

EQA Interpretation – Case Studies

WeQas Annual Conference

Samantha Jones

WeQas

Unit 6, Parc Tŷ Glas

Llanishen

Cardiff

Summary of Talk

- ❖ Problem solving checklist
- ❖ Audience participation
- ❖ Case Study answers and discussion

Problem Solving checklist

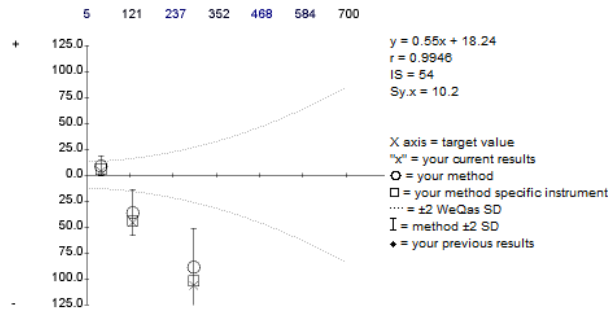
Analyte	SDI Score	Precision $r, S_{y.x}$	Accuracy $m, c,$	Previous dist.	Identify error	Possible Cause

Case Study 1 (Blood Gas)

Scheme: Blood Gas. Distribution Code: P227.				
Distribution Date: 20/01/14. Final Report Issued: 11/02/14				
Creatinine (µmol/L)	1	2	3	Analyte SDI
Reported Result	182	81	48	
Method Corrected Result	182.0	81.0	48.0	
Method A	Mean	200.0	91.0	53.0
	SD	19.4	11.4	5.1
	Number	3	3	3
Instrument A	Mean	11.22	6.60	2.94
	SD	186.5	83.0	49.5
	Number	2	2	2
Overall	Mean	3.18	1.41	1.06
	SD	4.5	2.0	1.5
	Number	2	2	2
Reference Values	Mean	292.4	129.0	44.2
	SD	16.1	7.9	4.4
	Number	58	106	61
Reference Values	Mean	2.11	0.77	0.56
	SD			
	Uncert.			
Ref. Value Uncertainty				
Non-scoring Reference Values				
WeQas SD		13.9	8.3	6.9
SDI		** -7.96	** -5.77	0.55
				** 4.76

Please note: Linear regression uses CF corrected data.

This Distribution P227



Precision

This Distribution P227	Previous Distributions	P226	P225	P224	P223	P222	P221
Sy.x = 10.2 µmol/L	Sy.x		17.9	24.9	24.7		6.3
IS = 54	IS	0	24	66	87	0	5

Sy.x is the average deviation from the best fit line and is an index of scatter.

Accuracy

This Distribution P227	Previous Distributions	P226	P225	P224	P223	P222	P221
Systematic proportional error (calibration) -44.97%	Proportional (%)		-22.45	-7.46	-36.00		15.33
Systematic constant error (blank) 18.2 µmol/L	Constant (µmol/L)	0.0	0.5	7.5	10.6	0.0	-28.4

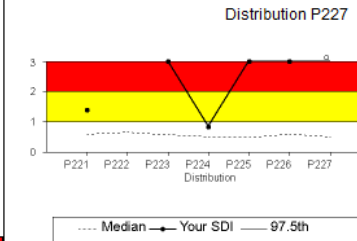
Bias includes components of proportional and constant errors. A proportional bias suggests an error of calibration whilst a constant bias suggests a blank error. Mixed errors will include significant components of both.

Total Error

SDI is a measurement of your total error and will include both inaccuracy and imprecision.

