hg
Arterial pO_2	< 40 mm Hg
Bilirubin, neonatal	> 15.0 mg/dL
Calcium, total	< 6.0 or > 13.0 mg/dL
Carbon dioxide	< 10 or > 40 mEq/L
Creatinine	> 5.0 mg/dL
Glucose	< 40 or > 450 mg/dL
Magnesium	< 1.0 or > 4.7 mg/dL
Phosphorus	< 1.0 mg/dL
Potassium	< 2.8 or > 6.2 mEq/L
Sodium	< 120 or > 160 mEq/L
Urea nitrogen	> 80 mg/dL

Emancipator K. Critical Values Practice Parameter. Am J. Clin Pathology 1997

Royal College of Pathologists

The Royal College of Pathologists
Pathology: the science behind the cure

The communication of critical and unexpected pathology results

October 2017

Author: Dr Bernie Croal, Aberdeen Royal Infirmary

Published/Revised 2005, 2010, 2017

- Original scope was defined for General Practitioner in the outpatient setting
- Revised to include "*all areas of clinical responsibility, including both primary and secondary care. Similarly, it will refer to within hours and out-of-hours periods where relevant.*"
- 2 defined communication types:
  - A: Rapid Communication within 2 hours usually by phone
  - B: Out of hours (OOHs) then communication within 24 hours to GP/GP OOHs service
- 28 "chemistry" analytes, but covers all lab sections as well (heme, coag, immunology, micro, blood bank)

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“Action Limits” from RCPath 2017

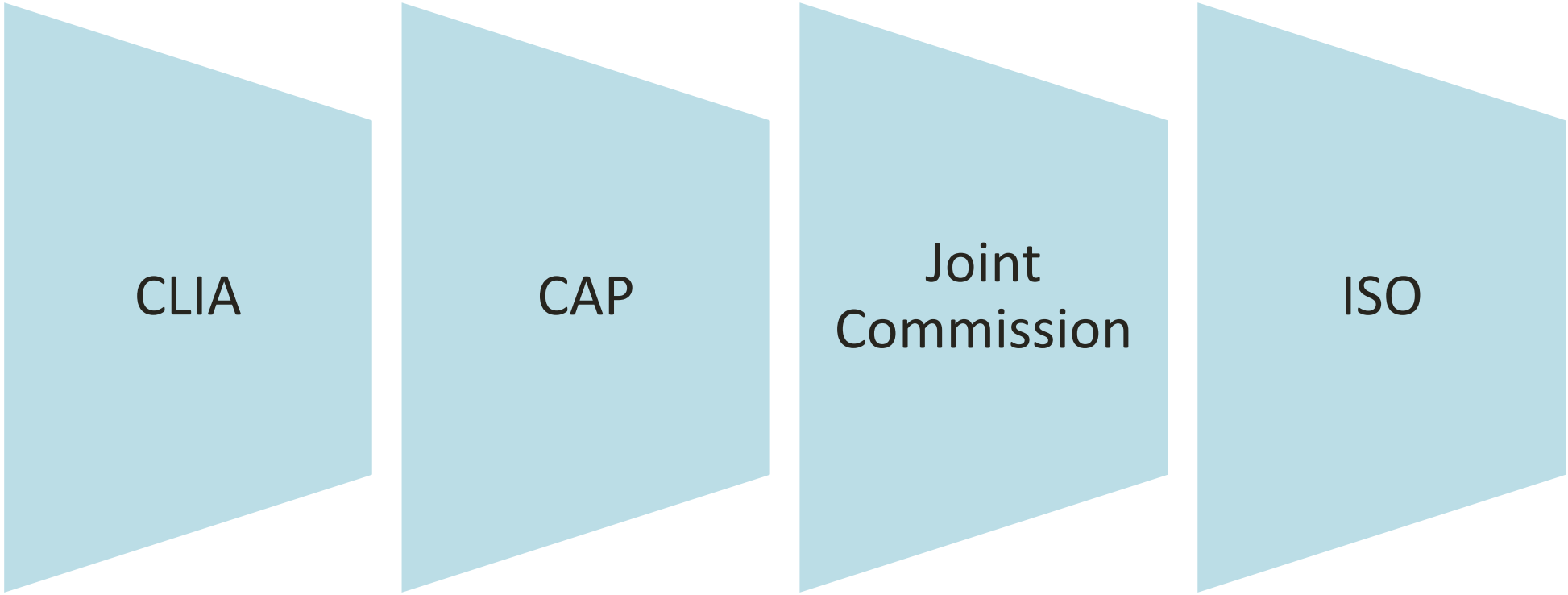
Analyte (serum/plasma)	Units	Action Limits[a]		Communication Type[b]		Comments
		Lower	Upper	Primary Care	Secondary Care	
Na	mmol/L	120 (130 if < 16 yrs)	160	A	A	Note particular concern of risk of death in children with hyponatraemia.
K	mmol/L	2.5	6.5	A	A	Exclude haemolysis/old samples/EDTA contamination first. Agree, by local consensus, higher thresholds for phoning results in patients with known kidney disease including those on dialysis.
urea	mmol/L		30 (≥ 10 if < 16 yrs)	A	A	Agree, by local consensus, higher thresholds for phoning results in patients with known kidney disease including those on dialysis. Specific local cut points likely to be required for babies and neonates.
creat	umol/L		354[c] (≥ 200 if < 16 yrs)	A	A	
glucose	mmol/L	2.5[d]	25 (≥ 15 if < 16 yrs)	A	A	Exact cut points and response should be determined locally. [d]Glucose results < 2.5 mmol/L from primary care may be less crucial to phone immediately. For GPs and OPD, upper cut point of 30 mmol/L in known type 2 DM may be more appropriate.

