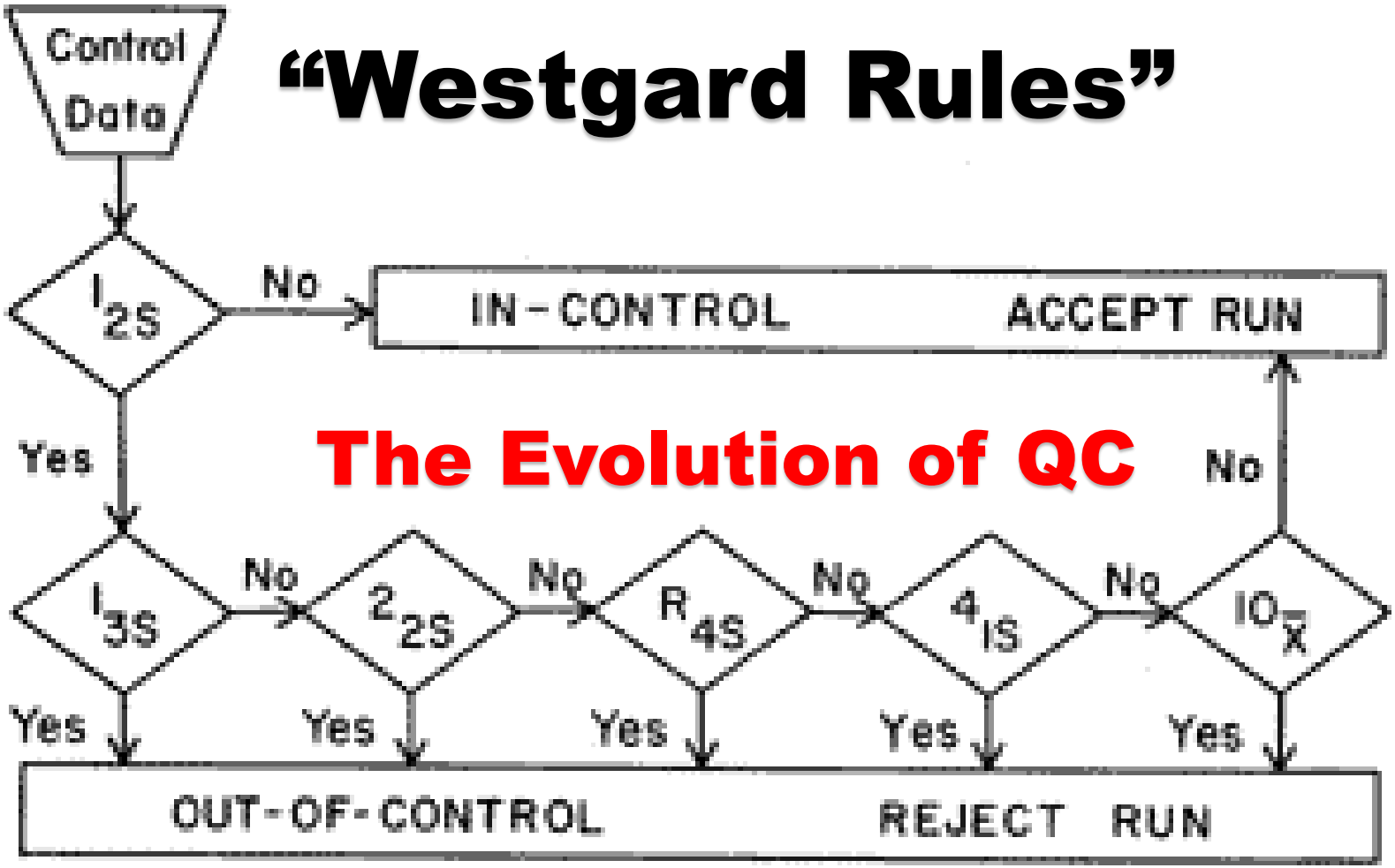
"WESTGARD RULES"

“Westgard Rules”



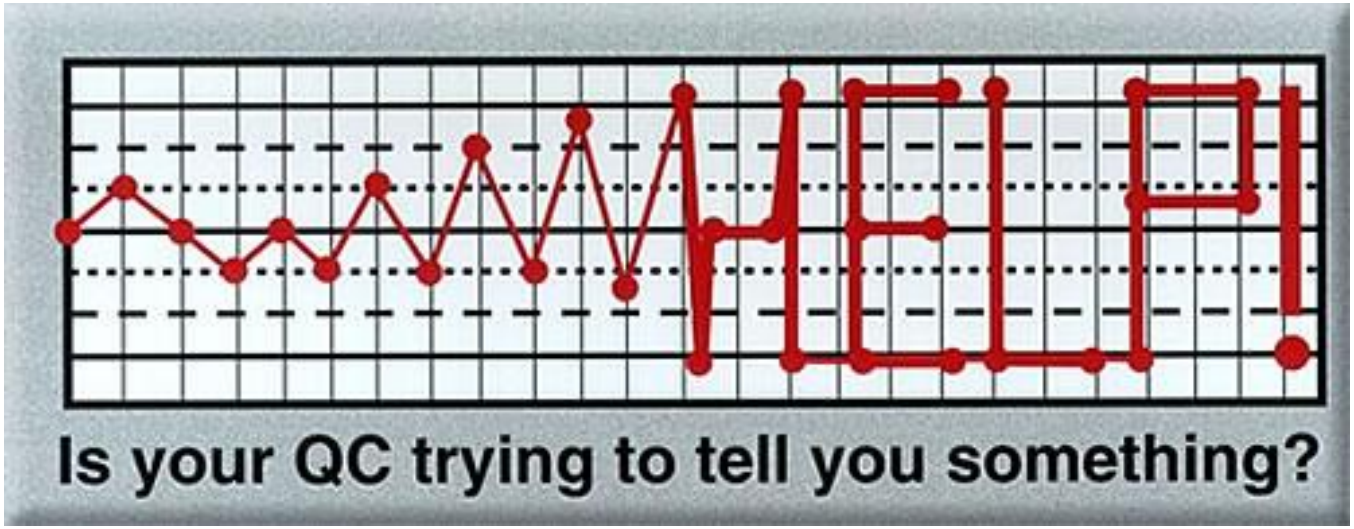
The Evolution of QC

STEN A WESTGARD
WESTGARD QC, INC.

MADISON, WI USA
WWW.WESTGARD.COM

WESTGARD QC

THE QUEST FOR QUALITY



How long have we running QC?
More than half a century!
(So why is it still so hard?)

FIRST RULE:
KNOW YOUR WESTGARDS

Father knows best!

"*The*" Westgard

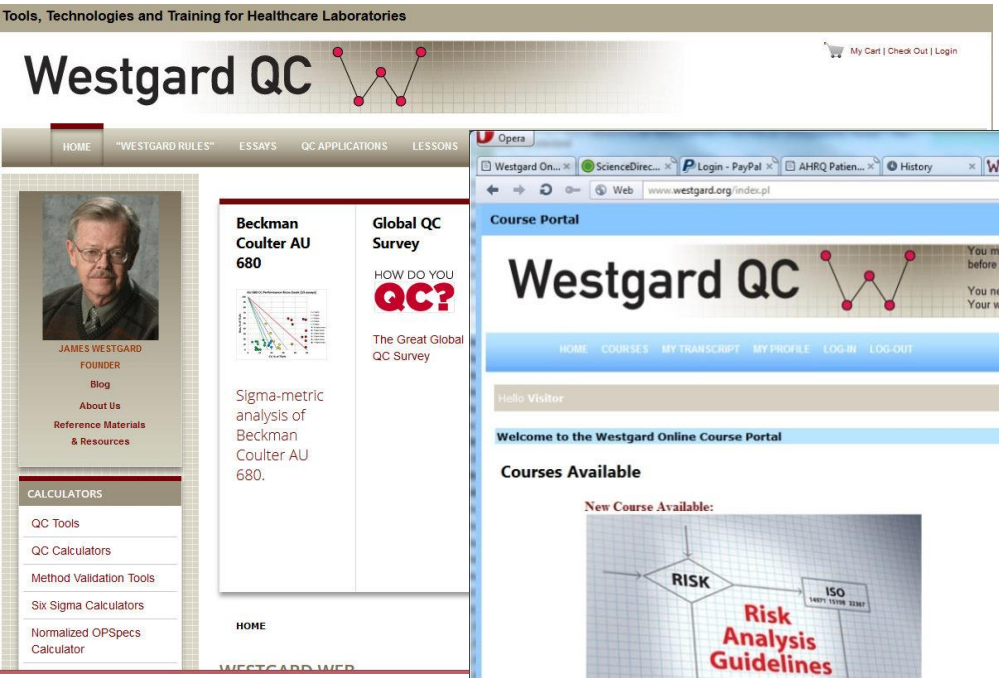
- 50 years in lab medicine
- 40+ years at the University of Wisconsin
- "Westgard Rules"
- Method Validation
- Critical-Error graphs
- OPSpecs

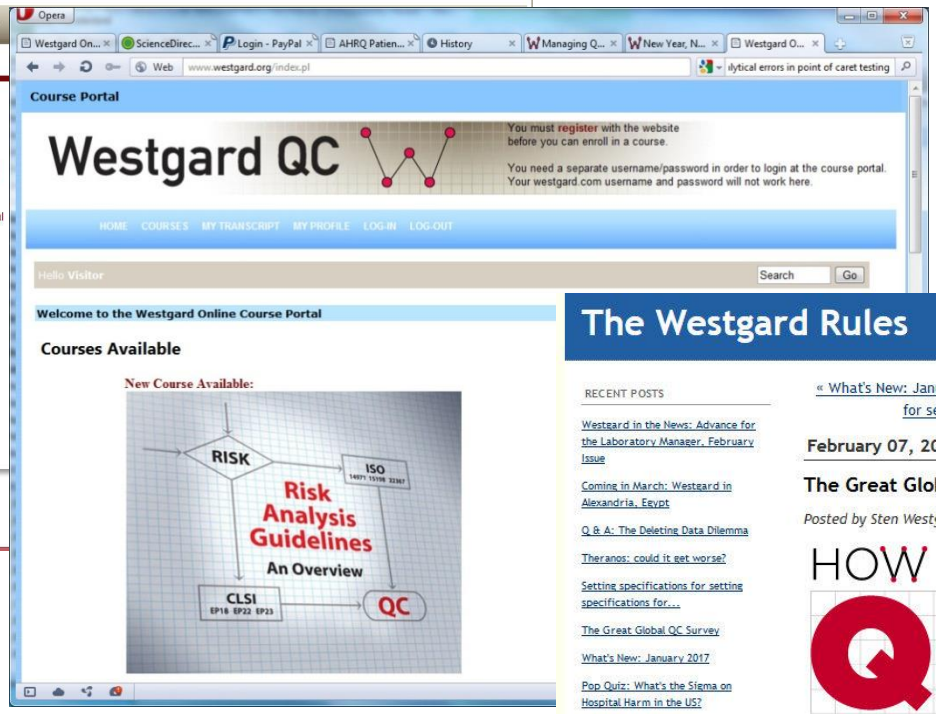
Son knows better?

