Clinical Chemistry

E. Fung, B.Y. Chan, C. H. Lam, K. F. Li, K.H. Lo, J. Yuen, W. Cheung

The Hong Kong Medical Technology Association Quality Assurance Program (HKMTA-QAP) in Clinical Chemistry has completed her eighth and ninth year's surveys. Four samples were delivered to each participating laboratory over a quarterly period in March, May, August and October in both 1997 and 1998. The sub-committee has decided to make a biannual (1997-1998) report.

Table 1 shows the types of laboratories participating in the Clinical Chemistry QAP in the years of 1997 and 1998 respectively.

Laboratories	Participants in 1997		Participants in 1998	
	Number	%	Number	%
Hospital Authority	22	34.4	19	31.1
Government Institutes/Clinics	4	6.3	4	6.6
University Laboratories	2	3.1	2	3.3
Private Laboratories	26	40.6	26	42.6
Private Hospitals	10	15.6	10	16.4
Total	64	100.0	61	100.0

Table 1. Outlook of Clinical Chemistry Participants in 1997 and 1998.

The total number of participants dropped from 64 in 1997 to 61 in 1998. This is probably a result of restructuring policy in Hospital Authority hospitals. However, the number of the other laboratories in the year 1998 from the rest of the sectors remained the same as in 1997.

Table 2 shows a list of the number of participants for various analytes in one cycle. There was a reduction in the number of participants and it was probably due to consolidation of instrumentation and re-organization of benches in some cases. However, the number of participants was increased in some enzymes.

Table 2. Number of Participants for various analytes in one cycle

Chemistries	Number		Enzymes	Number	
	1997	1998		1997	1998
Albumin	*69*	*65*	*ALT(Alanine aminotransferase)*	*69*	*67*
Bilirubin	*68*	*65*	*AST(Aspartate aminotransferase)*	*62*	*63*
Calcium	*60*	*62*	*ALP (Alkaline phosphatase)*	*68*	*65*
Chloride	*51*	*51*	*Amylase (Group A)*	*8*	*12*
Cholesterol	*66*	*61*	*Amylase (Group B)*	*43*	*41*
Creatinine	*69*	*66*	*CK (Creatine kinase)*	*54*	*59*
Glucose	*68*	*65*	*GGT (γ-glutamyltransferase)*	*53*	*57*
HDL Cholesterol	*47*	*49*	*LDH-L (Lactate dehydrogenase)*	*28*	*30*
Phosphate	*59*	*60*	*LDH-P (Lactate dehydrogenase)*	*23*	*25*
Potassium	*65*	*63*			
Sodium	*65*	*63*			
Total Protein	*69*	*65*			
Urea	*71*	*66*			
Urate	*63*	*59*			
Triglycerides	*63*	*60*			
Thyroxine	*27*	*28*			

Table 3. Various Instruments used in one cycle for Urea.

Instrument Model	Number of Laboratories
Abbott VP	*1*
Technicon RA 500/1000/XT	*5*
Other Technicon instruments	*1*
Beckman CX4/CX5	*2*
Abbott Spectrum	*5*
BM Hitachi 747	*7*
Other BM instruments	*1*
Dupont Dimension	*8*
Cobas Mira	*9*
IL Monarch	*1*
Kodak Ektachem E250	*5*
Kodak Ektachem DT6011	*3*
Other Kodak Instruments	*2*
Johnson & Johnson Vitros 750	*2*
Cobas Fara	*1*
Beckman CX3	*1*
Cobas Integra	*2*
Beckman CX7	3
Manual Method	*1*

How to Read Your Survey Report

From our example in Figure 1, you find a heading of the time of the report (i.e. Survey Report –IV- 1998). You also find your Lab code and sample code. More importantly, you need to identify your instrument, reagent and reference range of the analyte enrolled. A number of criteria are tabulated for All Method RCPA-QAP and All Method HKMTA-QAP under the items of Number of labs, all method mean, SD, Range (Min., Max). Your Value, and Your SDI. With the help of the chart on the upper portion of the report, you can easily locate your value on the chart. In this case, your value 20.70 means you are working very closely to the mean 21.97. Your SDI is computed based on the following formula :

SDI = (Your Result – Group Mean Result)/ Group SD
In this survey, your SDI (RCPA-QAP)= -0.97; SDI(HKMTA-QAP) = -1.09;
SDI (Your Group)= -1.08.