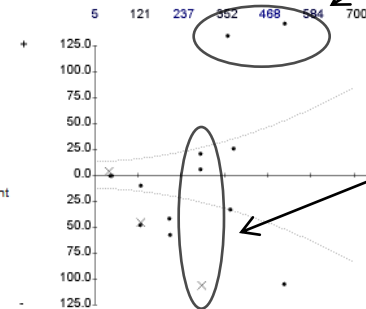
This Distribution P227
Your average analyte SDI for the 3 samples is 4.76

Previous SDI



Distribution P226

Previous Distributions



Same pool distributed 3 times

Case Study 1 - answer

- **Analyte:** Creatinine
- **SDI Score:** 4.76 (sample 3 SDI 0.55)
- **Precision:** Acceptable (IS 54, r value 0.9946)
- **Accuracy:** Systematic negative proportional error of 45% (0.55x), constant error of 18.24 $\mu\text{mol/L}$
- **Previous Dist / comments:** P221 SDI <2, P224 SDI <1, several non returns, constant poor SDI from P225. Inter assay precision poor. Negative bias to method mean, compares well with instrument mean (n=2). N<8 in method group, SDI calculated from overall mean value.
- **Error Identification:** Predominant negative proportional bias to the overall mean (with fliers at P226). Also shows poor between batch assay precision.
- **Possible Cause:** Participant investigated reagent lot to lot variation causing imprecision error – no confirmation of this to Weqas. Could potentially be user error / inexperienced operator.

Reported Results for all sections with Method Means and SDs

Distribution: P227
Distribution Date: 20 Jan, 2014
Analyte: Creatinine ($\mu\text{mol/L}$)
Method: [Redacted]

Distribution Code : P227		Sent on: 20/01/14		
Creatinine ($\mu\text{mol/L}$)		1	2	3
		191	85	51
		182	81	48
		227	107	60
Overall	Mean	292.4	129.0	44.2
	SD	16.1	7.9	4.4
	CV	5.50	6.13	9.90
	Number	58	106	61
	Reference Value			
	Reference Value NS			
Nova	Mean	200.0	91.0	53.0
	SD	19.4	11.4	5.1
	CV	9.72	12.56	9.62
	Number	3	3	3

Key: Red - Outside Range. * - Method Outlier

Same lab, 3 sites
using manufacturer A
meters

Reported Results for all sections with Instrument Means and SDs

Distribution: P227
Distribution Date: 20 Jan, 2014
Analyte: Creatinine ($\mu\text{mol/L}$)
Method: [Redacted]
Instrument: [Redacted]

Distribution Code : P227		Sent on: 20/01/14		
Creatinine ($\mu\text{mol/L}$)		1	2	3
		191	85	51
		182	81	48
Overall	Mean	292.4	129.0	44.2
	SD	16.1	7.9	4.4
	CV	5.50	6.13	9.90
	Number	58	106	61
	Reference Value			
	Reference Value NS			
Instrument Specific Data				
Nova	Mean	186.5	83.0	49.5
	SD	4.5	2.0	1.5
	CV	2.41	2.41	3.03
	Number	2	2	2

Key: Red - Outside Range. * - Instrument Outlier

Same lab, 2 sites
using same meter

Scheme: Blood Gas. Distribution Code: P233.				
Distribution Date: 14/07/14. Final Report Issued: 6/08/14				
Creatinine (µmol/L)	1	2	3	Analyte SDI
Reported Result	336	445	92	
Method Corrected Result	336.0	445.0	92.0	
Method A	Mean	360.0	439.8	135.7
	SD	64.9	39.7	32.4
	Number	6	5	6
	Uncert.	26.50	17.74	13.24
Instrument A	Mean	348.0	457.3	124.8
	SD	34.4	21.1	21.9
	Number	4	4	4
	Uncert.	17.19	10.54	10.95
Overall	Mean	282.8	357.1	124.1
	SD	19.2	13.6	7.5
	Number	77	125	74
	Uncert.	2.19	1.22	0.87
Reference Values				
Ref. Value Uncertainty				
Non-scoring Reference Values				
WeQas SD	13.4	17.1	8.2	
SDI	** 3.96	** 5.14	** -3.91	** 4.34

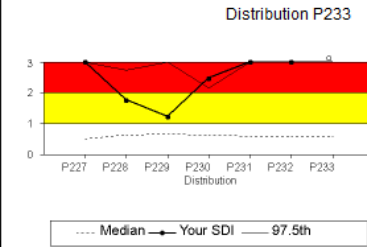
Please note: Linear regression uses CF corrected data.