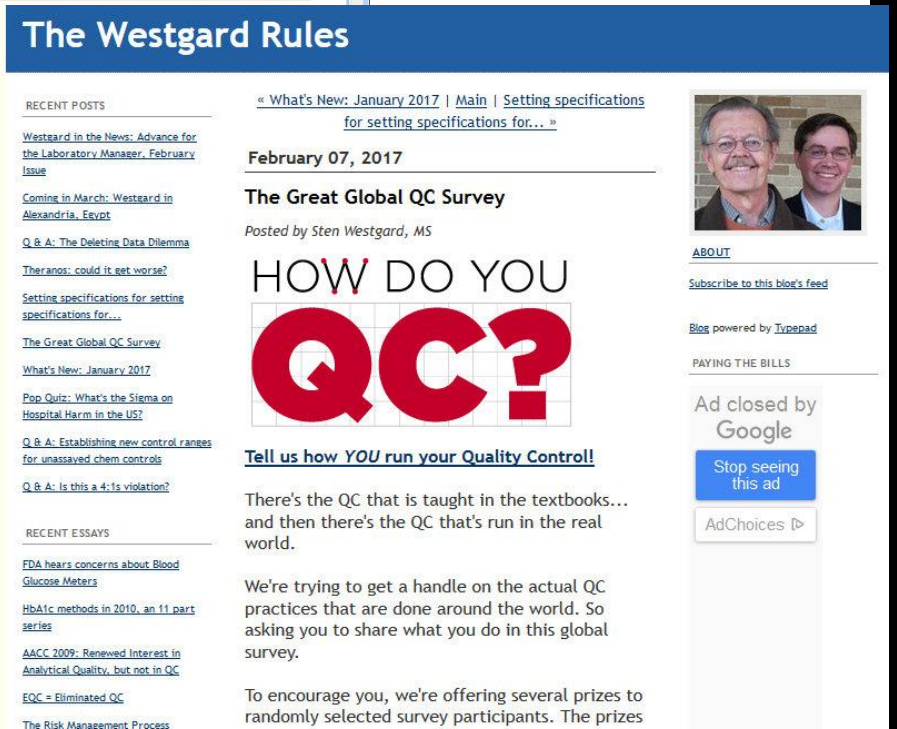
"A" Westgard

- 25 years at Westgard QC
- Publishing
- Web
- Blog
- course portal

SECOND RULE: KNOW YOUR WESTGARD WEB







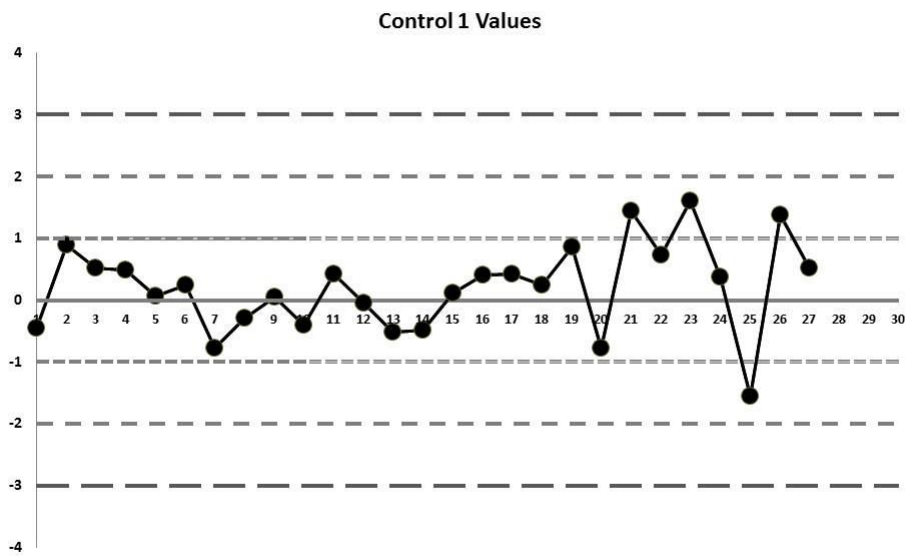
Blog:
>400 Short articles
Q&A

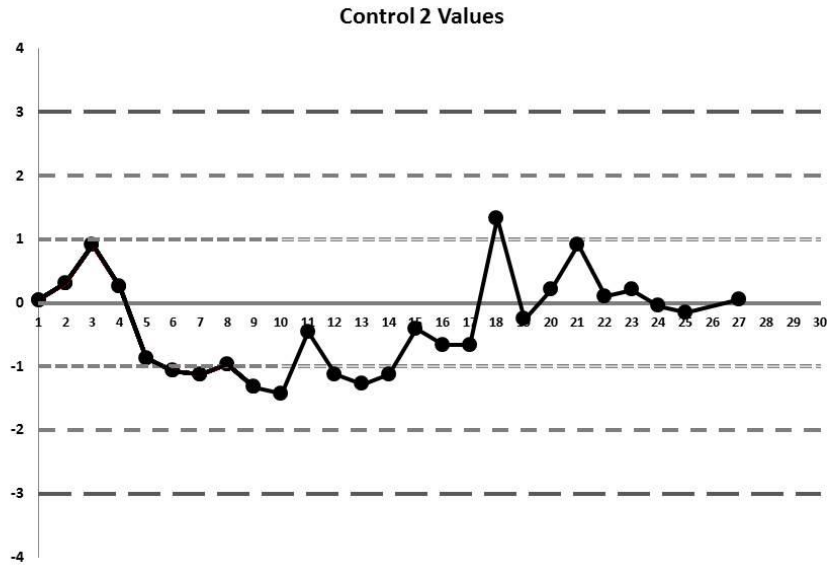
Website:
>60,000 members
>3 million views
>600+ essays, lessons,
QC case studies,
reference, resources

Course Portal:
Training in QC, Method Validation, Risk Analysis, Quality Management

WHY DO WE STILL WORRY ABOUT QC?

- Manufacturer mean and SD used for control limits
- All data within 2 SD. Too good to be true!





WESTGARD QC

POOR QC = POOR PATIENT CARE

Clinical consequences of erroneous laboratory results that went unnoticed for 10 days

Tse Ping Loh, Lennie Chua Lee, Sunil Kumar Sethi et al. *J Clin Pathol* March 2013, Vol 166, No.3 260-261

- 1 test error
- 5 tests in error
- 63 results in error

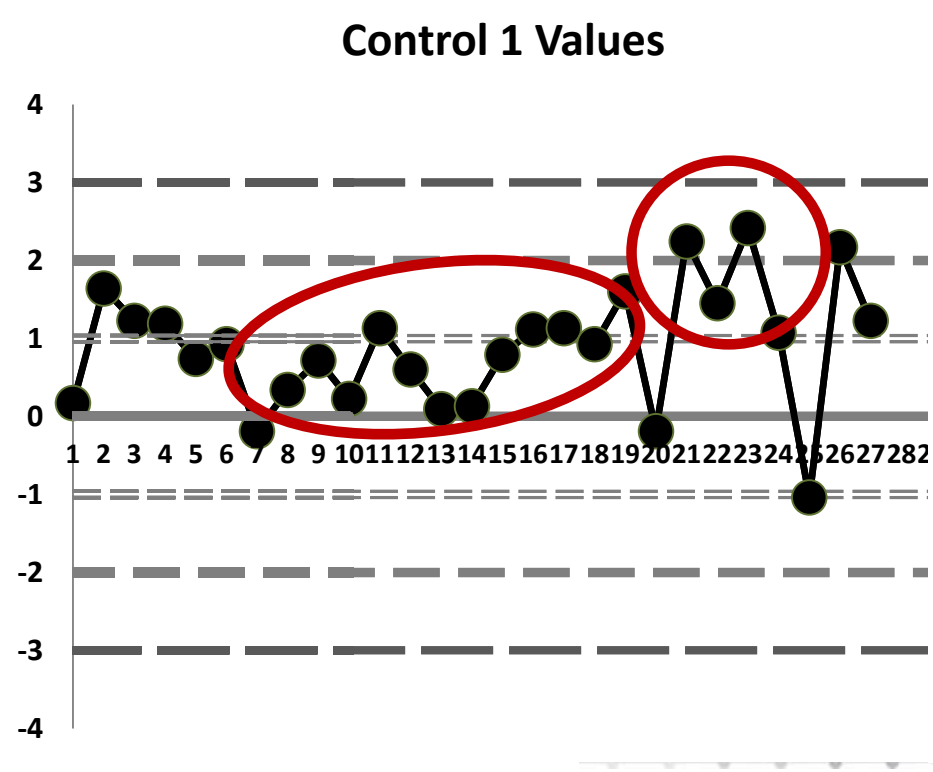
Case	Primary diagnosis	Purpose of testing	Laboratory test	Units	Erroneous results	Corrected results	Potential clinical consequence	Actual clinical consequence
1	Autoimmune thyroid disease on carbimazole	Diagnostic work-up	ATG ATPO	IU/l IU/l	>3000 >1000	404 876	Repeat testing TSH: <0.02 mIU/l Free T4: 16.6 pmol/l	None
2	Syncope	Diagnostic work-up	ATG ATPO	IU/l IU/l	69 691	<20 150	None TSH: 6.90 mIU/l Free T4: 16.6 pmol/l	None
3	Partial empty sella	Disease monitoring	IGF-1	ng/ml	1509	55	Repeat testing	Repeat testing
4	Pituitary microadenoma	Disease monitoring	GH IGF-1	µg/l ng/ml	38.5 614	2.09 130	MRI imaging for suspected GH secreting adenoma	Repeat testing
5	Automimmune thyroid disease	Disease monitoring	ATG ATPO	IU/l IU/l	96 277	<20 13	Erroneous results not seen by physician	None
6	Vitreous haemorrhage	Diagnostic work-up	ATG ATPO	IU/l IU/l	92 37	<20 <10	None TSH: 0.86 mIU/l Free T4: 16.8 pmol/l	None
7	Hypoadrenalism	Diagnostic	ACTH	pmol/l	41.1	2.1	Misdiagnosis as primary hypoadrenalism	Adrenal CT-scan ordered
8	Congenital adrenal hyperplasia	Disease monitoring	ACTH	pmol/l	102	36.6	Misdiagnosis of poor compliance to glucocorticoids	None
9	Hypothyroidism on L-thyroxine replacement	Diagnostic work-up	ATG ATPO	IU/l IU/l	126 366	23 <10	Misdiagnosis of Hashimoto's disease and need for repeat testing TSH 0.05 mIU/l Free T4: 18.4 pmol/l	None
10	Grave's disease	Diagnostic work-up	ATG ATPO	IU/l IU/l	300 >1000	<20 49	None TSH: <0.02 mIU/l Free T4: 12.7 pmol/L	None
11	Automimmune thyroid disease	Disease monitoring	ATPO	IU/l	>1000	191	None	None
12	Hypoglycaemia for investigation	Diagnostic	GH IGF-1 Repeat testing GH IGF-1	µg/l ng/ml µg/l ng/ml	39.5 765 6.82 783	2.16 178 0.97 180	Misdiagnosis of acromegaly	None
13	Metastatic thyroid cancer	Disease monitoring	ATG	IU/l	97	<20	None	None
14	Thyroid cancer, post-surgical removal	Disease monitoring	ATG	IU/l	>3000	28	Misdiagnosis of cancer recurrence, need for further laboratory and imaging studies	None
15	Thyroid cancer, post-surgical removal	Disease monitoring	ATG	IU/l	140	<20	Misdiagnosis of cancer recurrence, need for further laboratory and imaging studies	None