SDI is, therefore, the ratio of the difference between your result and the mean value to the standard deviation of the respective method.

Any test performance with "SDI out of 2SD range" will be alerted to individual participating laboratories in our Survey Report Summary for their attention of any inconsistencies in their assays.

An overall performance Index (OPI) is used to indicate the changes in the performance of individual laboratories with time. OPI is the mean absolute value of the SDI computed for each result. The nearer the OPI value to zero, the better will be the performance of the laboratory to her group mean.

Table 4. Individual Test Performance in coefficient of variation (CV%) of all method mean for the years 1997 and 1998 in comparison with the coefficient of variation (CV%) of all method mean of RCPA-QAP for general chemistries and enzymes.

Analyte	Specimen # CC 704 (1997)					Specimen # CC804 (1998)				
	No. lab	Mean Value	SD	Our CV%	RCPA CV%	No. lab	Mean Value	SD	Our CV%	RCPA CV%
Albumin (All Method)	69	30.60	2.22	6.8	5.1	65	49.88	3.14	6.3	4.7
BCG	51	33.14	2.09	6.3		48	49.90	3.78	7.6	
BCP	16	30.75	1.69	5.5		15	49.07	1.91	3.9	
Others	2	33.50				3	50.00	3.00	6.0	
Bilirubin (All Method)	68	39.68	4.46	11.2	9.4	65	96.63	13.30	13.8	8.2
Evelyn- Malloy	10	39.5	3.63	8.5		9	91.33	10.59	11.6	
Jendrassik-Grof	16	43.44	3.01	6.9		14	110.36	8.04	7.3	
Diazo salt/DPD	35	38.2	4.16	10.9		35	92.03	10.71	11.6	
Others	7	38.71	5.50	14.2		7	99.00	18.28	18.5	
Calcium (All Method)`	60	2.06	0.10	4.9	3.9	62	3.20	0.13	4.1	2.8
CPC	28	2.08	0.07	3.4		25	3.27	0.07	2.1	

Analyte	Specimen # CC 704 (1997)					Specimen # CC804 (1998)				
	No. lab	Mean Value	SD	Our CV%	RCPA CV%	No. lab	Mean Value	SD	Our CV%	RCPA CV%
Arsenazo dye	28	2.03	0.13	6.4		29	3.14	0.11	3.5	
Methylthymol Blue	1	2.18				1	3.30			
Alizarin	0					0				
Others	4	2.23	0.17	7.6		6	3.23	0.17	5.3	
Chloride (All Method)	51	87.96	2.9	3.3	2.5	51	108.84	3.68	3.4	2.9
Murcuric thiocyanate	6	87.5	4.81	5.5		4	110.00	2.45	2.2	
ISE	40	88.25	2.69	3.0		42	109.38	3.22	2.9	
Coulometry	2	85.5				1	106.00			
Others	4	90.00	6.73	7.5		4	102.75	4.57	4.4	
Cholesterol (All Method)	66	3.92	0.25	6.4		61	7.06	0.39	5.5	4.9
CHOD-PAP	54	3.92	0.26	6.6		48	7.08	0.38	5.4	
Others	12	3.90	0.26	6.7		12	6.99	0.43	6.2	
Creatinine (All Method)	69	165.49	10.28	6.2	5.0	66	404.14	46.63	11.5	7.5
Alkaline picrate/End point	13	172.15	11.75	6.8		12	361.83	114.38	31.6	
Alkaline picrate/kinetic	46	163.33	10.29	6.5		42	395.93	40.09	10.1	
Others	11	170.09	9.28	5.5		13	442.15	37.33	8.4	
Glucose (All Method)	68	8.51	0.32	3.8	4.3	65	20.09	0.67	3.3	4.0
Hexokinase	46	8.52	0.31	3.6		42	20.12	0.61	3.0	
Glucose oxidase	18	8.48	0.38	4.5		19	20.23	0.70	3.5	
Oxygen rate	2	8.65				1	18.30			
Others	2	8.40				3	19.47	0.35	1.8	
Phosphate (All Method)	59	1.18	0.09	7.6	6.0	60	2.42	0.14	5.9	4.6
Molybdenum Blue	5	1.24	0.06	4.8		7	2.50	0.14	5.6	
Phosphomolybdate/UV	49	1.17	0.08	6.8		46	2.41	0.13	5.4	
Others	5	1.15	0.21	18.3		7	2.40	0.18	7.5	
Potassium (All Method)	65	3.26	0.11	3.4	2.5	63	5.88	0.16	2.7	2.5
Direct ISE	37	3.27	0.13	4.0		36	5.86	0.21	3.6	
Indirect ISE	26	3.25	0.09	2.8		25	5.90	0.08	1.4	
Flame photometry	0									
Others	3	3.24	0.05	1.5		3	5.75	0.09	1.6	
Protein, Total (All Method)	69	60.28	2.18	3.6	2.9	65	83.23	2.82	3.4	3.3
Biuret/No Blank	40	60.03	2.02	3.4		33	82.36	2.93	3.6	
Biuret/With Blank	26	60.67	2.46	4.1		27	84.41	1.74	2.1	
Others	3	60.33	1.53	2.5		5	82.60	4.77	5.8	
Sodium (All Method)	65	125.35	1.85	1.5	1.4	63	160.35	3.08	1.9	1.6
Direct ISE	36	125.44	2.08	1.7		36	161.78	3.80	2.3	
Indirect ISE	26	125.31	1.52	1.2		25	158.72	1.34	0.8	
Flame photometry	0					0				
Others	3	124.67	2.08	1.7		3	160.33	2.52	1.6	