Total Error

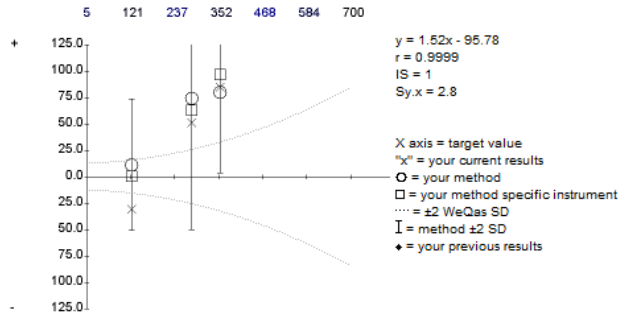
SDI is a measurement of your total error and will include both inaccuracy and imprecision.

This Distribution P233	
Your average analyte SDI for the 3 samples is 4.34	

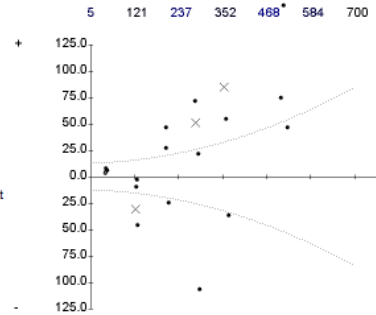
Previous SDI



This Distribution P233



Previous Distributions



Follow up: P228 and P229 good scores, P230 onwards worsening scores.

Reported Results for all sections with Method Means and SDs

Distribution: P233
 Distribution Date: 14 Jul, 2014
 Analyte: Creatinine (µmol/L)
 Metho: [redacted]

Distribution Code : P233 Sent on: 14/07/14			
Creatinine (µmol/L)	1	2	3
	406	432	150
	336	445	92
	334	488	138
	481	630	196
	316	464	119
	287	370	119
Overall	Mean	282.8	357.1 124.1
	SD	19.2	13.6 7.5
	CV	6.79	3.81 6.05
	Number	77	125 74
	Reference Value		
	Reference Value NS		
Nova	Mean	360.0	439.8 135.7
	SD	64.9	39.7 32.4
	CV	18.03	9.02 23.91
	Number	6	5 6
Key: Red - Outside Range. * - Method Outlier			

Further poor performance letter may follow. Manufacturer would be informed of wide variation within the group.

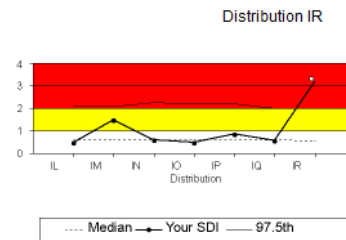
Case Study 2 (Mainline)

Potassium (mmol/l)		1	2	3	4	Analyte SDI
Reported Result		6.4	2.6	4.0	5.9	
Method Corrected Result		6.40	2.60	4.00	5.90	
Indirect ISE	Mean	2.59	4.00	6.48	5.97	
	SD	0.07	0.06	0.11	0.08	
	Number	298	299	296	279	
	Uncert.	0.004	0.004	0.007	0.005	
Instrument B	Mean	2.61	3.99	6.42	5.93	
	SD	0.06	0.06	0.09	0.06	
	Number	21	21	21	21	
	Uncert.	0.013	0.013	0.020	0.014	
Overall	Mean	2.59	4.00	6.45	5.97	
	SD	0.07	0.07	0.12	0.10	
	Number	379	378	375	377	
	Uncert.	0.004	0.003	0.006	0.005	
Reference Values		2.58	3.94	6.34	5.85	
Ref. Value Uncertainty						
Non-scoring Reference Values						
WeQas SD		0.07	0.07	0.13	0.11	
SDI		** 4.00	** -4.00	** -4.00	-0.65	** 3.16

SDI is a measurement of your total error and will include both inaccuracy and imprecision.