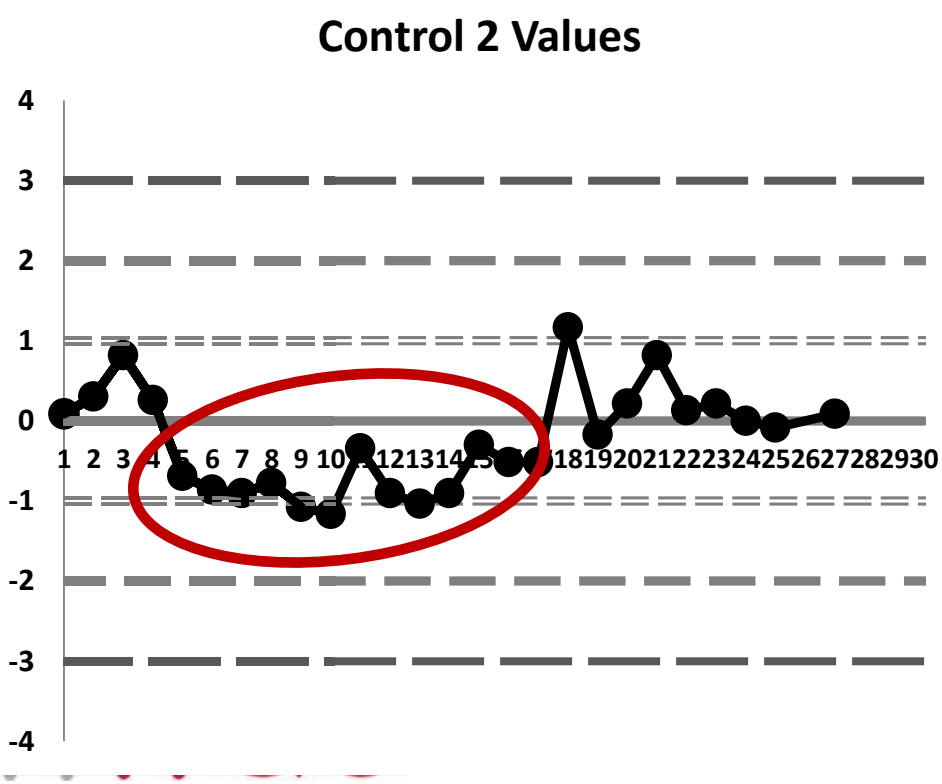
The free thyroxine and thyrotropin concentrations measured together with the thyroid auto-antibody tests are provided.
ACTH, adrenocorticotrophic hormone (reference interval: 0.0–10.2 pmol/l), ATG, anti-thyroglobulin antibodies (negative if <40 IU/l), ATPO, anti-thyroid peroxidase antibodies (negative if <50 IU/l), GH, growth hormone (male <3.00 µg/l; female <8.00 µg/l), IGF-1, insulin-like growth factor-1 (87–238 ng/ml), free T4, free thyroxine (10.0–23.0 pmol/l), TSH, thyrotropin, (0.45–4.50 mIU/l).

THE RIGHT QC COULD HAVE CAUGHT THE ERRORS

49 patients Affected

- **4 procedures ordered in error (including CT Scan)**
- **7 patients ordered for retesting**
- **6 misdiagnoses**





HOW COULD THIS LAB MISS THIS ERROR?

CAP certified

JCI certified 2004

Singapore Service Class award 2004

ISO 15189 certified

Triple ISO certification

- ISO 9001
- ISO 14001
- ISO 18001

Awards and Awards and Awards…

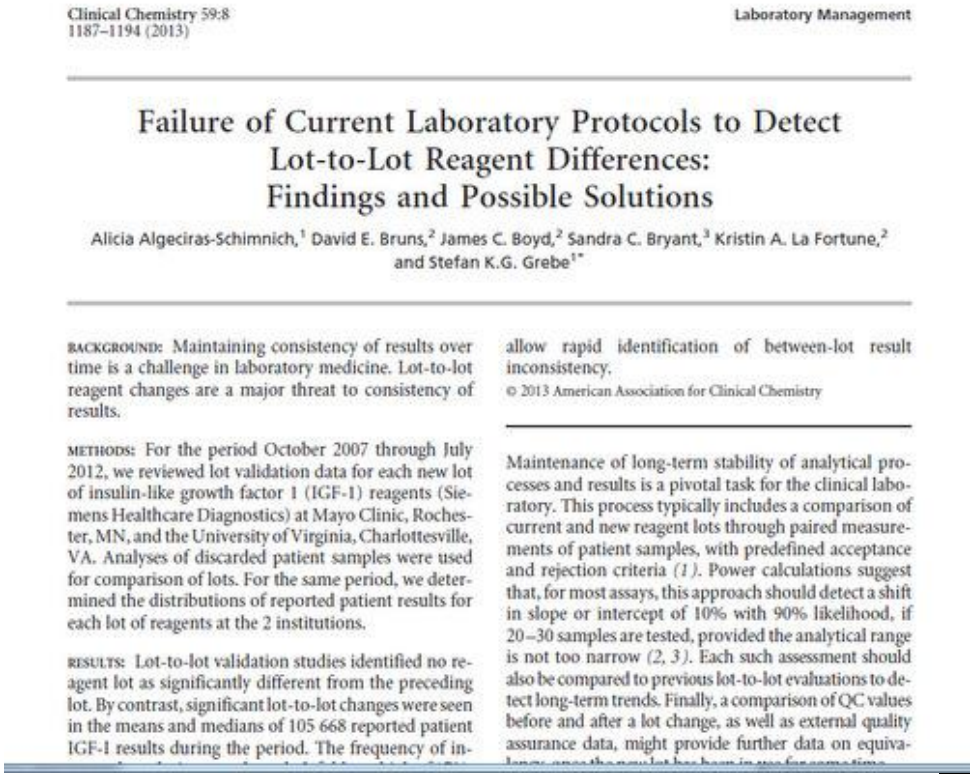
We need Detailed QC HELP!

IS WASN'T JUST ONE BAD LAB – IT WAS A BAD MANUFACTURER

For 2 YEARS, Mayo Clinic: about 5% of all IGF-1 tests were false positives.

"If the Mayo Clinic observations are generalized, a laboratory performing 1000 IGF-1 tests/month would be expected to generate around 50 false-positive results each month. Some of these can be expected to lead to follow-up appointments or further testing and, ultimately, increased financial burden and anxiety for patients."

UVA: 8-month period in 2011, "20 abnormally high IGF-1 results in 17 patients that did not agree with clinical findings. In 17 of the 20 samples, the IGF-1 concentrations measured by a mass spectrometric method were within reference intervals. In 7 of the patients, expensive growth hormone suppression tests were done; the results were within reference intervals in 6, with the result in the seventh nondiagnostic."



Clinical Chemistry 59:8
1187–1194 (2013)

Failure of Current Laboratory Protocols to Detect Lot-to-Lot Reagent Differences: Findings and Possible Solutions

Alicia Algeciras-Schimnich,[1] David E. Bruns,[2] James C. Boyd,[2] Sandra C. Bryant,[3] Kristin A. La Fortune,[2] and Stefan K.G. Grebe[1*]

BACKGROUND: Maintaining consistency of results over time is a challenge in laboratory medicine. Lot-to-lot reagent changes are a major threat to consistency of results.

METHODS: For the period October 2007 through July 2012, we reviewed lot validation data for each new lot of insulin-like growth factor 1 (IGF-1) reagents (Siemens Healthcare Diagnostics) at Mayo Clinic, Rochester, MN, and the University of Virginia, Charlottesville, VA. Analyses of discarded patient samples were used for comparison of lots. For the same period, we determined the distributions of reported patient results for each lot of reagents at the 2 institutions.

RESULTS: Lot-to-lot validation studies identified no reagent lot as significantly different from the preceding lot. By contrast, significant lot-to-lot changes were seen in the means and medians of 105 668 reported patient IGF-1 results during the period. The frequency of in-

allow rapid identification of between-lot result inconsistency.