	Glucose mg/dL
Lower	45
Upper	450

- Two major distinctions from previous CV publications
  - Clear need for delineation of age specific CV
  - Clear need for differentiation for specific populations (IP/OP/Clinics)

Royal College of Pathologists, The Communication of critical and unexpected laboratory results 2017

Regulatory Requirements and Guidance



CLIA 1988

THE CONCEPT OF CV WAS ENDORSED IN THE FIRST CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988

§493.1291 Standard: Test report.

- The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values.

§493.1299 Standard: Post-analytic systems quality assessment.

- The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the post-analytic systems specified in §493.1291.

CLIA 1988

THE CONCEPT OF CV WAS ENDORSED IN THE FIRST CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988

What it says	What it doesn't say
Need a written policy	Specific tests that need critical value limits
Defined as life threatening, panic *or* alert values	Specific critical value limits
Need to follow the policy (documentation)	How to perform the notification
Who can receive results*	How to document the notification

*Except as provided in §493.1291(l), test results must be released only to authorized persons and, if applicable, the persons responsible for using the test results and the laboratory that initially requested the test.

Critical Values and CAP

COLLEGE of AMERICAN PATHOLOGISTS

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Checklists contains 5 areas related to critical value limits

PROCEDURE MANUAL

The procedure manual should be used by personnel at the workbench and must include the following elements, when applicable to the test procedure:

1. *Principle and clinical significance*
2. *Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection*
3. *Microscopic examination, including the detection of inadequately prepared slides*
4. *Step-by-step performance of the procedure, including test calculations and interpretation of results*
5. *Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing*
6. *Calibration and calibration verification procedures*
7. *The analytic measurement range for test results for the test system, if applicable**
8. *Control procedures*
9. *Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability*
10. *Limitations in the test methodology, including interfering substances*
11. *Reference intervals (normal values)*
12. *Imminently life-threatening (critical) test results*
13. *Pertinent literature references*
14. *The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the procedure for reporting imminently life-threatening (critical) results*
15. *Description of the course of action to take if a test system becomes inoperable*

All Common: 3
Cytopathology: 1
Anatomic Pathology: 1

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CAP COM.30000 Critical Result Notification

