Examining healthcare cost of lab error as a risk management metric

Zoe Brooks Poster # 126 AACC 2022 Tuesday July 26, 2022

AWEsome numbers

1 Background:

CLSI EP23A defines risk as the "combination of the probability and severity of harm. The number of "incorrect results - with "a failure of measurement that exceeds a limit based on medical utility" drives the probability of harm. The severity of harm from lab error is reflected by the healthcare costs from unnecessary follow-up procedures or delayed or incorrect diagnosis or treatment reflect. The relationship between size and cost of error was established in 2004 for calcium tests by examining 89,000 Mayo Clinic charts to healthcare expenses incurred compared to initial calcium tests.

Method:

The author examined 357 routine QC samples collected for various posters available on ResearchGate . Sigma was calculated in Excel as [(TEa-|bias|)/SD]. The average cost of error was calculated by CatalystQC software from AWEsome Numbers Inc.

Results:

18% failed an acceptable risk standard of 3 sigma and had a cost of error above $30.
69% passed the 3 sigma standard and had a cost of error below $30.
11% passed the 3 sigma standard and had a cost of error greater than $30.
2% of QC samples had a sigma above 6 with a cost of error above $30.

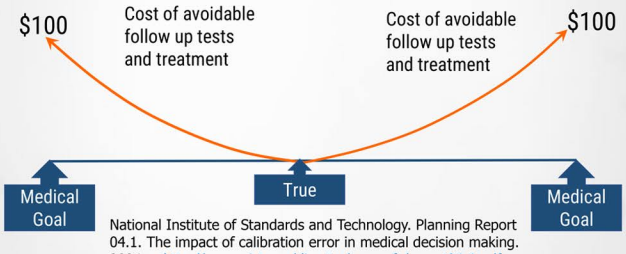
Conclusion:

This study reveals that there is no significant correlation between sigma and healthcare cost of error.

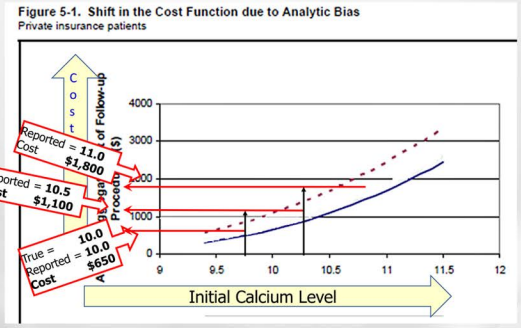
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"Based on analysis of over 89,000 patients receiving serum calcium tests at the Mayo Clinic in 1998–1999, we find that **the number of follow-up procedures, and hence health care costs, is directly related to initial calcium test values."**
"For an analytical bias of 0.5 mg/dL, …, **the potential health care cost increase ranged from $34 to $89 per patient** having a calcium test. … **the potential economic impacts range from $60 million to $199 million per year**

Cost of error increases with size of error



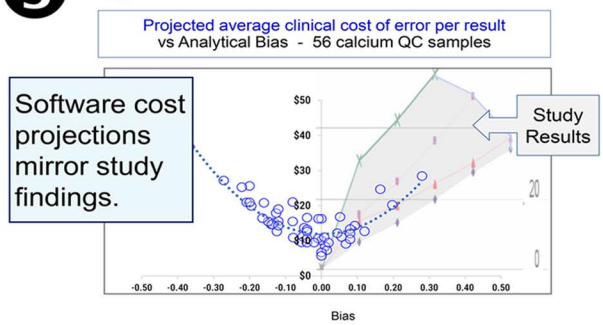
National Institute of Standards and Technology. Planning Report 04.1. The impact of calibration error in medical decision making. 2004. http://www.nist.gov/director/prog-ofc/report04-1.pdf



This poster demonstrates a new process that brings risk management as described in CLSI EP 23A to life. Updating sigma metrics to the number and cost of error per year enables meaningful communication between laboratory management and the C-suite and demonstrates the value of quality laboratory services.

1. Abstract
2. This NIST study proved that the healthcare cost of patient calcium results rises with the value reported because of the increased follow-up tests and procedures ordered.
3. CatalystQC software extrapolates on that knowledge to allow users to specify the healthcare cost at failure of the allowable error limit. I set healthcare cost for calcium that failed the CLIA limit of +/- 1.0 mg/dL (0.25 mmol/L) at $100 (comparable to their 2004 cost of $89 with error of 0.5 mg/dL (0.125 mmol/L.)
4. Just follow the definitions! Estimate risk as the PROBABILITY (number) of Medically Unreliable Results (MURs) per year & SEVERITY of harm as healthcare cost.
5. Candidate metrics include sigma metrics, average healthcare cost per patient result, and the number of MURs per year.(Patient results were set at 100/day / QC sample)
6. Cost of error is proportional to the distribution of data between the TEa limits. Results close to true add zero healthcare cost while results at TEa cost $100 / each.
7. Many results have cost above $30 with sigma values well above 3.0. Some have sigma below 3.0, appearing bad, while average cost is < $30.
8. With 100 patients per day, the vast majority of methods produce less than one MUR/year while a 3-sigma standard allows 49. The sigma histogram (#5) mask the fact that only a few methods produce >1 MUR/yr.
9. Software algorithms consistently identify methods that are close to, or fail, acceptable risk levels. (Acceptable risk was set at 49 MUR/year to mirror a 3 sigma standard, with acceptable cost varying between $40 and $50 per analyte.) Software then re-analyses data with modeled improvements to show resultant reductions of 40,000 MURs per year with potential medical mishaps and litigation.
10. **These 348 QC samples represent methods with attainable healthcare savings of >$65 million.**
(Nine samples were removed from the original data set.)