Maintenance of long-term stability of analytical processes and results is a pivotal task for the clinical laboratory. This process typically includes a comparison of current and new reagent lots through paired measurements of patient samples, with predefined acceptance and rejection criteria (*1*). Power calculations suggest that, for most assays, this approach should detect a shift in slope or intercept of 10% with 90% likelihood, if 20–30 samples are tested, provided the analytical range is not too narrow (*2*, *3*). Each such assessment should also be compared to previous lot-to-lot evaluations to detect long-term trends. Finally, a comparison of QC values before and after a lot change, as well as external quality assurance data, might provide further data on equiva-

WESTGARD QC

THE GREAT GLOBAL QC SURVEY 2017

Collected March - June 2017
More than 900 labs responded
More than 105 countries represented

COUNTRIES THAT PARTICIPATED

AE - United Arab Emirates	23
AL - Albania	1
AM – Armenia	2
AO – Angola	2
AR – Argentina	5
AS - American Samoa	1
AT - Austria	1
AU - Australia	16
AW - Aruba	1
BA - Bosnia Herzegovina	8
BB - Barbados	1
BD - Bangladesh	1
BE - Belgium	7
BH - Bahrain	2
BI - Burundi	1
BO - Bolivia	1
BR - Brazil	6
BW - Botswana	3
BY – Belarus	1
CA - Canada	41
CH - Switzerland	3
CL - Chile	5
CN - China	3
CO – Colombia	2
CR - Costa Rica	1
CZ - Czech Republic	1
DE - Germany	2
DK - Denmark	2
DZ - Algeria	1
EC – Ecuador	1
EE – Estonia	2
EG – Egypt	6
ES - Spain	4
ET - Ethiopia	3
FI - Finland	1
FJ - Fiji	1
FR - France	5
FX - France, Met	3
GB - United Kingdom	44
GH - Ghana	3
GR - Greece	3
GY - Guyana	4
HK - Hong Kong	3
HR - Croatia	5
ID - Indonesia	2
IE – Ireland	8
IL – Israel	1
IN - India	25
IR - Iran	4
IS – Iceland	1
IT – Italy	8
JM - Jamaica	5
JO – Jordan	3
JP – Japan	1
KE – Kenya	3
KR - Korea, South	2
KW – Kuwait	6
KZ - Kazakhstan	2
LB - Lebanon	12
LK - Sri Lanka	2
LT - Lithuania	1
LV - Latvia	1
LY - Libya	1
ME - Montenegro	1
MK - Macedonia	4
ML – Mali	1
MT - Malta	1
MW - Malawi	4
MX – Mexico	9
MY – Malaysia	13
MZ – Mozambique	1
NA – Namibia	3
NG - Nigeria	4
NL - Netherlands	6
NO – Norway	2
NP – Nepal	1
NZ - New Zealand	2
OM – Oman	6
PA – Panama	3
PE – Peru	5
PG - Papua New Guinea	1
PH – Philippines	10
PK – Pakistan	3
PL – Poland	3
PR - Puerto Rico	9
PT - Portugal	10
QA - Qatar	5
RO - Romania	1
RS - Serbia	49
RU – Russia	1
SA - Saudi Arabia	12
SD - Sudan	2
SE – Sweden	1
SG – Singapore	7
SI - Slovenia	1
SV - El Salvador	1
SX - Sint Maarten	1
TH - Thailand	5
TR - Turkey	7
TW - Taiwan	2
TZ – Tanzania	1
UA – Ukraine	2
US - United States	350
UY – Uruguay	2
VE - Venezuela	4
VI - Virgin Islands	1
VN – Vietnam	7
ZA - South Africa	8
ZM - Zambia	7
ZW - Zimbabwe	9

Top countries

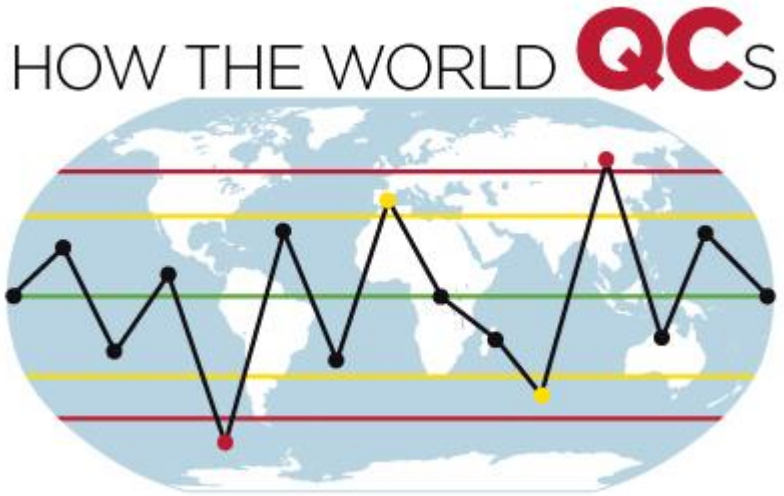
US - United States	38.5%	350
RS - Serbia	5.4%	49
GB - United Kingdom	4.8%	44
CA - Canada	4.5%	41
IN - India	2.8%	25
AE - United Arab Emirates	2.5%	23

WHAT QC PRACTICES ARE BEING IMPLEMENTED IN THE "REAL WORLD"?