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PHASE II

The laboratory has written procedures for immediate notification of a physician (or other clinical personnel responsible for the patient's care) when results of designated tests exceed established "critical" values that are important for prompt patient management decisions. Records of notification are retained

What it says	What it doesn't say
Need a written policy	Specific tests that need critical value limits
Defined as "critical" values	Specific critical value limits
May establish different limits for sub-populations	How to perform the notification
Documentation must have: date, time, responsible lab individual, person notified, test result	
Discourages clinician "opt out"	
Communication can be direct dialog *or* electronic	

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CAP COM.30100 Critical Result Read-back

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PHASE I

When critical results are communicated verbally,
"read-back" of the results is requested and recorded

What it says	What it doesn't say
Transmission of CV electronically is acceptable	How to confirm receipt
The lab must confirm electronic receipt by the intended recipient	
No read-back required for electronic transmission	

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CAP CYP.06450 Significant and Unexpected Findings

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PHASE II

There is a written policy regarding the communication of significant and unexpected cytopathology findings. Records of communication are retained.

- Largely the same as COM.30000
- Additional emphasis on documentation of the communication either directly in the patient report or in a separate location
- Findings may be communicated or summarized or reference via a case number
- Same requirements for documentation
  - Date
  - Time
  - Responsible lab individual
  - Person notified
  - Findings communicated

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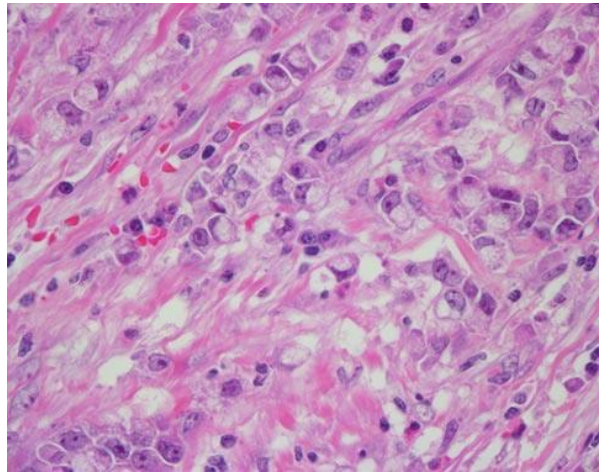
CAP ANP.12175 Significant and Unexpected Findings

COLLEGE of AMERICAN PATHOLOGISTS

PHASE II

There is a written policy regarding the communication of significant and unexpected surgical pathology findings. Records of communication are retained.

- Largely identical to CYP.06450
- Additional emphasis on documentation of the communication either directly in the patient report or in a separate location
- Findings may be communicated or summarized or reference via a case number
- Same requirements for documentation
  - Date
  - Time
  - Responsible lab individual
  - Person notified
  - Findings communicated



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Document and Process Control Chapter

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DC.02.01.01: The laboratory has procedures for each laboratory test.

- The procedures include but are not limited to…….
  - Reporting patient results, including when appropriate, the process for reporting imminent life-threatening results, or panic, or alert values

Quality System Assessment NW Testing Chapter

JOINT COMMISSION IS AN ACCREDITATION AGENCY FOR ENFORCING CLIA

QSA.02.11.01: The laboratory conducts surveillance of patient results and related records as part of its quality control program.

- The general supervisor performs or delegates to technical staff the daily supervisory review of patient results. The supervisory review is documented. (See also LD.04.05.01, EP 1; QSA.02.02.01, EP 5)
- Note: Technical staff performing the review use specific criteria or computer algorithms to identify outlier results for manual review
- Examples of criteria include the following:
  - Unacceptable quality control results
  - Test results that do not correlate with a patient's known condition, age, sex, diagnosis, or pertinent clinical data; distribution of
  - Patient test results; and relationship with other test parameters
  - Incongruent test results on one patient
  - Abnormal test results
  - *Critical values*

