Acceptability of Current Patient Risk

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ABSTRACT

CLSI EP 23-A states that risk is acceptable when it is "small enough such that patients, physicians, institutions, and society are willing to risk the consequences." This study was designed: 1) to evaluate acceptability of risk in four laboratories for urea, alanine aminotransferase (ALT), and alkaline phosphatase (ALP); 2) to identify the predominant source of faults; and 3) to compare the effectiveness of existing QC processes to those recommended 'Mathematically-OptimiZed Risk Evaluation™.'

Each lab set TEa limits according to common practice.
We set the acceptable current risk level at 2.275% to reflect the practice of considering a 2-sigma method acceptable.

We calculated current risk as the percent, number and existing cost of medically-unreliable results (MURs) from sigma values for each QC sample based on verified QC data and patient test volumes. We assigned the average cost of errors reported at $10US (90LE) per MUR. We applied the process of Mathematically-OptimiZed Risk Evaluation™ to assess the acceptability of risk, identify faults and advise action.

Seventeen of the 24 QC samples had error rates less than 2.275%; 10 samples reflected methods currently producing <1 medically-unreliable result /year; and 7* samples failed the TEa limits set.

Selected total allowable error (TEa) limits varied from 11.7% to 30% for Alkaline Phosphatase. This practice is incongruous with recommendations to set medical goals.

Evaluation of risk and recommended action varied between laboratories and between analytes. Faults creating imprecision were more common than those causing imprecision.

We concluded that the calculated risk level is generally not accepted in healthcare. Adjustment of these procedures is mandatory. Mathematically-OptimiZed Risk Evaluation detects laboratory risks that are missed by commonly used statistical QC.

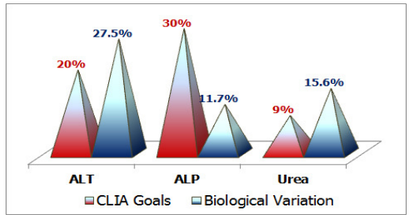
* Recalculation showed 6 QC samples failed.

METHODS

1. Two university laboratories and two private laboratories in Egypt submitted risk drivers QC samples run on Roche and Beckman Coulter instrumentation. The hospital laboratories selected total allowable error limits based on biological variation; the private laboratories chose CLIA limits.
2. Risk drivers were entered into proprietary software that applies the M.O.R.E. Quality method.
3. We examined only current risk based on the measured mean and SD of each QC sample in the one month period relative to the package insert mean (estimated true value). Effectiveness of the existing QC Process to detect unexpected failure was beyond the scope of this study.
4. We compared performance to various allowable error limits.

METHODS

1. Define risk



Cast Your Vote: Which goal is BEST?

CLIA Limits	Biological Variation	Medical Goals

2. Set Acceptable Risk Criteria

Cast Your Vote:

What do you consider acceptable quality/risk at routine/monthly QC review?	5% allowable error	2 sigma	3 sigma	1 error/Year

 # MUR considered acceptable, by quality standard (Viewed by lifting panel at poster)

Patient samples / Day	Total Patient samples / Year	5% allowable error	2 sigma	3 sigma	1 error/Year
		5.0%	2.275%	0.135%	Auto-calc'd
100	36,000	1,800	819	49	1
300	108,000	5,400	2,457	146	1
500	180,000	9,000	4,095	243	1
1,000	360,000	18,000	8,190	486	1

3. Evaluate risk:
process of comparing the estimated risk against given risk criteria to determine the acceptability of the risk (ISO 14971

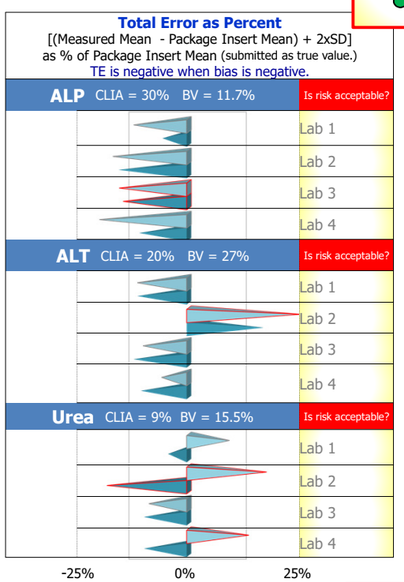
Is risk acceptable?

Cast Your Vote Yes No

RESULTS

Level 1
Level 2
Red line = failed lab-selected TEa limit

Total Error as Percent
[(Measured Mean - Package Insert Mean) + 2xSD]
as % of Package Insert Mean (submitted as true value.)
TE is negative when bias is negative.



Is risk acceptable?

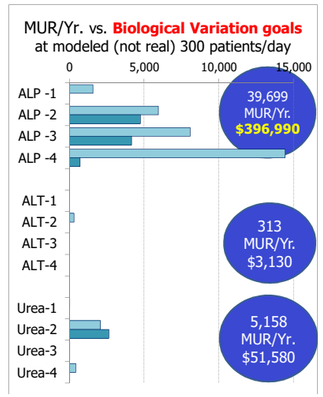
Cast Your Vote Yes No

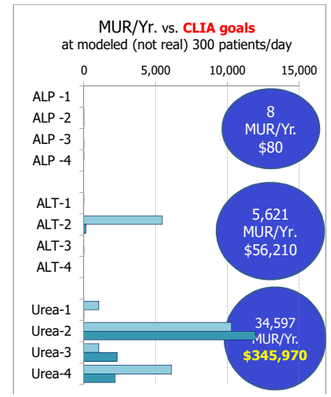
Cost of MUR/Yr. in 4 labs @ 300 pt/day;
Total patient volume = 432,000/year;
Cost arbitrarily set at $10USD/MUR

Analyte	BV	CLIA	
USD	$451,698	$405,856	
Egyptian Pounds	£ 40,652,819	£ 36,527,035	

RESULTS

Number and cost of results that fail Biological Variation and CLIA Limits
-at a simulated patient volume of 300 patents/day. (Most study labs reported fewer.)





6 of the 24 QC samples had sigma values less than 2.0 compared to CLIA goals.
7 samples had sigma values less than 2.0 versus biological variation goals.
There were only 2 QC samples from 1 analyte in 1 laboratory that failed vs. both TEa limits.

DISCUSSION:

We are faced with two options:

1. Laboratory errors are causing harm to a staggering number pf people and adding millions of dollars or pounds to healthcare costs, or
2. Neither CLIA or Biological Variation goals can be chosen as a single source to define medical results that are 'relevant, accurate, and reliable for patient care' (CLIA.)

CONCLUSIONS

1. We chose option 2 above.
2. We support recommendations from the Milan conference , CLIA, and CLSI EP 23-A that allowable analytical error limits be based on local medical need.
3. We concluded that the calculated risk level is generally not accepted in healthcare.
4. Mathematically-OptimiZed Risk Evaluation detected laboratory risks that are missed by commonly used statistical QC.

REFERENCES

1. Clinical & Laboratory Standards Institute. Guideline EP23-A Laboratory quality control based on risk management. Wayne, PA. 2011
2. Milan Consensus International Federation of Clinical Chemistry and Laboratory Medicine
3. Brooks Z. M.O.R.E. Quality: Lev 1. Risk Assessor. Worthington, ON: AWEsome Numbers Inc.; 2016

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Zoe Brooks is CEO and Director of Innovation and Research at AWEsome Numbers, Inc. Kim Przekop has no financial interest in the company.