Analyte	Specimen # CC 704 (1997)					Specimen # CC804 (1998)				
	No. lab	Mean Value	SD	Our CV%	RCPA CV%	No. lab	Mean Value	SD	Our CV%	RCPA CV%
Triglycerides (All Method)	63	1.23	0.13	10.6		60	2.91	0.36	12.4	10.2
Enzymatic/No glycerol blank	58	1.24	0.13	10.5		51	2.89	0.34	11.8	
Enzymatic/glycerol blank	4	1.14	0.19	16.7		8	2.83	0.75	26.5	
Others	2	1.01				3	2.28	1.26	55.3	
Urea (All Method)	71	8.04	0.57	7.1	7.3	66	21.97	1.17	5.3	5.9
Diacetylmonoxime	1	8.30				1	19.50			
Urease	63	7.99	0.59	7.4		59	21.99	1.19	5.4	
Conductimetric	5	8.28	0.16	1.9		4	22.43	0.10	0.45	
Others	2	8.72				3	23.68	3.15	13.3	
Urate (All Method)	63	0.33	0.02	6.1	6.1	59	0.68	0.07	10.3	7.6
Phosphotungstate	0					0				
Uricase	62	0.33	0.02	6.1		55	0.68	0.06	8.8	
Others	2	0.39				4	0.67	0.16	23.9	
HDL Cholesterol (All Method)	47	1.00	0.22	22.0		49	1.85	0.68	36.8	25.2
PTA/Magnesium (All Method)	15	1.06	0.24	22.6		12	2.62	0.88	33.6	
PEG	5	1.01	0.30	29.7		2	0.94			
Dextran sulphate/Magnesium	13	0.98	0.15	15.3		14	1.97	0.32	16.2	
Heparin/Manganese	0					0				
Others	14	0.97	0.23	23.7		22	1.55	0.59	38.1	
T4 (All Method)	27	107.81	9.78	9.1	8.4	28	204.29	23.97	11.7	12.5
RIA	0					0				
EIA/ELISA	6	104.17	12.61	12.1		6	214.17	29.85	13.9	
FPIA	15	107.87	8.42	7.8		12	210.17	8.74	4.2	
ICMA	1	117.00				2	199.00			
Others	5	110.20	11.26	10.2		7	196.00	28.56	14.6	
ALT (All Method)	69	53.97	7.05	13.1	11.2	67	158.6	9.73	6.1	6.8
Pyruvate/NADH	43	51.98	6.14	11.8		44	159.57	10.55	6.6	
Pyruvate/NADH/P5P	23	58.43	6.49	11.1		19	158.16	6.92	4.4	
Others	3	48.33	8.62	17.8		4	150.00	9.42	6.3	
ALP (All Method)	68	241.18	29.12	12.1	12.4	65	601.8	102.16	16.9	15.0
PNPP/AMP	59	239.05	29.02	12.1		57	604.82	105.39	17.4	
PNPP/DEA	5	265.20	15.16	5.7		2	668.00			
PNPP/HCO3	0					0				
Others	4	242.50	36.02	14.9		6	551.00	62.42		
Amylase-Group A (All Method)	8	305.25	81.99	26.8	7.8	12	718.00	219.68	30.6	10.9
Blocked 4-NP-maltoheptaoside	4	337.25	80.83	23.9		6	877.33	181.26	20.7	
2-chloro-4-NP-maltotrioside	2	261.00				3	585.67	146.65	25.0	
2-chloro-4-NP-maltoheptaoside	1	209.00				2	543.00			
Others	1	362.00				1	509.00			
Amylase-Group B (All Method)	43	175.88	34.24	19.5	7.8	41	435.17	93.91	21.6	10.9
Blocked 4-NP-maltoheptaoside	15	162.47	25.19	15.5		15	426.47	46.36	10.9	
2-chloro-4-NP-maltotrioside	7	172.57	8.68	5.0		7	402.86	23.42	5.8	