National Patient Safety Goals Chapter

JOINT COMMISSION IS AN ACCREDITATION AGENCY FOR ENFORCING CLIA

NPSG.02.03.01: Report critical results of tests and diagnostic procedures on a timely basis

- Collaborate with organization leaders to develop written procedures for managing the critical results of tests and diagnostic procedures that address the following:

What it says	What it doesn't say
Develop a procedure	How to achieve this goal
Define critical value limits	
Define who can receive a critical value notification	
Define an acceptable time for critical value notification	
Implement procedure	
Monitor timeliness of reporting critical values	

ISO C950 – GENERAL CHECKLIST

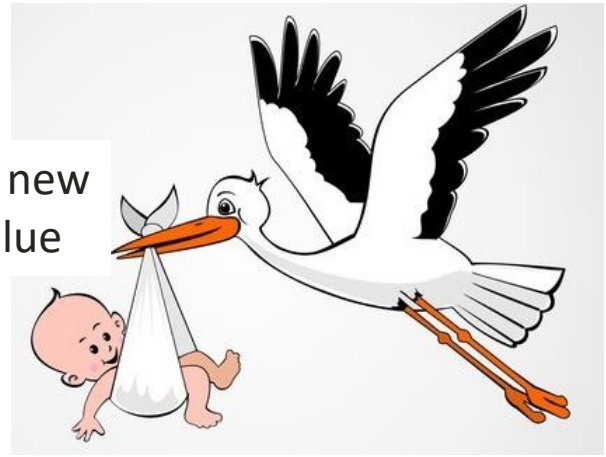
ISO 15189:2012 TESTING LABORATORY ACCREDITATION PROGRAM

5.9 Release of results
5.9.1 General The laboratory shall establish documented procedures for the release of examination results, including details of who may release results and to whom. The procedures shall ensure that the following conditions are met.
a) When the quality of the primary sample received is unsuitable for examination, or could have compromised the result, this is indicated in the report.
b) When examination results fall within established "alert" or "critical" intervals:
— a physician (or other authorized health professional) is notified immediately [this includes results received on samples sent to referral laboratories for examination (see 4.5)];
— records are maintained of actions taken that document date, time, responsible laboratory staff member, person notified and examination results conveyed, and any difficulties encountered in notifications.
c) Results are legible, without mistakes in transcription, and reported to persons authorized to receive and use the information.
d) When results are transmitted as an interim report, the final report is always forwarded to the requester.

What it says	What it doesn't say
Establish procedure for critical results	Critical Result Limit
Notify authorized professional immediately	Method for notification
Document, date, time, lab staff, person notified, critical value and any difficulty with the notification	

The Birth of A New Critical Value

Sentinel event



Request for new Critical Value

Sentinel Event → Root Cause Analysis → New Critical Value?

A *Diagnostic Error* is made (important result missed)

If we had acted on the result we could have changed the outcome

You should have called us with such an important result

To prevent this in the future please call us with all other results like this

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Glucose Critical Value Limits: A Case Study

What is the role of a glucose critical value limit?

Critical Value?

Vital Value?

Alert Value?

Panic Value?

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Standards of Medical Care in Diabetes 2019 (ADA)

Let's play follow the references

Guidelines published by the American Diabetes Association annually

- New tiers of hypoglycemia emerged in 2016
- Values have been adopted by hospitals for hypoglycemic protocols
- Values are tied to therapeutic intervention
- *Push for using 54 mg/dL as a critical value limit for glucose*

Table 6.3—Classification of hypoglycemia (44)

Level	Glycemic criteria/description
Level 1	Glucose <70 mg/dL (3.9 mmol/L) and glucose ≥54 mg/dL (3.0 mmol/L)
Level 2	Glucose <54 mg/dL (3.0 mmol/L)
Level 3	A severe event characterized by altered mental and/or physical status requiring assistance

