B-157

Metrics to express risk in terms of A. risk sources, B. potential events, C. their consequences and D. their likelihood - as recommended by ISO 31000

Zoe. C. BROOKS. *AWEsome Numbers Inc, Worthington, ON, Canada,*

Background

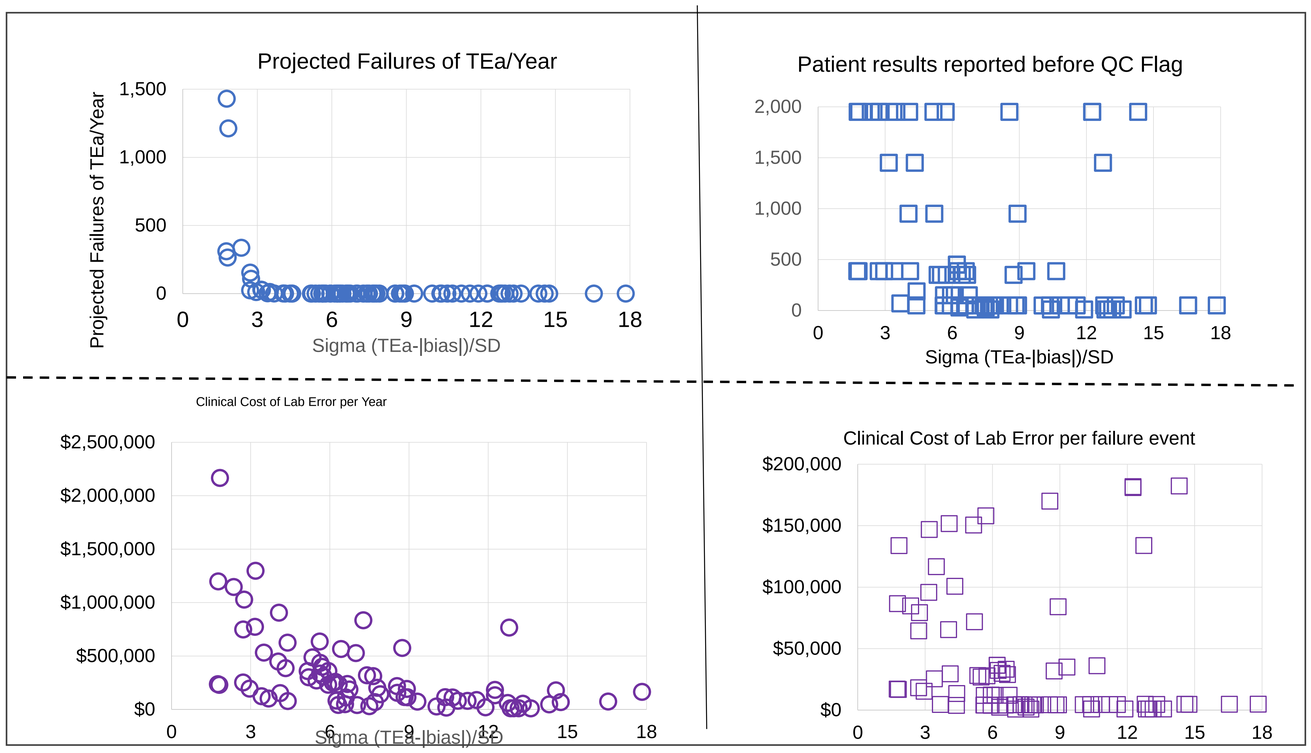
ISO 31000 Risk Management Guidelines provides guidelines on managing risk faced by all organizations. "Risk is usually expressed in terms of
A. risk sources,
B. potential events,
C. their consequences, and
D. their likelihood.“

I compared risk metrics to implement these guidelines in medical laboratories to sigma metrics to examine the most effective way to enable risk evaluation as *‘the process of comparing the estimated risk against given risk criteria to determine the acceptability of the risk’ (*CLSI EP 23A.)

Methods

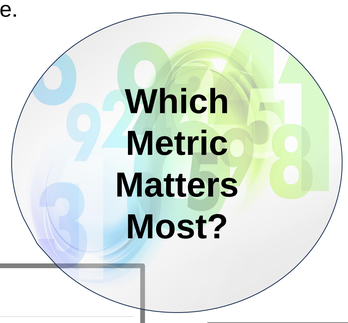
Eighty QC sample mean and SD values were compared to Peer Means and CLIA TEa limits for 14 routine chemistry analytes and four cardiac markers tested on two Ortho Vitros 5600 analyzers in December 2022. Risk evaluation was divided into Current Risk, driven by analytical accuracy and precision, and Potential Risk driven by effectiveness of the daily QC system to detect a simulated shift to a 5% error rate.

Current risk consequences were quantified as the number of failures per million opportunities and per year, and the estimated healthcare cost of lab error based on the costing process established for calcium in 2004.i
Potential risk consequences were quantified as the number of failures reported and healthcare cost of lab error following a simulated shift to create a 5% error rate.



Results

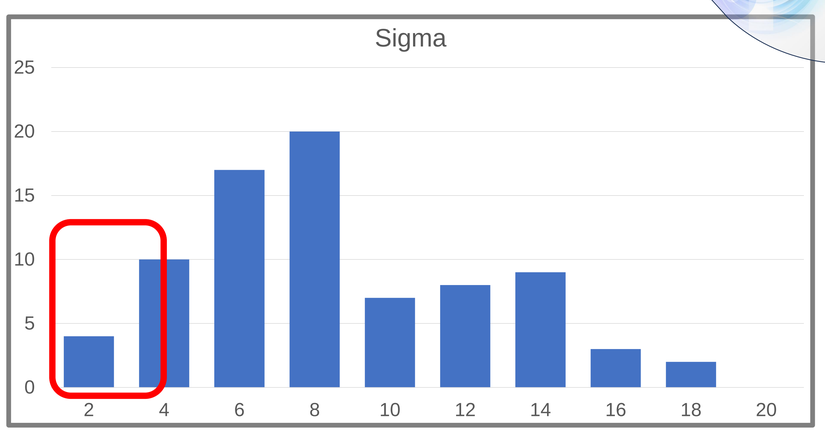
See graphs.