Anorexic QC

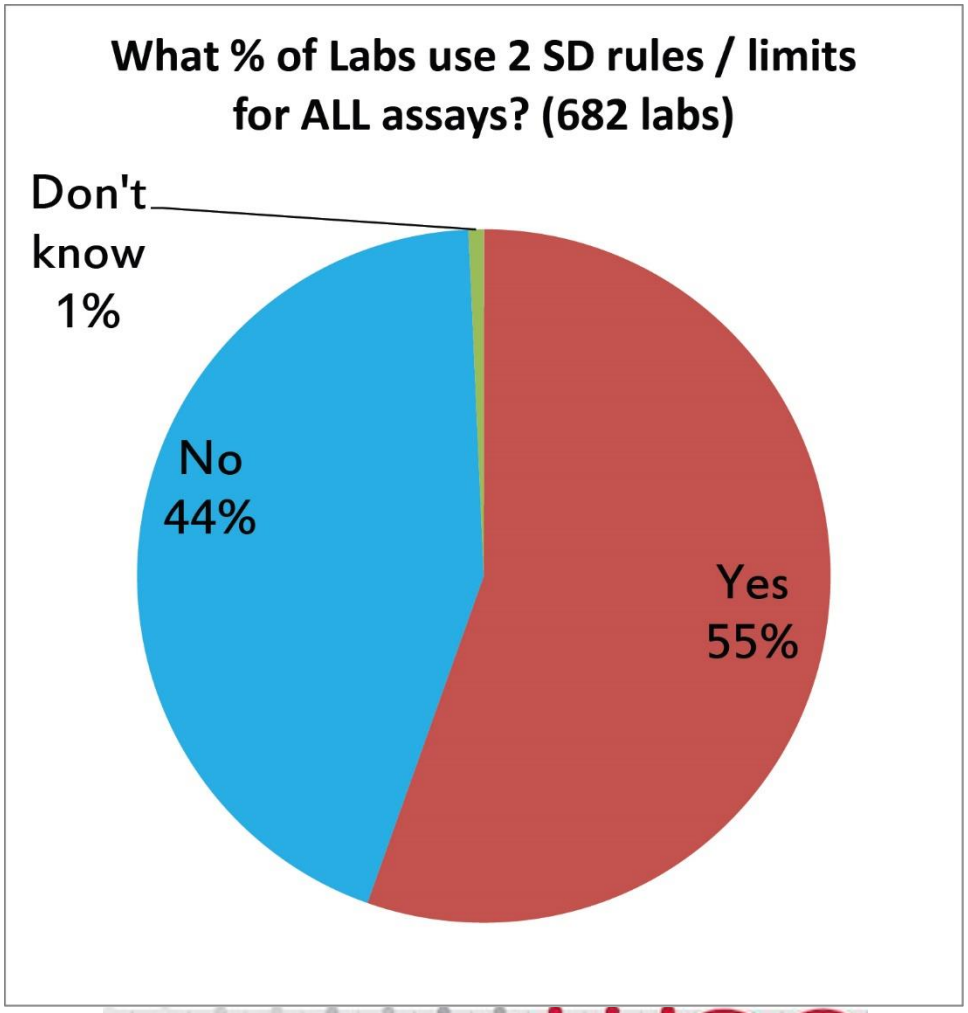
Gambler QC

Blind Man QC

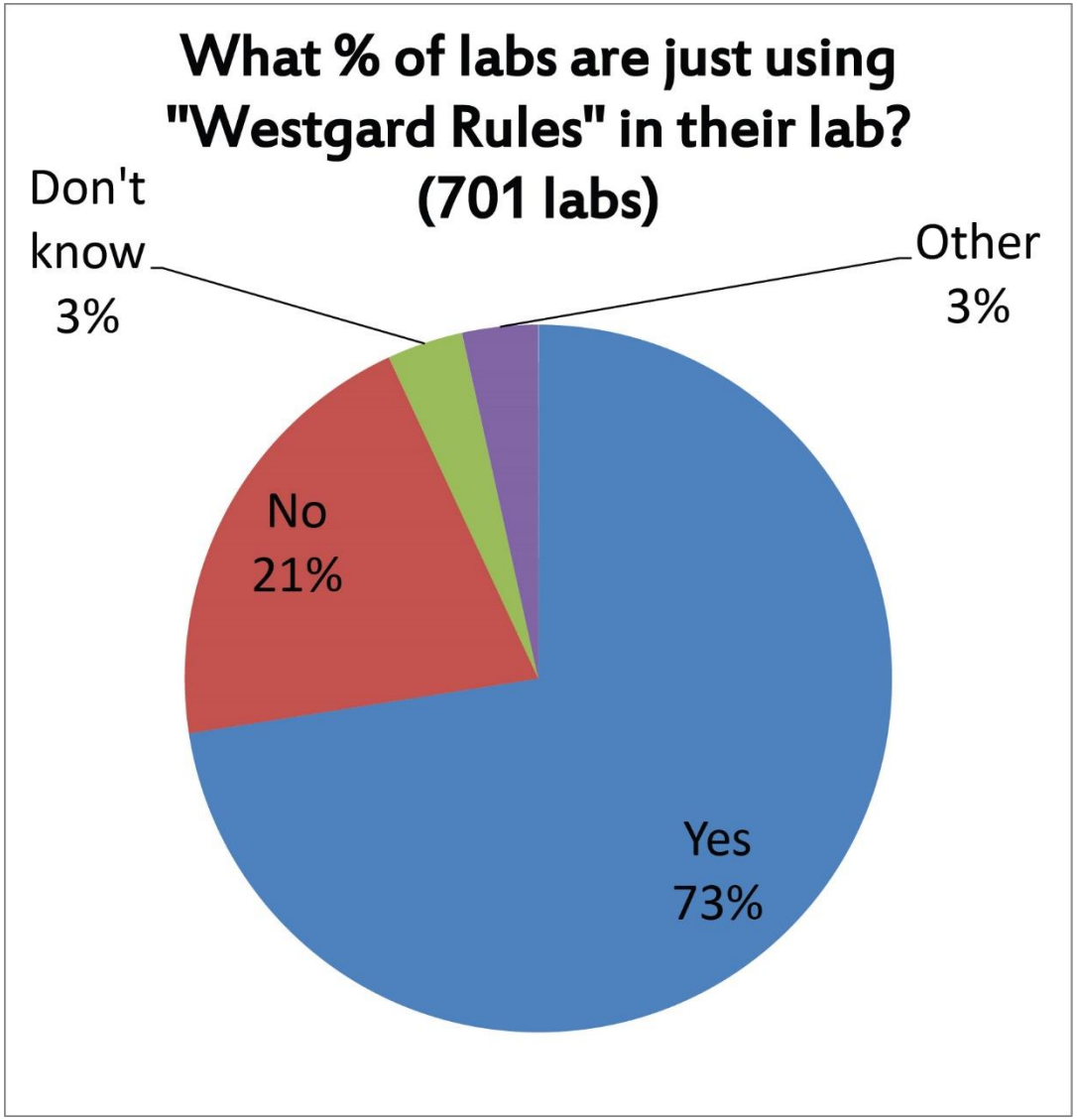


Nearly 900 laboratories
> 105 countries

ANTIQUATED QC PRACTICES

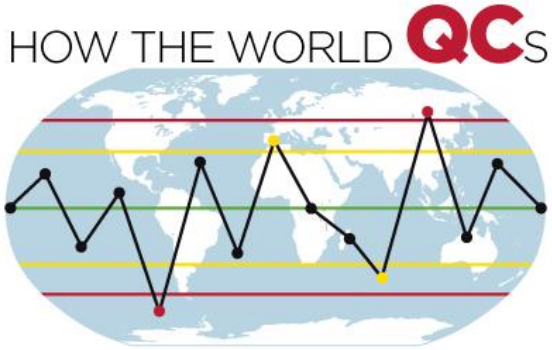


FLATTERING, BUT POSSIBLY OVERKILL



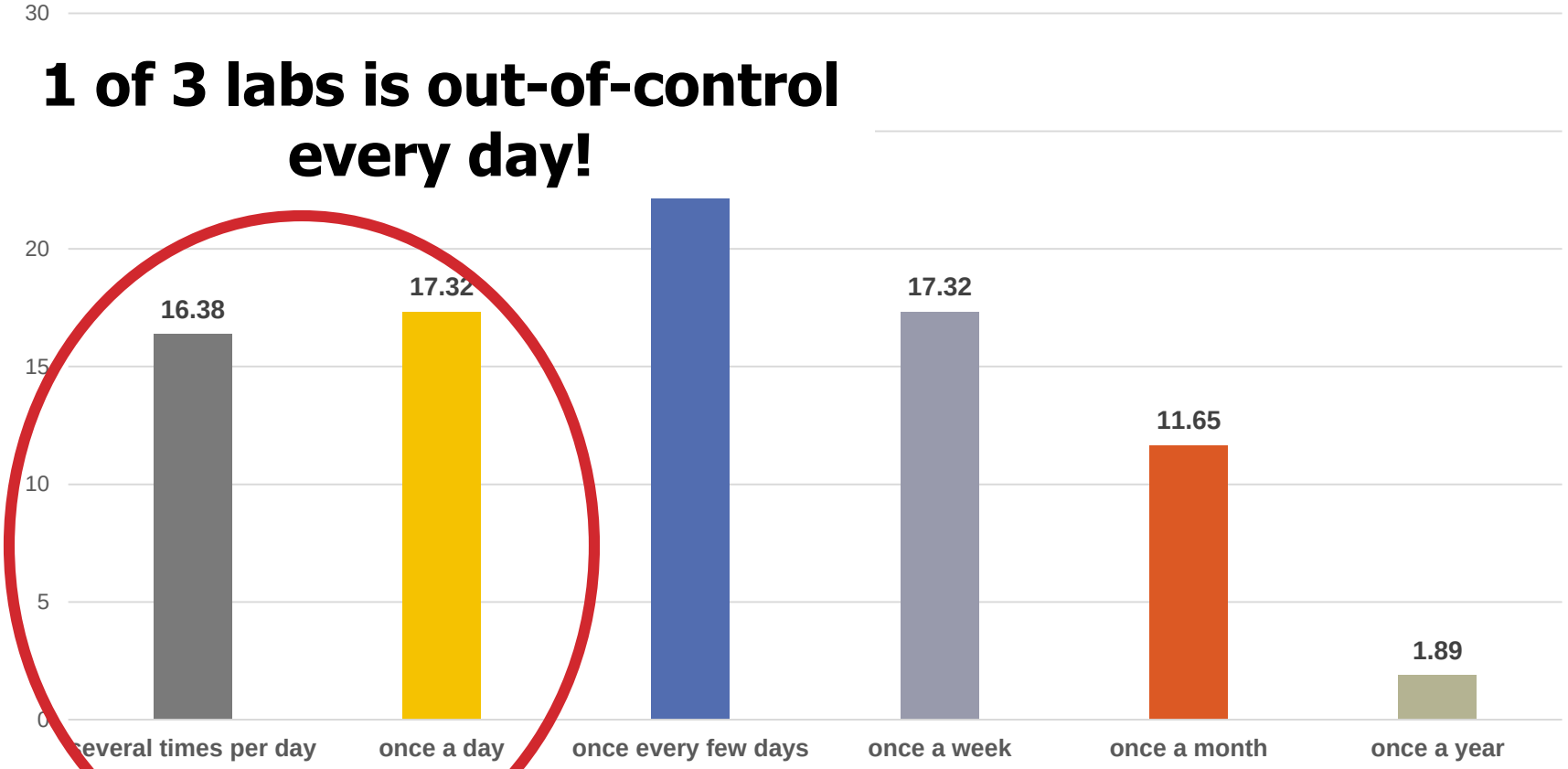
WESTGARD QC

ALARM FATIGUE

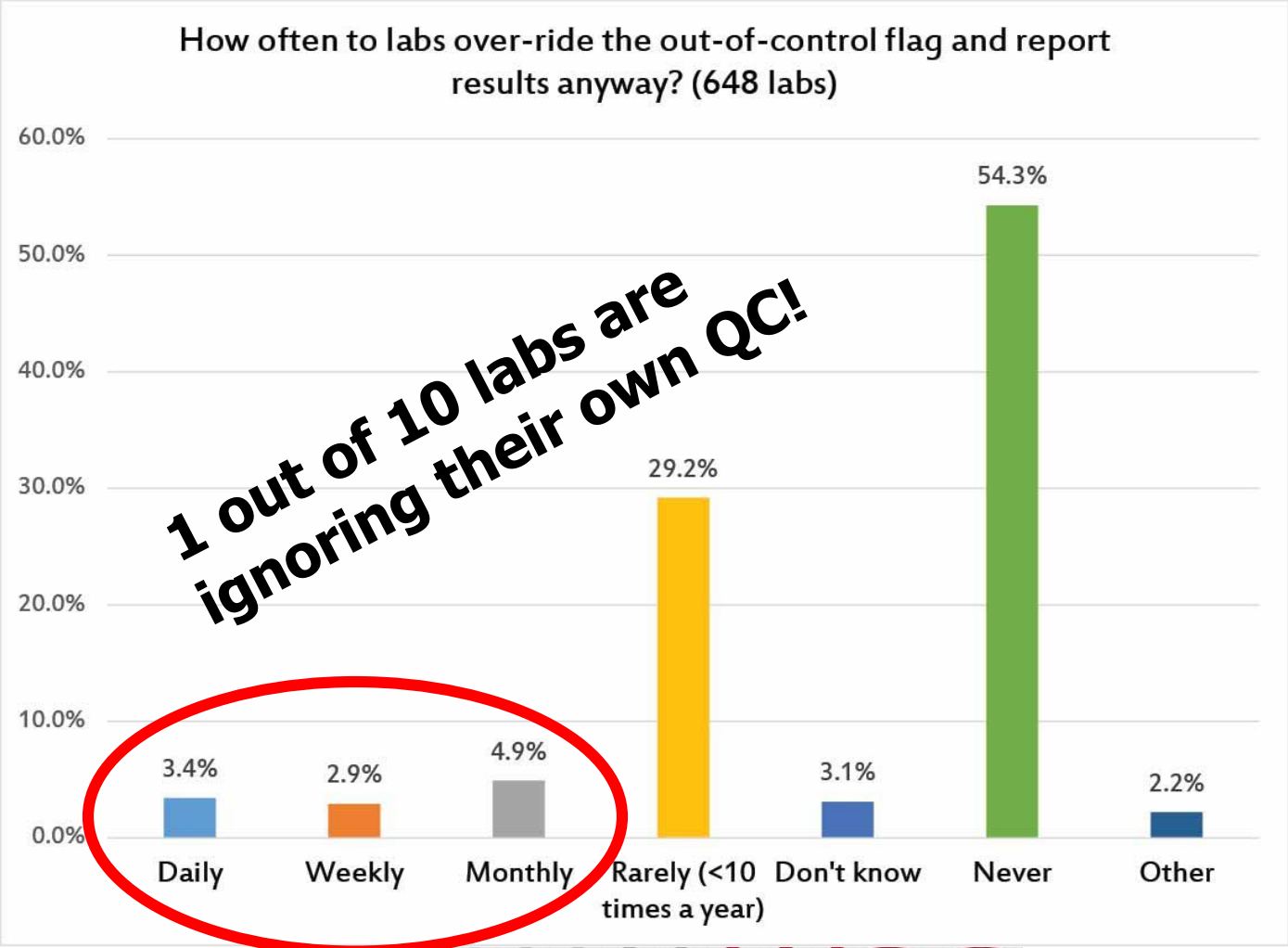


How often is the laboratory out of control? (635 labs)

1 of 3 labs is out-of-control every day!