Endorsed by ADA and European Association for the Study of Diabetes

Reference 44 → Reference 19 and 20

2017

Standardizing Clinically Meaningful Outcome Measures Beyond HbA_{1c} for Type 1 Diabetes: A Consensus Report of the American Association of Clinical Endocrinologists, the American Association of Diabetes Educators, the American Diabetes Association, the Endocrine Society, JDRF International, The Leona M. and Harry B. Helmsley Charitable Trust, the Pediatric Endocrine Society, and the T1D Exchange

Diabetes Care 2017;40:1622–1630 | https://doi.org/10.2337/dc17-1624

Level 2

Level 2 hypoglycemia is defined as a measurable glucose concentration <54 mg/dL (3.0 mmol/L) that needs immediate action. At ~54 mg/dL (3.0 mmol/L), neurogenic and neuroglycopenic hypoglycemic symptoms begin to occur, ultimately leading to brain dysfunction at levels <50 mg/dL (2.8 mmol/L) (19,20). Neuroglycopenic symptoms—including behavioral changes, visual changes, seizure, and loss of consciousness—are the result of central nervous system neuronal glucose deprivation (21–23).

19. Graveling AJ, Deary IJ, Frier BM. Acute hypoglycemia impairs executive cognitive function in adults with and without type 1 diabetes. Diabetes Care 2013;36:3240–3246

20. van de Ven KCC, Tack CJ, Heerschap A, van der Graaf M, de Galan BE. Patients with type 1 diabetes exhibit altered cerebral metabolism during hypoglycemia. J Clin Invest 2013;123:623–629

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Acute Hypoglycemia Impairs Executive Cognitive Function in Adults With and Without Type 1 Diabetes

Reference 19 (2013)

- <54 mg/dL cutoff mentioned in the introductory paragraph.
- Study is n=32

The human brain depends on glucose as its energy source; acute hypoglycemia results in neuroglycopenia with subsequent cognitive impairment. Individuals with type 1 diabetes are exposed to an average of two episodes of self-treated hypoglycemia per week (1). In general, performance on complex cognitive tasks deteriorates when blood glucose declines to <3.0 mmol/L (54 mg/dL) (2,3). Previous studies have demon-

References

2. Mitrakou A, Ryan C, Veneman T, et al. Hierarchy of glycemic thresholds for counterregulatory hormone secretion, symptoms, and cerebral dysfunction. Am J Physiol 1991;260:E67–E74
3. Maran A, Lomas J, Macdonald IA, Amiel SA. Lack of preservation of higher brain function during hypoglycaemia in patients with intensively-treated IDDM. Diabetologia 1995;38:1412–1418

Reference 2 (1991)

Am J Physiol. 1991 Jan;260(1 Pt 1):E67-74.

Hierarchy of glycemic thresholds for counterregulatory hormone secretion, symptoms, and cerebral dysfunction.

Mitrakou A[1], Ryan C, Veneman T, Mokan M, Jenssen T, Kiss I, Durrant J, Cryer P, Gerich J.

