Original Article

Establishment of Long-Term Monitoring System for Blood Chemistry Data by the National Health and Nutrition Survey in Japan

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Aim: We established a monitoring system for the annual follow-up of blood chemistry data obtained by the National Health and Nutrition Survey in Japan.
Methods: Blood chemistry testing has been entrusted to SRL Inc. We used two external quality control assurance programs established by the Japan Medical Association (JMA) and by CDC/CRMLN during the previous 8-year period. Ten analytes were measured: total cholesterol, HDL cholesterol, triglycerides, urea nitrogen, uric acid, creatinine, AST (GOT), ALT (GPT), γ-GT (γ-GTP), and glucose. Total error (TE) was calculated from accuracy by the JMA program and precision by internal quality control of SRL. The permissible range of TE values was determined to be 50% of the evaluation limit on one side in the evaluation criteria of the College of American Pathologists (CAP). When TE fell within the permissible range, the follow-up of annual changes was considered possible.
Results: Annual follow-up of blood chemistry data was considered possible for all the analytes except urea nitrogen. Based on this study, new permissible TE ranges are proposed.
Conclusion: We confirmed the functioning of the monitoring system for the annual follow-up of blood chemistry data obtained by the National Health and Nutrition Survey in Japan.

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Key words; Monitoring system, Total error, Accuracy, Precision

Introduction

The correct evaluation of performance in blood chemistry testing as port of the National Health and Nutrition Survey in Japan and annual follow-up of the results of the survey are important in predicting changes in diseases in Japan through "Health Japan 21" and "Health Promotion Law" and in taking appropriate measures. Other countries are also interested in the present status of diseases in Japan as it undergoes a rapid aging of the population. The acquisition of accurate data allowing international comparison has become important.

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In Japan, there is no monitoring system facilitating the comparison of blood chemistry data obtained by the National Health and Nutrition Survey among years[1-3]. To solve this problem, we calculated TE both from measurements of accuracy based on results of the annual report on the external quality assessment of clinical laboratories (EQA) conducted by the JMA and from measurements of precision based on the results of internal quality control by SRL, and established a monitoring system allowing the determination of whether an annual follow-up of blood chemistry data by the National Health and Nutrition Survey is possible, by referring to the permissible range of TE established separately.

There are various external quality control assurance programs for blood chemistry analysis in Japan such as the EQA by the JMA and by prefectures, and quality control surveys by companies such as manufacturers of reagents. These programs are short-term surveys of the current status in Japan, and do not guaran-

tee the comparison of measurement results among years or international compatibility. On the other hand, external quality control assurance programs for blood chemistry testing in other countries include the CAP program[4, 5] in the U.S., which is performed on a global scale, that by the European Committee on External Quality Assurance in Laboratory Medicine (EQALM)[6], which is widely used in European countries, and the Proficiency Testing Program (PT Program)[4, 7] for the measurement of proficiency in laboratory skills. The mean annual number of laboratories that participated in the EQA by the JMA during the 8-year period was about 2,800, showing an annual increase. About 4,600 laboratories in various countries participated in the CAP, also showing an increase. Reports of assessments have been organized for both projects, and each program has been performed for almost 20 years.

Materials and Methods

The National Health and Nutrition Survey is a basic survey project performed annually by the Ministry of Health, Labour and Welfare in November in 300 areas in Japan in principle. Blood chemistry analysis has been entrusted to the SRL (153 Komiya-cho, Hachioji, Tokyo, 192-0031 Japan) every year. SRL has participated in both the EQA conducted by the JMA and the Lipid Standardization Program (LSP) performed by the CDC/CRMLN. The period of this study was 8 years, between 1999 and 2006. The following 10 analytes were evaluated: total cholesterol, HDL cholesterol, triglycerides, urea nitrogen, uric acid, creatinine, AST (GOT), ALT (GPT), γ-GT (γ-GTP), and glucose.

The evaluation method[8] of the EQA by the JMA in 2006 was as follows: 1) After values deviated by 3 standard deviation (SD) or more from the mean were cut off once according to the measurement method adopted by clinical laboratories participating in the survey, the mean and SD were obtained, and the coefficient of variation (CV) according to the measurement method was calculated. 2) The measurement methods were arranged in order of increasing CV. 3) Measurement methods with a high ranking that included 80% of the laboratories were selected. 4) The total mean of the participating laboratories using the methods selected in 3) was obtained. In addition, intra-method variation was calculated by a one-way analysis of variance and expressed as the SD, and a common CV was obtained. 5) The common CV was corrected for the minimum reporting unit of each analyte, and a new, corrected, common CV was obtained. From both the adjusted mean obtained by this repeated cut-off correction method and values generated by SRL itself, %bias according to samples was calculated, and the mean of multiple %bias values was numerically expressed as an index of accuracy. For precision, the SD described in the EQA represents dispersion in all participants, not the precision of measurements by SRL itself. Therefore, we were provided with measurements of internal quality control sera at 2 concentrations for a 1-month period including values in November, when the samples in the National Health and Nutrition Survey were measured in the SRL, 1 randomly sampled measurement ($n=1$) per day for 20 days, calculated the CV from the mean value and SD, and expressed the precision as a percentage. However, when differences of ≥10% in the CV were present between the concentrations of the internal quality control sera, the higher CV was adopted.