HOW OFTEN DO LABS REPORT RESULTS? (EVEN THOUGH THEY'RE OUT OF CONTROL)



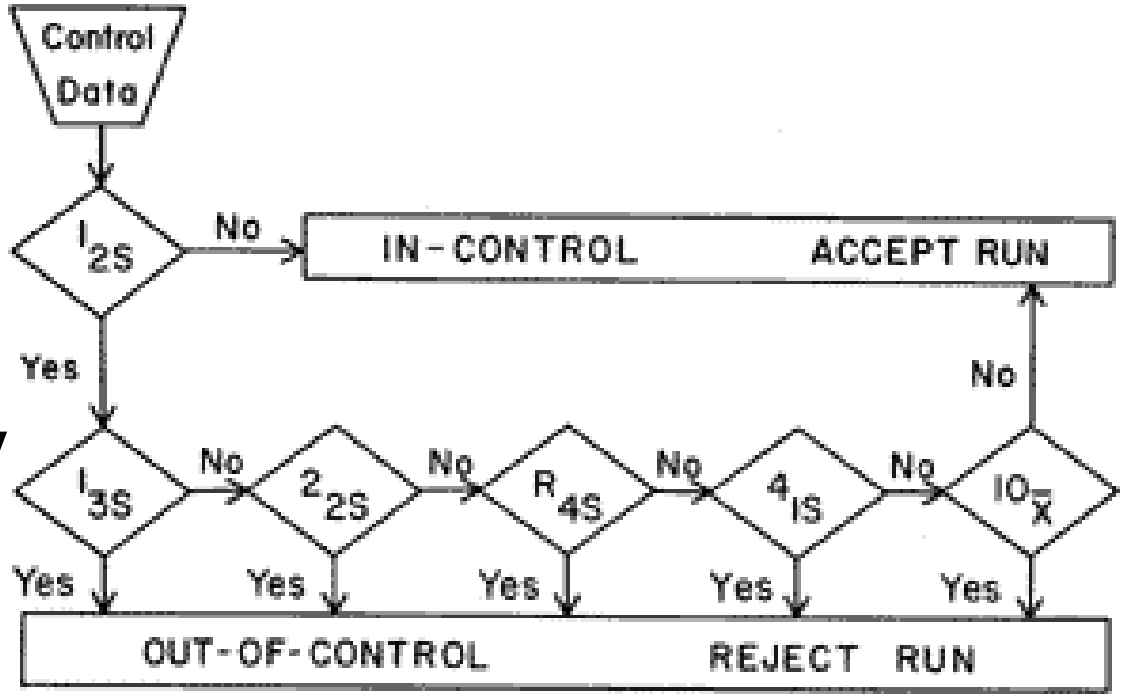
“WESTGARD RULES”

THE ORIGINAL

THE FIRST INNOVATION IN QUALITY CONTROL FOR LABORATORIES

THE ORIGINAL "WESTGARD RULES"

- **Maximize error detection from few measurements**
- **Attempt to balance work with practicality**
- **Classic laboratory workaround**



Westgard JO, Barry PL, Hunt MR, Groth T. A multi-rule Shewhart chart for quality control in clinical chemistry. Clin Chem 1981;27:493-501.

https://www.westgard.com/mltirule.htm
https://www.westgard.com/westgard-rules.htm

"WESTGARD RULES"

THE PRESENT

Are we weary and wary of the 2s "warning rule"?

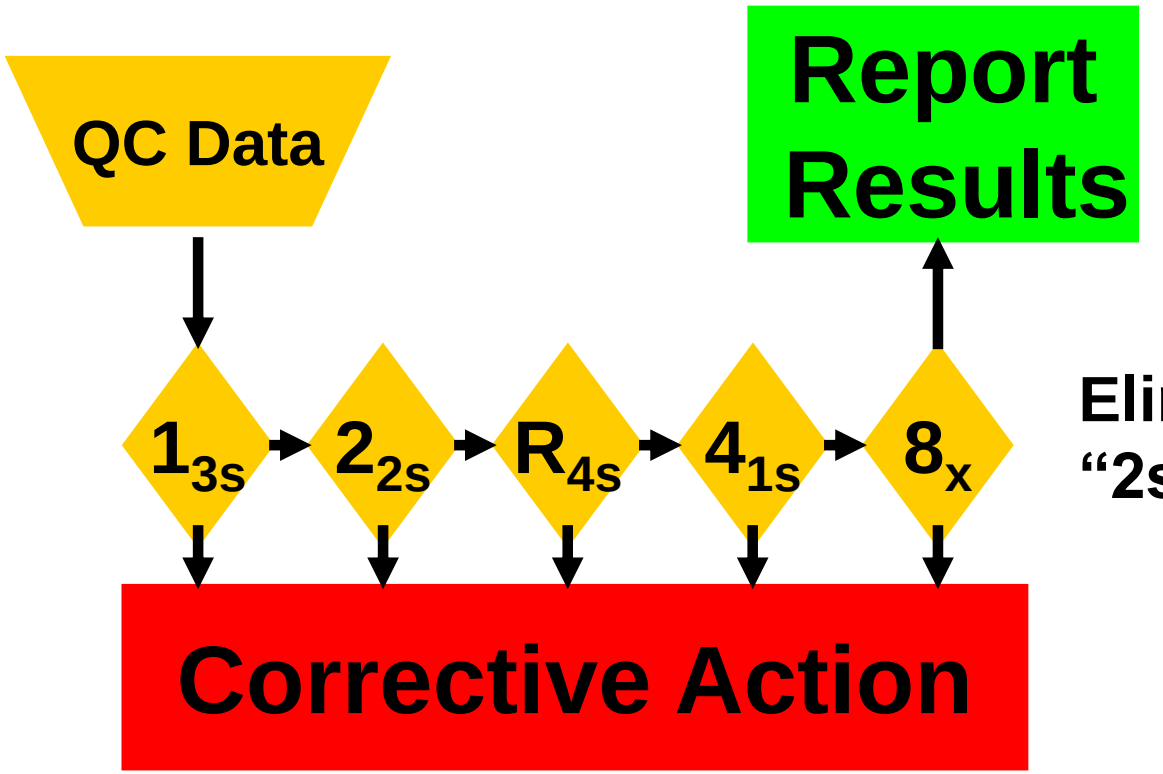
WHEN DO WE NEED "WARNING" RULES?

In the "classic/manual" multirule, the "2s warning" was used to alert operators to start checking other rules (otherwise, don't)

Today's labs often have QC automated by software. The computer can check all the rules all the time – no warning necessary.

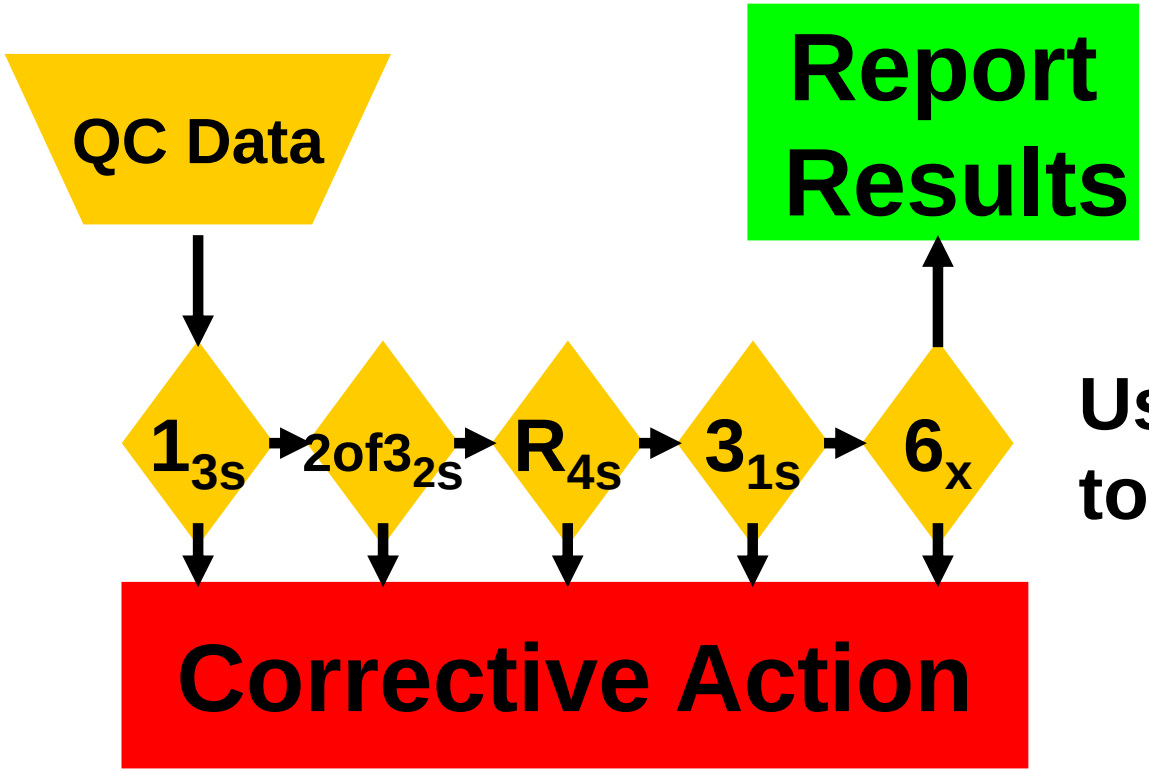
In that case, what do "Westgard Rules" look like?

MODERN MULTIRULE QC PROCEDURE (N=2)



Eliminate the "2s Warning" rule

MODERN MULTIRULE QC PROCEDURE (N=3)