Author information

1 Department of Medicine, University of Pittsburgh, School of Medicine, PA 15261.

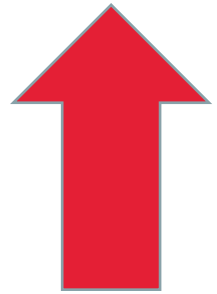
Abstract

To define glycemic thresholds for activation of counterregulatory hormone secretion, initiation of symptoms (autonomic and neuroglycopenic), and onset of deterioration of cognitive function, we measured indexes of these responses during glycemic plateaus of 90, 78, 66, 54, and 42 mg/dl in 10 normal volunteers, with the use of the hyperinsulinemic glucose clamp technique. Activation of glucagon, epinephrine, norepinephrine, and growth hormone secretion began at arterialized venous plasma glucose concentrations of 68 +/- 1, 68 +/- 1, 65 +/- 1, and 67 +/- 2 (SE) mg/dl, respectively. Autonomic symptoms (anxiety, palpitations, sweating, irritability, and tremor) began at 58 +/- 2 mg/dl, which was significantly (P = 0.0001) lower. Neuroglycopenic symptoms (hunger, dizziness, tingling, blurred vision, difficulty thinking, and faintness) and deterioration in cognitive function tests began at 51 +/- 3 and 49 +/- 2 mg/dl, respectively, values that were both significantly (P = 0.018 and 0.004, respectively) lower than that for initiation of autonomic symptoms. We therefore conclude that there is a distinct hierarchy of responses to decrements in plasma glucose, such that the threshold for activation of counterregulatory hormone secretion occurs at higher plasma glucose levels than that for initiation of autonomic warning symptoms, which in turn occurs at higher plasma glucose levels than that for onset of neuroglycopenic symptoms and deterioration in cerebral function. Such a hierarchy would maximize the opportunity to avoid incapacitating hypoglycemia.

PMID: 1987794 DOI: 10.1152/ajpendo.1991.260.1.E67

n = 10 patients

Symptoms began at 51 +/- 3mg/dL



The origin of 54 mg/dL?

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Reference 3 (1995)

Diabetologia. 1995 Dec;38(12):1412-8.

Lack of preservation of higher brain function during hypoglycaemia in patients with intensively-treated IDDM.

Maran A[1], Lomas J, Macdonald IA, Amiel SA.

Author information

1 Unit for Metabolic Medicine, United Medical and Dental Schools of Guy's and St Thomas' Hospitals, London, UK.

Abstract

Severe hypoglycaemia with cognitive dysfunction is 3 times more common in intensively, rather than conventionally, treated insulin-dependent diabetes mellitus (IDDM). To investigate the effect of diabetes control on higher brain function during acute hypoglycaemia, we studied one of the earliest detectable changes in cognitive function, i.e. the four-choice reaction time, and symptomatic and hormonal responses during euglycaemic and hypoglycaemic clamping in human subjects. There were no changes in symptoms or counterregulatory hormones and four-choice reaction time was stable during 220 min of euglycaemic insulin clamping in five men with IDDM, with a coefficient of variation of less than 2.2% (1% for accuracy) for the cognitive function test. During stepped hypoglycaemic clamping however, hormonal responses and subjective awareness of hypoglycaemia occurred in all groups but started at much lower blood glucose concentrations in eight intensively-treated diabetic subjects (Group 1) than in ten conventionally-treated (Group 2) or in eight non-diabetic subjects (Group 3). For example, for adrenaline, plasma glucose thresholds were 2.7 +/- 0.2 vs 3.4 +/- 0.2 and 3.2 +/- 0.1 mmol/l, respectively, $p < 0.05$, Group 1 vs Groups 2 or 3 and for subjective awareness of hypoglycaemia 2.3 +/- 0.2 vs 3.0 +/- 0.1 and 3.2 +/- 0.1 mmol/l, p < or = 0.003), as in previous studies. In contrast, deterioration in reaction time occurred at 3.2 +/- 0.3, 3.2 +/- 0.2 and 3.0 +/- 0.2 mmol/l, respectively (p = NS), thus occurring at higher glucose levels than subjective awareness in the intensively-treated subjects only. The altered hierarchy of responses to hypoglycaemia in well-controlled intensively-treated diabetes explains the increased risk of severe hypoglycaemia without warning seen in such patients.

N=26
Measurement was “subjective awareness of hypoglycemia”

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Back to Reference 20 from the consensus statement 2013

JCI The Journal of Clinical Investigation

Patients with type 1 diabetes exhibit altered cerebral metabolism during hypoglycemia

Kim C.C. van de Ven, … , Marinette van der Graaf, Bastiaan E. de Galan

J Clin Invest. 2013;123(2):623-629. https://doi.org/10.1172/JCI62742.