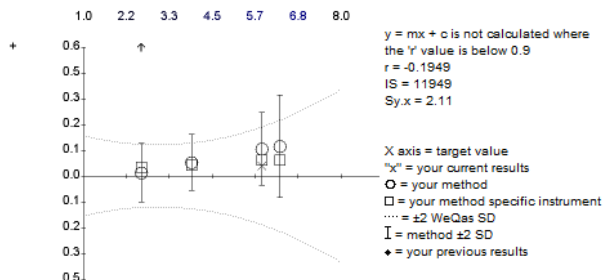
This Distribution IR
Your average analyte SDI for the 4 samples is 3.16

Previous SDI

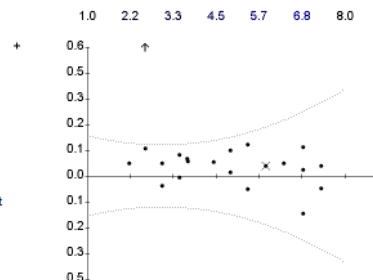


Please note: Linear regression uses CF corrected data.

This Distribution IR



Previous Distributions



Precision

This Distribution IR	Previous Distributions	IQ	IP	IO	IN	IM	IL
$Sy.x = 2.11$ mmol/l	Sy.x	0.06	0.04	0.01	0.04	0.04	0.02
$IS = 11949$	IS	3	1	0	1	2	0

$Sy.x$ is the average deviation from the best fit line and is an index of scatter.

Accuracy

Double click to edit this text

This Distribution IR	Previous Distributions	IQ	IP	IO	IN	IM	IL
Systematic proportional error (calibration) -119.61%	Proportional (%)	-0.06	-0.59	-0.50	-0.08	-6.17	1.64
Systematic constant error (blank) 5.64 mmol/l	Constant (mmol/l)	0.07	0.00	0.08	0.07	0.25	0.02

Bias includes components of proportional and constant errors. A proportional bias suggests an error of calibration whilst a constant bias suggests a blank error. Mixed errors will include significant components of both.

Case Study 2 - answer

- **Analyte:** Creatinine
- **SDI Score:** Unacceptable, overall SDI 3.16, (All except sample 4 SDI scores are >4 SDI)
- **Precision:** linear regression not calculated as r value is <0.9. IS = 11,949
- **Previous Dist / comments:** Cumulative graph and precision / accuracy tables show good previous performance. Results vastly different to the method mean (n=298), instrument mean (n=21) and overall mean.
- **Error Identification:** One off error at this distribution – results look as if they have been mixed up for samples 1, 2 and 3.
- **Possible Cause:** Pre / Post analytical error by the laboratory.

Case Study 3 (Mainline)

Scheme: Mainline Chemistry, Distribution Code: PZ Distribution Date: 2/03/15, Final Report Issued: 27/03/15						
Lactate dehydrogenase (IU/l)	1	2	3	4	Analyte SDI	
Reported Result	102	291	140	252		
Method Corrected Result	102.0	291.0	140.0	252.0		
L→P (IFCC)	Mean	117.5	305.0	146.8	264.7	
	SD	4.0	9.1	5.0	8.3	
	Number	17	18	18	18	
	Uncert.	0.97	2.15	1.17	1.95	
Instrument C	Mean	102.0	291.0	140.0	252.0	
	SD	0.0	0.0	0.0	0.0	
	Number	1	1	1	1	
	Uncert.	0.00	0.00	0.00	0.00	
Overall	Mean	118.4	311.1	150.2	272.2	
	SD	5.3	12.6	7.0	12.2	
	Number	138	137	134	136	
	Uncert.	0.45	1.08	0.60	1.05	
Reference Values UV / Vis Spec	125.8	329.0	161.6	287.7		
Ref. Value Uncertainty	1.73	4.53	2.22	3.96		
Non-scoring Reference Values						
WeGas SD	7.1	18.7	9.0	16.3		
SDI	** -3.35	** -2.04	** -2.40	** -2.19	** 2.49	

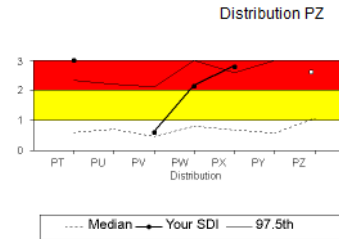
Please note: Linear regression uses CF corrected data.