Use rules suited to multiples of 3

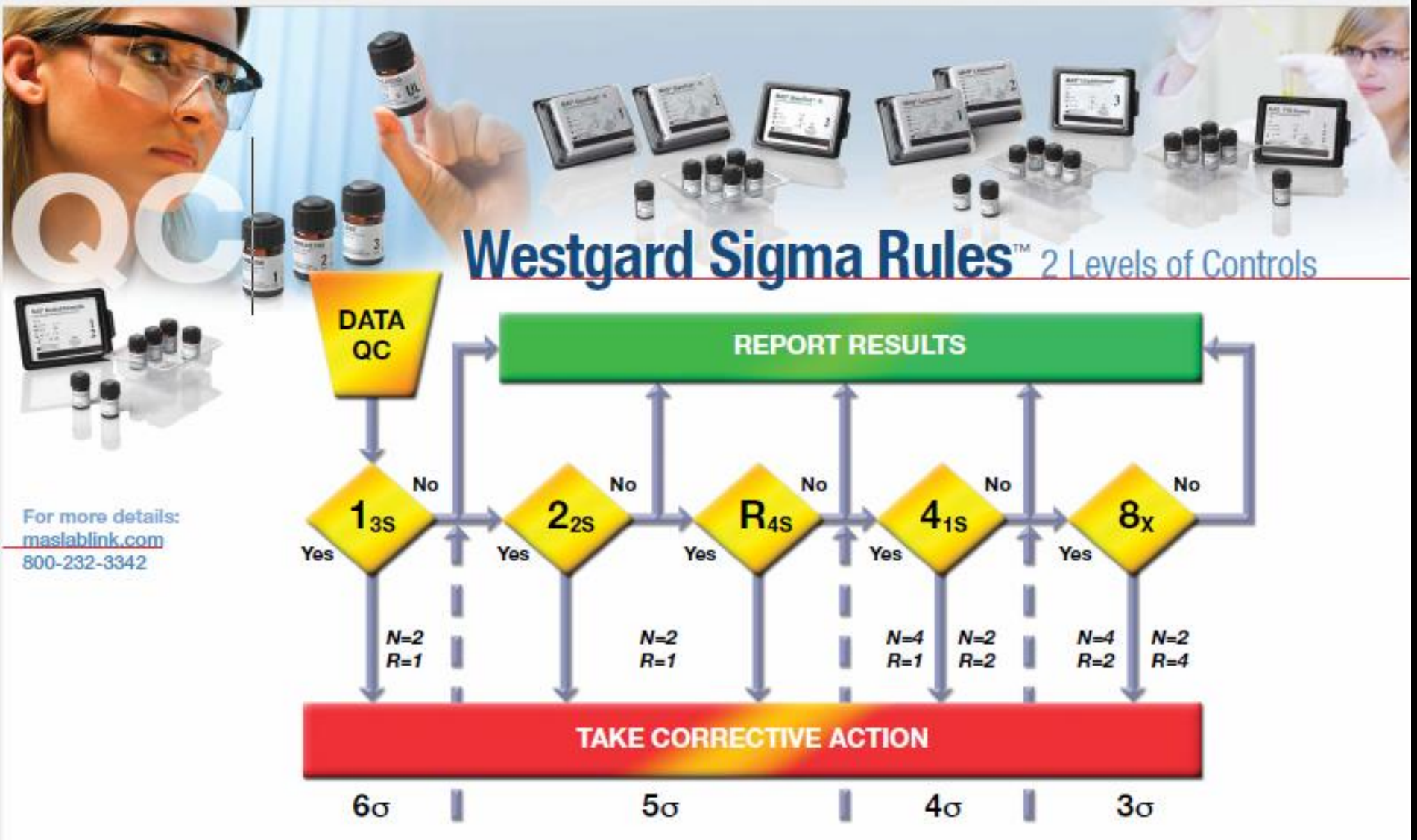
“WESTGARD RULES”

THE FUTURE

SIX SIGMA QUALITY INTEGRATED INTO QUALITY ASSESSMENT AND CONTROL

WESTGARD QC

THE LATEST EVOLUTION: WESTGARD SIGMA RULES



WHAT ARE THE BENEFITS OF REDESIGN OF QC ?

ChiMei Hospitals, Tainan, Taiwan

- **>85% in control costs**
- **>$50,000 annual savings in reduced reagent and control consumption**
- **>200 hours saved in troubleshooting** (240 hours down to 35 hours)

Hung, HY et al. Laboratory Labor and Cost Efficiency Improvement with the Implementation of Six-Sigma Statistical Quality Control Management, Poster from Chi Mei Medical Center, Tainan, Taiwan.

UNDERSTANDING THE IMPACT OF LABORATORY PERFORMANCE ON OUTCOMES IN A SCREENING POPULATION FOR CARDIOVASCULAR DISEASE IN TAIWAN

[1]ChiMei Medical Center, Tainan, Taiwan; [2]Abbott Diagnostics, Wiesbaden, Germany; [3]ChiMei Medical Center, Health Management Center, Tainan, Taiwan

ISPOR 7th Asia-Pacific Conference, 3-6 September 2016, Singapore

Introduction

Risk scores for cardiovascular disease (CVD) events based on laboratory values have been established in primary prevention programs [1]. The performance of laboratory test systems may lead to discordant treatment decisions in some cases. The goal of this study was to investigate the impact of laboratory diagnostic system performance on outcomes in a screening population for CVD in Taiwan.

Methods

Data were collected from 1,396 people (Age >=40 years) enrolled for CVD screening between January and April 2015 in Tainan (Table 1).

A time-to-event microsimulation model was developed (Figure 1). Starting with screening, each individual was classified into risk categories based on observed values for LDL-, HDL-, total cholesterol, and a 10-years CVD risk score. Patients with observed values of LDL≥190mg/L, 70<LDL<190 and a risk score ≥7.5%, and diabetic patients with LDL between 70 and 190 plus a risk score between 5 and 7.5% were referred for treatment. They received lipid lowering drugs thus reducing risk for a CVD event. Individuals not assigned to treatment remained in the "No treatment"- state until the next screening cycle after 1-4 years, the occurrence of a CVD event, or death.

Minimum and optimum test specifications as suggested in literature were tested against a control scenario assuming perfect performances (Table 2).

Samples were bootstrapped from the cohort with 100,000 iterations. Model followed a lifetime horizon and a health system perspective. Results were expressed in costs, quality 1-

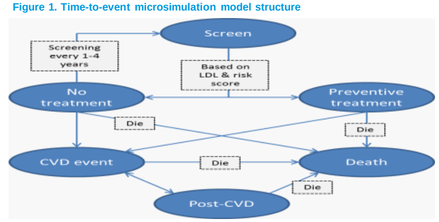
Table 2. Test performance of comparing strategies

Strategy	Total -C Bias, %	Total -C CV, %	HDL-C Bias, %	HDL-C CV, %	LDL-C Bias, %	LDL-C CV, %	Source
Mimimun (MIN)	6.2	4.5	8.4	5.5	8.2	5.9	[16,17]
Optimum (OPT)	2.1	1.5	2.8	1.8	2.7	2.9	
Control (CON)	0.0	0.0	0.0	0.0	0.0	0.0	Assumption

Table 1.
Characteristics of screening cohort
(n=1,396)

Variable	Mean (SE)
Sex (% women)	35.9
Age, years*	52.9 (40-85)
BMI	24.2 (0.1)
Pulse	72.9 (0.3)
BPSys (mmHg)	116.5 (0.5)
BPDia (mmHg)	74.2 (0.3)
GLUC_FAST	100.8 (0.8)
TCHOL (mg/dL)	202.2 (1.0)
HDL-C (mg/dL)	54.7 (0.4)
LDL-C (mg/dL)	132.1 (0.9)

Figure 1. Time-to-event microsimulation model structure



Variable	Value	Distribution	Source
Setting, risk & events			
CVD risk (10 years)	Risk based equations		[1]
In-hospital mortality from stroke	10.1	Beta	[2]
In-hospital mortality from AMI	6.5	Beta	[3]
Mortality from stroke at 1 year, %	12.0	Weibull	[2]
Mortality from MI at 1 year, %	6.0	Weibull	[4]
Mortality (non-CVD)	Age-, sex-specific lifetable	Weibull	[5]
Annual risk for recurrent CVD, %	6.8	Weibull	[4]
Risk reduction under treatment, % (95%CI)	65 (58, 73)	Uniform	[6]
CVD event type (Stroke vs. MI), %	76	Beta	[7]
Smoking prevalence Male, % (95%CI)	31 (28.0, 35.2)	Uniform	[8]
Smoking prevalence Female, % (95%CI)	3.4 (2.8, 4.2)	Uniform	[8]
Laboratory results	Mean from cohort	Normal	Assumption
Screening cycle, years	1 to 4	Uniform	Assumption
Utility			
Baseline	0.936	Beta	[9]
Lipid lowering treatment, Mean (SD)	0.934 (0.001)	Beta	[10]
MI (disutility), Mean (SD)	0.080 (0.048)	Beta	[9]
Stroke (disutility), Mean (SD)	0.242 (0.039)	Beta	[9]
Post MI	0.799 (0.010)	Beta	[9]
Post stroke	0.576 (0.010)	Beta	[9]
Costs, NT$[1,2]			
Screening & visit	5,585	Uniform	[11]
Permanent lipid lowering treatment	15,639	Uniform	[12]
Stroke	74,832	Uniform	[13]
Post-stroke	45,630	Uniform	[14]
MI	189,497	Uniform	[15]
Post MI	82,897	Uniform	[14]
Annual discount rate for costs and utility, %	3.0		

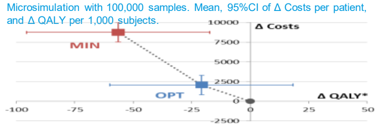
Table 3. Model input assumptions.
(1) All costs adjusted for inflation with a 3% rate to 2015 New Taiwan dollar.(2) A range of ±25% was used to create upper and lower bounds.

Results

Results in terms of incremental values compared to the control scenario are summarized in Table 2.

Analytical measurement uncertainty caused by CV and bias resulted in discordant management in some cases. The MIN and OPT strategy led to different decisions in 14.1% and 4.1%, respectively. Patients who had not received preventive treatment based on erroneous results had a higher risk for CVD events at an earlier time. The observed strategies showed a small but significantly

Figure 2. Incremental costs and QALY per strategy compared to the Control.
Microsimulation with 100,000 samples. Mean, 95%CI of Δ Costs per patient, and Δ QALY per 1,000 subjects.



per 1,000 subjects (95%CI 43, 220), whereas a non-significant trend was observed for the OPT performance. Loss in QALY resulting from unnecessary treatment, earlier and increased risk for events, or increased mortality was found to be significant for MIN but not for OPT.

CVD related life-time costs were significantly higher compared to CON for MIN (+NT$ 8,753) and OPT (+NT$ 2,075).

Table 2. Incremental results from microsimulation.
Minimum strategy (MIN), Optimum strategy (OPT), Control strategy (CON) as defined in Table 2. *Per 1,000 individuals screened.

Outcome value	MIN vs. CON Mean	MIN vs. CON (95%CI)	OPT vs. CON Mean	OPT vs. CON 95%CI	MIN vs.OPT Mean	MIN vs.OPT 95%CI
Δ Costs per patient, NT$	8753	(7516; 9990)	2075	(844; 3307)	6678	(5440;791

The "Minimum" and "Optimum" strategy led to higher costs compared to the Control for 32% and 27%, respectively (Fig. 3).

As revealed from a sensitivity analysis, for each increase in percent point of CV, negative or positive bias 22, 43 or 7 individuals per 1,000 screened subjects would be either over- or under-treated compared to the control (Fig. 4, Tab. 3). Negative bias particularly increased the risk for denying preventive treatment, and would affect six times more patients than positive bias.

Incremental costs per patients caused from discordant management decisions and related consequences would accrue to NT$786 (96%CI 734,838), NT$762 (612;912) and NT$699 (668;729) per percent increase in negative bias, positive bias and CV (Tab. 3).

Table 3. Impact of CV and bias on over- and under-treated individuals, and incremental costs.
OT/ UT: Over-/Under-treated, Data based on linear regression model. Sensitivity analyses assumed perfect %CV or bias.