Measured glucose metabolism with ^{13}C magnetic resonance spectroscopy to calculate the tricarboxylic acid cycle flux (V_{TCA})
N= 10 patients

Recently, we showed that brain glucose metabolism in healthy subjects at glucose levels of approximately 3 mmol/l did not differ from that at normal glucose levels, as reflected by similar tricarboxylic acid (TCA) cycle rates (V_{TCA}) (5). This remarkable maintenance of normal V_{TCA} during symptomatic hypoglycemia indicates that the glucose threshold for effects on cerebral metabolism lies below 3 mmol/l, either because the brain can endure low glucose levels or because entrance of nonglucose energy substrates such as lactate compensates for the fall in glucose (6–9). Whether these findings can be extrapolated to patients with T1DM remains to be determined.

Evidence supporting 54 mg/dL as a critical value?

- No mention of <54 mg/dL being recommended as a critical value notification limit for laboratories by the ADA
- No studies with hospitalized patients
- Total of 4 studies with 78 patients
  - Origin of 54 mg/dL was n=10 patients
- No studies measuring outcomes with a glycemic control target of 54 mg/dL
- 54 mg/dL is only used as a classification of stage II hypoglycemia.

From the 2017 Consensus Statement

clusive from level 1 or level 2. The Steering Committee considered it important to classify "altered mental and/or physical status requiring assistance" as its own category of hypoglycemia given that there are individuals who are able to function independently at a blood glucose <54 mg/dL (3.0 mmol/L) and therefore should not be grouped into the same category as those individuals who require third-party assistance. It is also important

Can we *support* 54 mg/dL as an *alert or vital* value?

Reference	Lower Limit Glucose Critical Value
Lundberg JAMA 1990	46 mg/dL (mean)
ASCP Practice Parameter 1997	40 mg/dL
Q-Probes 2002	45 mg/dL (median)
Royal College of Pathologists 2017	45 mg/dL

Impact of moving from 40 to 54?

- 100 additional calls from the lab per month
- 6.5 min per call→10.8 hr phone time per month

- 540 additional critical results in the point of care setting per month. Compliance issue?

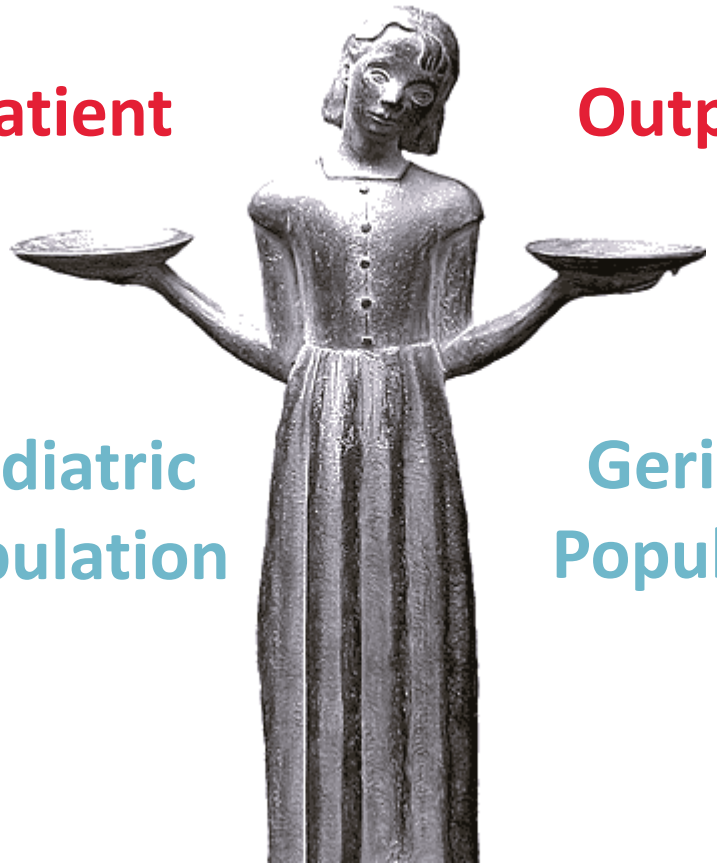
One size may not fit all

Health System

Independent Hospital

Inpatient

Outpatient



Pediatric Population

Geriatric Population

Campus Health

Reference Lab

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“Calling” critical values to providers