Analyte	Specimen # CC 704 (1997)					Specimen # CC804 (1998)				
	No. lab	Mean Value	SD	Our CV%	RCPA CV%	No. lab	Mean Value	SD	Our CV%	RCPA CV%
Maltotetraose	6	242.88	8.11	3.3		6	634.00	8.90	1.4	
Dyed amylopectin	13	165.15	21.17	12.8		8	358.50	24.45	7.1	
Others	2	157.00				4	368.75	27.83	7.5	
AST (All Method)	62	109.94	8.13	7.4	8.2	63	347.52	36.01	10.4	9.3
Oxaloacetate/NADH	39	107.13	7.67	7.2		39	335.26	31.26	9.3	
Oxaloacetate/NADH/P5P	18	114.67	6.51	5.7		17	364.82	34.67	9.5	
Others	5	114.80	7.82	6.8		7	373.86	37	9.9	
CK (All Method)	54	228.76	17.07	7.5	7.2	59	618.10	67.65	10.9	12.9
Hexokinase/G6PD	21	230.33	16.04	7.0		20	650.95	39.73	6.1	
Hexokinase/G6PD/NAC	21	228.67	16.65	7.3		28	628.27	54.27	8.6	
Others	12	226.17	20.52	9.1		10	540.60	67.15	12.4	
LDH-L (All Method)	28	248.39	20.39	8.2	6.9	30	532.97	52.65	9.9	6.9
Lactate/NAD	27	246.85	19.04	7.7		29	533.62	53.46	10.0	
Others	1	290.00				1	514.00			
LDH-P (All Method)	23	731.61	143.34	18.8	19.1	25	1587.76	254.48	16.0	12.4
Pyruvate/NAD	22	752.77	140.16	18.6		24	1582.42	258.52	16.3	
Others	1	956.00				1	1716.00			
GGT (All Method)	53	64.87	10.94	16.9	13.5	57	204.26	47.41	23.2	19.5
GG-p-nitroanilide	21	67.43	9.88	14.7		23	219.17	53.69	24.5	
GG-3-carboxy-nitroanilide	27	61.70	11.01	17.8		27	185.22	32.30	17.4	
Others	5	71.20	11.32	15.9		7	228.71	52.03	22.7	

General chemistries

Table 4 lists the individual test performance of HKMTA-QAP in the Survey CC704 and CC804 in comparison with that of RCPA-QAP. The overall performance of Survey CC704 for general chemistries was satisfactory. The performance of glucose, urea and urate was “as good as” RCPA performance. The performance of albumin and total protein in the Survey CC804 was satisfactorily improved as compared with that of CC704. This was probably due to the use of human-based protein calibrators and unique standardization of standards.

There was obviously an improvement in the performance of calcium and phosphate in Survey CC804 in comparing with that of CC704. It was probably due to the tendency of the other users in changing their existing methodology to the other for some reasons.

Fortunately, bilirubin performed satisfactorily as it was not well expected. Poor CV was probably due to the improper storage and inaccurate standardization of calibrators. Under CC704 survey, bilirubin has obtained a better correlation with the “peers”, whereas the CV is slightly elevated due to imprecision in some individual methods.