Variable	Response	Coeff.	(95%CI)	R-Sq, %
(-) bias	ΔUT, per 1,000 subjects	43.3	(40.6; 45.9)	
	ΔCosts, NT$	786	(734;838)	
(+) bias	[illegible]	[illegible]	[illegible]	
	ΔCosts, NT$	762	(612; 912)	
CV	ΔUT, per 1,000 subjects	10.2	(9.8;10.6)	
	ΔOT, per 1,000 subjects	12.1	(11.8;12.5)	
	ΔCosts, NT$	699	(668;729)	

Figure 3. Distribution of incremental costs (IC) per strategy.

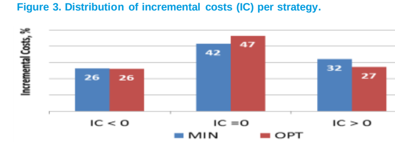
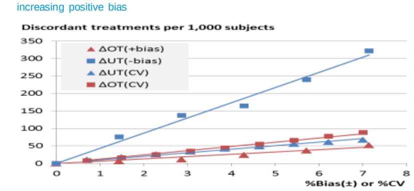


Figure 4. Impact of increasing Bias and CV on discordant treatments.
OT: Over-treated; UT: Under-treated. No significant deviation from the Control strategy was observed for both, the number of individuals over-treated with increasing negative bias, and the number of individuals under-treated with increasing positive bias



Conclusions

- Analytical measurement uncertainty may impose a higher risk for missing prevention opportunities.
- The selection of high performance diagnostic systems plus a strict quality control management in the laboratory conforming to the optimum specification is critical to consistently providing high and efficient quality of care.

Limitations

Results are limited to the information derived from the cohort. Risk scores may not accurately estimate the actual risk. Patient characteristics were sampled from distributions in order to reflect variability and uncertainty. The model assumed a stable lipid status over the time span of the simulation.

Acknowledgement

We thank Roger Low and Sten Westgard for motivation and fruitful discussions.

References

1. Stone NJ, Robinson JG, Lichtenstein AH, et al. 2013 ACC/AHA guideline on the treatment of blood cholesterol to reduce atherosclerotic cardiovascular risk in adults. *Circulation.* 2014;129(25 Suppl 2):S1-45.
2. Lee HC, Chang KC, Huang YC, et al. Readmission, mortality, and first-year medical costs after stroke. *JCMA.* 2013;76(12):703-714.
3. Yin WH, Lu TH, Chen KC, et al. The temporal trends of incidence, treatment, and in-hospital mortality of acute myocardial infarction over 15years in a Taiwanese population. *Int J Card.* 2016;209:103-113.
4. Chiang FT, Shyu KG, Wu CJ, et al. Predictors of 1-year outcomes in the Taiwan Acute Coronary Syndrome Full Spectrum Registry. *J Formos Med Assoc.* 2014;113(11):794-802
5. Ministry of Interior, Department of Statistics, Taiwan. Liftetable 2013. http://sowf.moi.gov.tw/stat/english/elife/te102210.htm. Accessed May 18, 2016.
6. Taylor F, Huffman M, Macedo A, et al. Statins for the primary prevention of cardiovascular disease. *The Cochrane database of systematic reviews.* 2013(1).
7. Cheng CL, Chien HC, Lee CH, Lin SJ, Yang YH. Validity of in-hospital mortality data among patients with acute myocardial infarction or stroke in National Health Insurance Research Database in Taiwan. *Int J Card.* 2015;201:96-101
8. Ng M, Freeman MK, Fleming TD, et al. Smoking prevalence and cigarette consumption in 187 countries, 1980-2012. JAMA. 2014; 311(2):183-92.
9. Kang EJ, Ko SK. A catalogue of EQ-5D utility weights for chronic diseases among noninstitutionalized community residents in Korea. *Value Health.* 2009;12 Suppl 3:S114-117.
10. Pandya A, Sy S, Cho S, Weinstein MC, Gaziano TA. Cost-effectiveness of 10-Year Risk Thresholds for Initiation of Statin Therapy for Primary Prevention of Cardiovascular Disease. *JAMA.* 2015;314(2):142-150.
11. Lin YK, Chen CP, Tsai WC, Chiao YC, Lin BY. Cost-effectiveness of clinical pathway in coronary artery bypass surgery. *J Med Sys.* 2011;35(2):203-213.
12. Cobiac LJ, Magnus A, Barendregt JJ, Carter R, Vos T. Improving the cost-effectiveness of cardiovascular disease prevention in Australia: a modelling study. *BMC Public Health.* 2012;12(389).
13. Lien HM, Chou SY, Liu JT. Hospital ownership and performance: evidence from stroke and cardiac treatment in Taiwan. *J Health Econ.* 2008;27(5):1208-1223.
14. Chung CW, Wang JD, Yu CF, Yang MC. Lifetime medical expenditure and life expectancy lost attributable to smoking through major smoking related diseases in Taiwan. *Tob Control.* 2007;16(6):394-399.

HEALTH ECONOMICS OUTCOMES OF OPTIMAL SIX SIGMA QUALITY

HEOR Focus: impact of individual risk categorization and 10-year CVD score. Samples bootstrapped from [historical database] cohort with 100,000 iterations. Model followed a lifetime horizon and a health system perspective.

Tests included:

- LDL
- HDL
- total cholesterol

Variables studied:

- Minimum (low Sigma) test performance
- Optimum (high Sigma) test performance

Outcomes assessed:

- Costs of patient care
- Over- and under-treatment of patient
- Quality-adjusted life-years (QALY) of patient

HOW SIX SIGMA METHODS IMPACT QC AND PATIENT OUTCOMES

Discordant Treatment Impact:

For each percentage increase in…

+1% Imprecision = + 22 / 1,000 patients over/under-treated

-1% Negative bias = + 43 / 1,000 patients undertreated

+1% Positive bias = + 22 / 1,000 patients overtreated

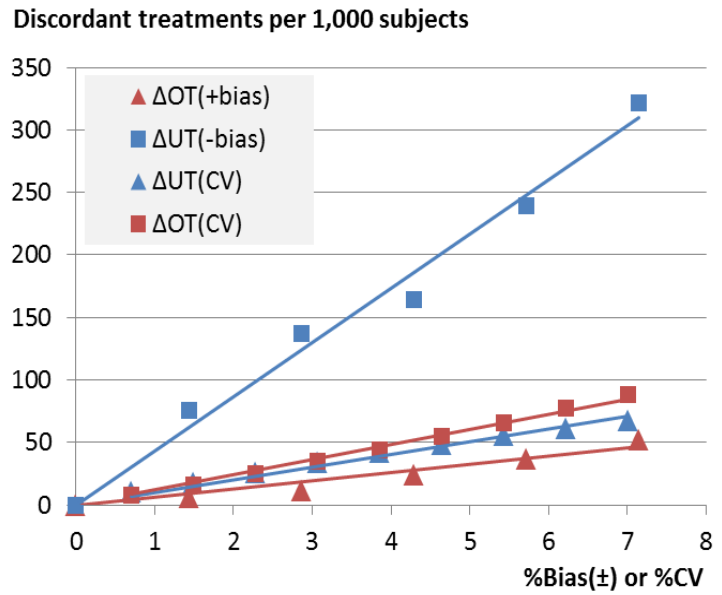
Cost Impact:

For each percentage increase in…

-1% Negative bias = NT$786 (96%CI 734;838),

+1% Negative bias = NT$762 (612;912)

+1% Imprecision = NT$699 (668;729)



HOW SIX SIGMA METHODS IMPACT QC AND PATIENT OUTCOMES

Impact of both CV and Bias on Discordant Management:

Minimum (low Sigma) causes 14.1% of patients to incur discordant health management

Optimum (high Sigma) causes 4.1% of patients to incur discordant health management

LOSS OF LIFE YEARS PER 1,000 PATIENTS:

Minimum (low Sigma) causes 131 Life Years Loss

Optimum (high Sigma) causes no statistically significant loss of life versus perfect scenario.

CVD LIFETIME COSTS PER PATIENT:

MIN (+NT$ 8,753) vs. OPT (+NT$ 2,075).

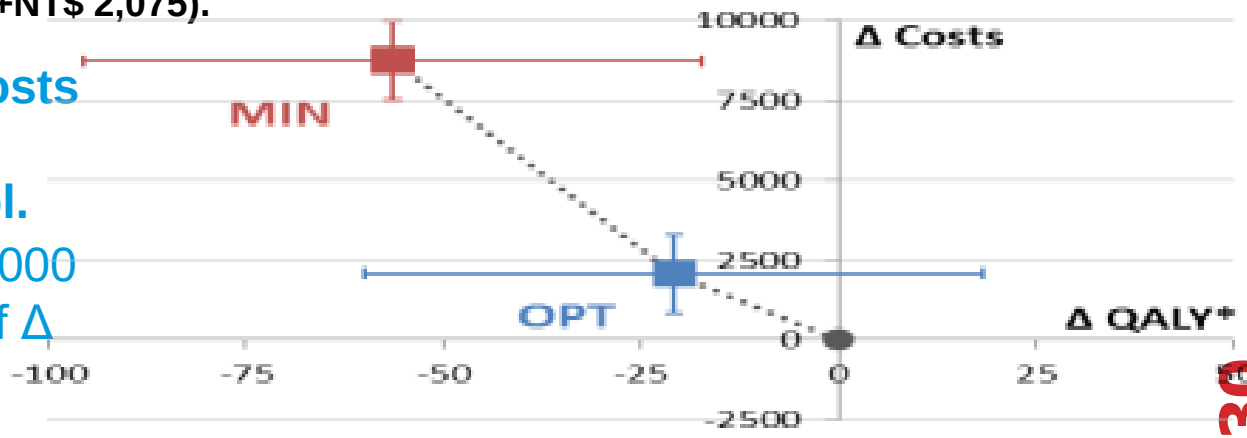


Figure 2. Incremental costs and QALY per strategy compared to the Control. Microsimulation with 100,000 samples. Mean, 95%CI of Δ Costs per patient, and Δ QALY per 1,000 subjects.

CONCLUSION

QC must evolve with the laboratory and the instruments

Six Sigma tools allow the laboratory to

- **Identify the RIGHT method**
- **Select the RIGHT rules**
- **Run the RIGHT number of controls**
- ***(NEW! Run controls at the RIGHT frequency!)***
- **Most importantly, enable the RIGHT patient outcomes**

ENTER YOUR VIEWS IN OUR POC QC SURVEY ON JAMES.WESTGARD.COM

QUESTIONS?

STEN@WESTGARD.COM