Total Error

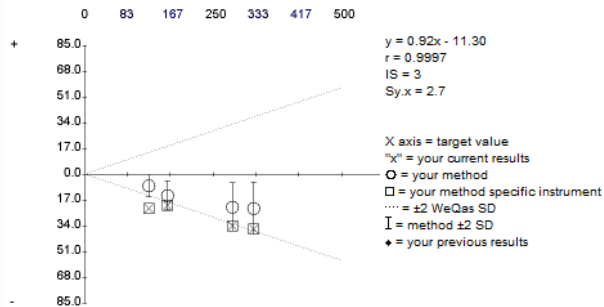
SDI is a measurement of your total error and will include both inaccuracy and imprecision.

This Distribution PZ
Your average analyte SDI for the 4 samples is 2.49

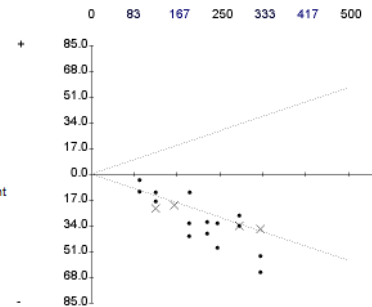
Previous SDI



This Distribution PZ



Previous Distributions



Precision

This Distribution PZ	Previous Distributions	PY	PX	PW	PV	PU	PT
Sy.x = 2.7 IU/l	Sy.x		5.3	8.2	1.7	4.5	
IS = 3	IS	0	20	49	1	0	12

Sy.x is the average deviation from the best fit line and is an index of scatter.

Accuracy

This Distribution PZ	Previous Distributions	PY	PX	PW	PV	PU	PT
Systematic proportional error (calibration) -8.17%	Proportional (%)		-18.25	-16.64	-6.20		-23.46
Systematic constant error (blank) - 11.3 IU/l	Constant (IU/l)	0.0	4.5	6.5	0.6	0.0	6.8

Bias includes components of proportional and constant errors. A proportional bias suggests an error of calibration whilst a constant bias suggests a blank error. Mixed errors will include significant components of both.

Case Study 3 - answer

- **Analyte:** LDH
- **SDI Score:** Unacceptable, overall SDI 2.49, (All 4 SDI scores are >2 SDI)
- **Precision:** Good (IS 3, r value 0.9997)
- **Accuracy:** Linear regression shows 8% negative proportional bias and 11.3 IU/L constant negative bias.
- **Previous Dist / comments:** Previous SDI graph shows SDI >3 at Dist PT, no return, Dist PV shows good score (although still 6% bias) then increasing SDI scores from that point. Negative bias compared to Method mean, Overall mean and Reference values. Previous distribution graph shows long standing negative bias.
- **Error Identification:** Mixed error, components of both proportional and constant errors. Long standing negative proportional bias can be seen on accuracy table.
- **Possible Cause:** Check calibrators including zero, check reagent on board stability, check lamp.

Case Study 3 – follow up

- Kit on board stability checked – no issues.
- Reagent lots checked – no issues.
- IQC performance reviewed – no pattern linked to poor performance. Shift seen in IQC a few months before poor performance letter issued but did not coincide with change in kit lot number or poor EQA scores.
- Poor SDI scores do not coincide with kit changes or instrument maintenance.
- Lamp changed – no improvement seen
- Engagement with manufacturer ongoing.