HDL-cholesterol has been introduced to this program since 1996. It seems to us that the performance of this analyte has not

been improved since then. The reasons are probably due to discrepancies in pre-treatment of specimen before assaying and matrix effect of lyopholised material. Therefore, special attention should be paid to techniques in specimen treatment procedures. Calibrators referenced to CCRF (Canadian Cholesterol Reference Foundation) or CDC (Center for Disease Control) are strongly recommended.

Enzymes

It is difficult to obtain accuracy in enzyme measurement. It is simply due to unavailability of referenced enzyme materials and the measurement by enzyme activity over time. These two factors, if remained, give poor accuracy and precision to enzyme performance.

Table 4 also lists individual enzyme performance of HKMTA-QAP Surveys CC704 and CC804 in comparison with RCPA-QAP. ALT, ALP, AST, CK, and LDH-L are reasonably good performers as compared with their "peers". ALP and AST under the Survey CC704 together with ALT and CK under the Survey CC804 perform as good as their peers.

LDH-P, GGT and amylase are poor performers with unreasonably high CV as compared with their peers.

The diversity of amylase results seems to be due to the sources of reagents. From the reference values quoted by the participants, we could identify two groups of laboratories, one with the upper reference limits around 100 IU/L and the other with the upper limits around 200 IU/L. We found that laboratories quoting higher reference values were using reagents from European countries while those giving lower values were using reagents from the United States. We felt that it was meaningless to treat the two groups as one, as the mean value would be unattainable by both groups. We did not know which results were more correct or which reagents were better, as there was no recommendation from IFCC. However, in order to provide a more meaningful statistical report, we felt that it was necessary to divide the participants into two groups, and calculate the statistical values separately. Nevertheless, in the last two years' survey, we found that the dispersion of amylase results was still quite wide.

As a matter of fact, the doctors should be properly informed of the instrumentation and methodology used for such enzyme assays with specific attention to the reference values used for patient care and diagnosis.

Conclusion

Quality assurance program is a quality tool for monitoring continuous quality improvement in laboratory performance. The Hong Kong Medical Technology Association Quality Assurance Program (HKMTA-QAP) serves this purpose for local laboratories to share their excellence with their peers in the community. Unfortunately, the small population size of participating laboratories is a limitation in providing "realistic" figures for actual situation in quality performance. With the Australian RCPA-QAP, local subscribers can correlate their results with their peers from the other part of the world.

To conclude, quality assessment should be a continuous improvement program for achieving the ultimate goal in total quality management of laboratory performance.

Reference

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Figure 1 shows an example of the 1998 survey report

HONG KONG MEDICAL TECHNOLOGY ASSOCIATION
Quality Assurance Programme

Clinical Chemistry
Survey Report (IV-1998)

Lab code: XXX
Sample code: CC804

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UREA

	No.	TARGET (RCPA)	ALL METHOD 2 SD (HKMTAQAP)	YOUR METHOD 2 SD	YOURS	FREQUENCY BY TEST METHOD
mmol/L						
> 25.48	1					O
25.48	1					B
24.90	1					B
24.31	1					B
23.73	0					
23.14	10					BBBBBBBBBB
22.56	17					BBBBBBBBBBBBBCCCC
21.97	10	22.20				BBBBBBBBBO
21.39	10					BBBBBBBBBO
20.80	11				*	BBBBBBBBBB
20.22	2					BB
19.63	3					ABB
19.05	0					
18.46	0					
< 18.46	1					B
CLINICAL ASSESSMENT						
LOW	0					
NORMAL	0					
BORDERLINE	0					
ELEVATED	60				*	

METHODS	No.	MEAN	SD	MIN.	MAX.	YOUR VALUE	YOUR SDI
ALL METHODS (RCPA-QAP)	390	21.95	1.29			20.70	-0.97
ALL METHODS (HKMTAQAP)	66	21.97	1.17	15.98	27.29	20.70	-1.09
A = Diacetylmonoxime	1	19.50		19.50	19.50		
B = Urease	59	21.99	1.19	15.98	25.30	20.70	-1.08
C = Conductimetric	4	22.43	0.10	22.30	22.50		
O = Others	3	23.68	3.15	21.50	27.29		

Your instrument: (0601) Dimension
Your reagent: (10) Dupont
Your reference range: 3.40 - 8.90