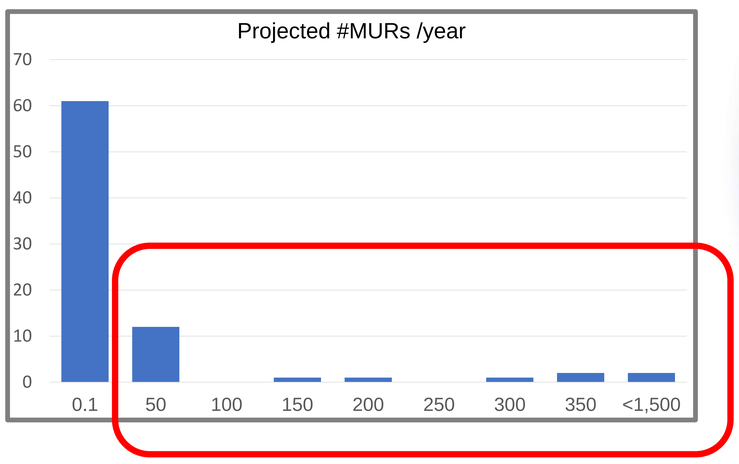


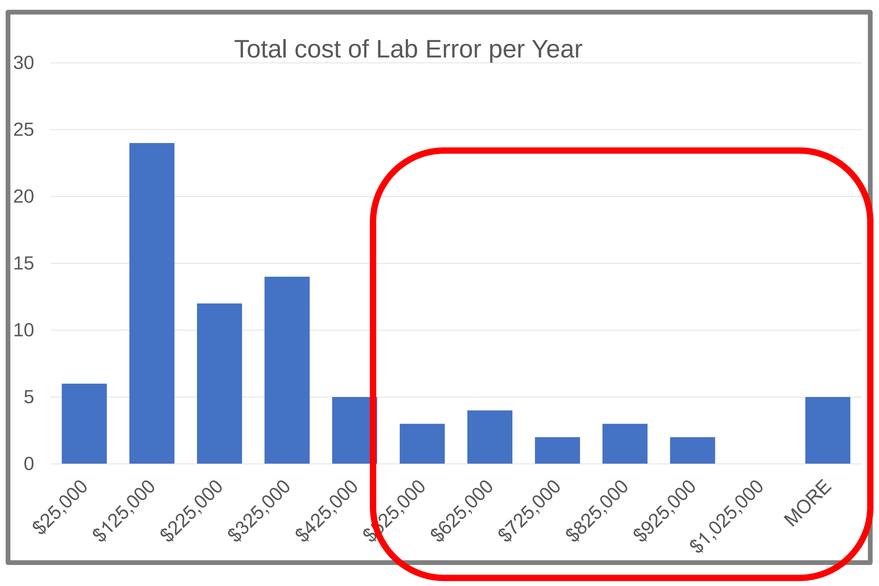
Conclusion:

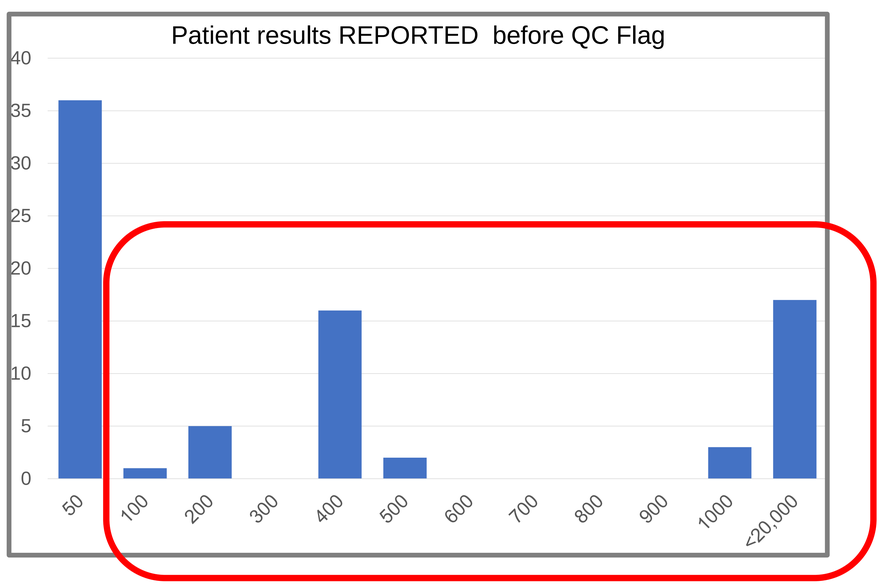
There is a good relationship between sigma and projected failures per year. Sigma is NOT a good indicator of cost of error per year, or the number or cost of failures reported after a simulated failure











Risk metrics enable risk evaluation as *‘the process of comparing the estimated risk against given risk criteria to determine the acceptability of the risk’*
*(*CLSI EP 23A.)

National Institute of Standards and Technology. Planning Report 04.1. The impact of calibration error in medical decision making.