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risk – combination of the probability of occurrence of harm and the severity of that harm[1]

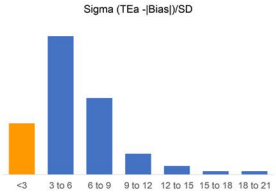
risk estimation – process used to assign values to the probability of occurrence of harm and the severity of that harm[1]

risk evaluation – process of comparing the estimated risk against given risk criteria to determine the acceptability of the risk[1]

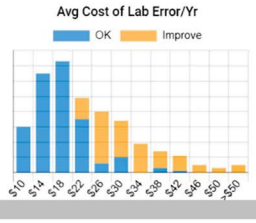
What are the best metrics to estimate and evaluate the probability and severity of harm?

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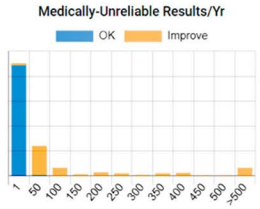
1. Sigma metrics measure (the number of SD from the mean to TEa)



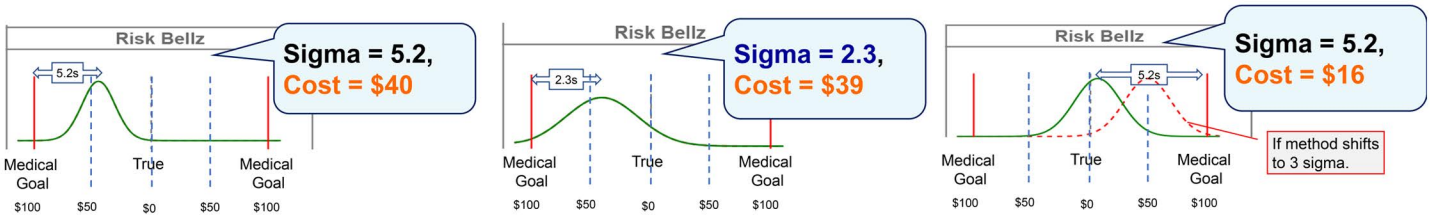
2. Healthcare Cost caused by Lab Error per Patient Result measures **SEVERITY** of harm



3. Number of Medically Unreliable Results (MURs) / Yr. per QC Sample measures **PROBABILITY** of harm



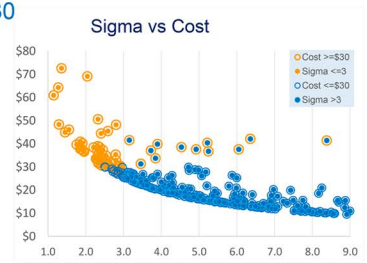
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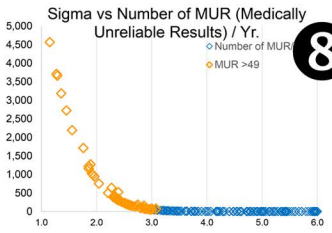


Sigma ✓= <3 Cost ✓= <$30

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- Sigma ✓ Cost ✓
- Sigma ☒ Cost ☒
- Sigma ✓ Cost ☒
- Sigma ☒ Cost ✓





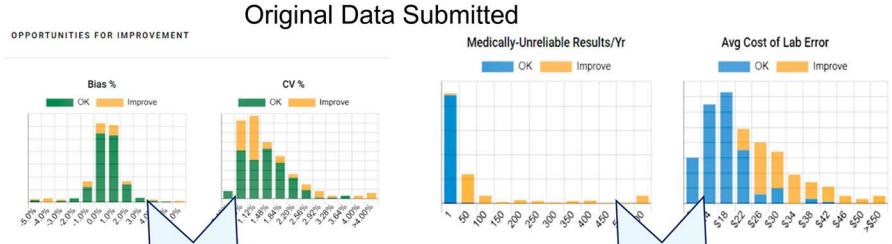
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A 3-sigma standard equates to acceptable risk of 49 MUR/Yr. with 100 patient samples / day / QC sample.

66% of 0riginal results and 100% of improved results produce less than one MUR/yr.

Software identifies QC samples that are close to, or fail, acceptable risk as number of cost of error and advises improving bias or CV.

Original Data Submitted

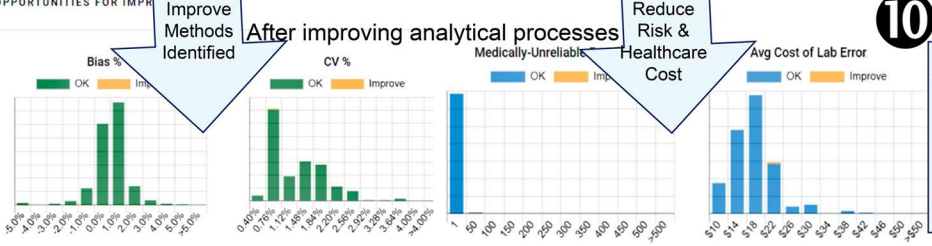


Improving bias & CV to the average of acceptable peers prevents potential medical mishaps and litigation and reduces cost.

Improve Methods Identified

Reduce Risk & Healthcare Cost

After improving analytical processes



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Prevent 40K MURs/Yr. with potential medical mishaps & litigation

10

Save $65M / Yr. >$5 for each patient result reported

11

Original Data submitted

QC PROCESSES	PATIENT RESULTS/YR	PROJECTED #MURS/YR	COST OF ERROR
348	12,699,408	40,263	$266,652,325

After improving analytical processes

PROJECTED #MURS/YR	COST OF ERROR
21	$197,768,973

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