NOTIFICATION METHODS CONTINUE TO EVOLVE

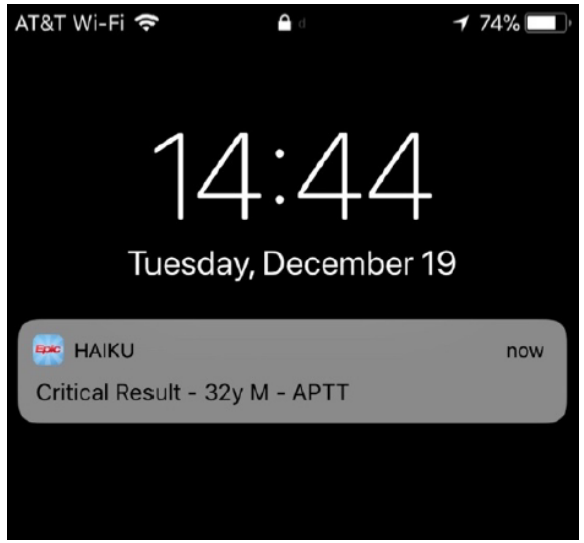
Telephone

Pager

EHR-embedded

Push Notifications

Secure Chat



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Combining Secure Chat and Push Notifications

EHR-EMBEDDED CRITICAL VALUE NOTIFICATION:

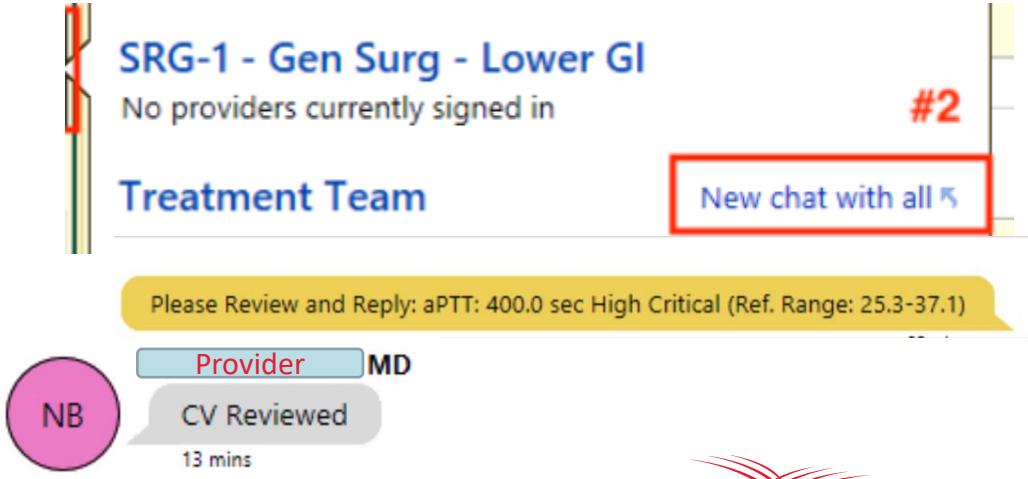
Lab Verifies Critical Value

Outpatients

- In basket message sent
- Push notification sent to mobile device
- If not acknowledged, traditional workflow starts (phone call/page)

Inpatients (select services)

- Secure Chat initiated with entire care team
- After acknowledgement, Communication Log completed by lab
- If no response within 15 minutes, traditional workflow started (phone call/page)



Conclusions

- Several documents exist which have published aggregated data for critical value limits
- Accrediting agencies provide flexibility in setting critical value limits and how notifications are made
- Laboratories can leverage new features in the electronic health record to make critical value notifications to providers (Push notification + Secure Chat)
- The lower critical value limit for glucose requires careful consideration to align with your institution's utilization of laboratory result notification

Questions?

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