From both the accuracy and precision, the TE was calculated. In calculating the TE, the equation (TE = absolute %bias + 1.96 × CV for the 20-day period) used by the National Cholesterol Education Program (NCEP) in the U.S. and by the CDC lipid standardization programs was employed[9].

As the permissible TE range, 50% of the evaluation limit on one side in the evaluation criteria adopted by the CAP was used[10, 11]. The reliability of the CAP evaluation criteria is considered to be 80%. In the standardization of total cholesterol and HDL cholesterol[12, 13], evaluation criteria consisting of accuracy, precision, and TE in the performance by the NCEP are widely applied internationally.

We considered the follow-up of annual changes to be possible when the TE fell within the permissible range. Concerning the accuracy of lipid measurements, the following evaluation criteria of the NCEP were applied: accuracy ≤ ± 3% of the target value, precision as CV ≤3%, and TE ≤9% for cholesterol; and accuracy ≤ ± 5% of the target value, precision as CV ≤4%, and TE ≤13% for HDL cholesterol[9, 14-16].

Results

(1) **Table 1** shows the performance of SRL in the EQA by the JMA for the 8-year period between 1999 and 2006, and **Table 2** shows the performance in the LSP by the CDC/CRMLN. In the EQA, accuracy was expressed as JMA/%Bias, precision as SRL/CV, and TE as JMA/TE (**Table 1**). For the CDC/CRMLN, accuracy was expressed as CDC/%Bias, precision as CDC/CV, and TE as CDC/TE (**Table 2**). Average absolute %bias values for the 8 years are shown in **Table 1** and **Table 2**.

Table 1. SRL Performance based on External Quality Assessment of Clinical Laboratory by JMA

Analyte	Performance	TE Criteria	CDC Criteria	Proposed Criteria	Year								Average	Average absolute %bias
					1999	2000	2001	2002	2003	2004	2005	2006		
Total Cholesterol	JMA/%Bias				0.19	−0.48	0.27	0.34	−0.15	−0.06	0.13	−0.82	−0.07	0.31
	SRL/CV				1.74	1.57	1.26	1.11	1.63	1.02	1.15	0.97	1.31	
	JMA/TE	5.0%	9.0%	4.8%	3.60	3.56	2.74	2.52	3.34	2.06	2.38	2.72	2.87	
HDL Cholesterol	JMA/%Bias				−0.19	−1.57	−1.09	1.60	0.02	−0.33	0.70	1.29	0.05	0.85
	SRL/CV				2.39	1.82	1.57	2.08	2.02	1.45	1.57	2.26	1.90	
	JMA/TE	15.0%	13.0%	7.8%	4.87	5.14	4.17	5.68	3.98	3.17	3.78	5.72	4.56	
Triglycerides	JMA/%Bias				1.91	−0.58	−1.34	0.37	1.56	−0.12	−0.36	0.00	0.18	0.78
	SRL/CV				1.82	2.33	2.41	2.60	2.34	1.48	1.42	2.32	2.09	
	JMA/TE	12.5%		8.8%	5.48	5.15	6.06	5.47	6.15	3.02	3.14	4.55	4.88	
Urea Nitrogen	JMA/%Bias				−1.69	0.16	0.25	1.74	−0.17	0.75	−0.33	0.69	0.18	0.72
	SRL/CV				1.33	1.22	1.23	1.72	1.79	1.12	1.92	1.40	1.47	
	JMA/TE	4.5%		4.5%	4.30	2.55	2.66	5.11	3.68	2.95	4.09	3.43	3.60	
Uric Acid	JMA/%Bias				0.21	−0.59	−0.43	0.25	−0.26	0.81	−0.44	0.88	0.05	0.48
	SRL/CV				2.12	2.12	1.42	1.50	1.43	1.40	1.82	1.49	1.66	
	JMA/TE	8.5%		5.7%	4.37	4.75	3.21	3.19	3.06	3.55	4.01	3.80	3.74	
Creatinine	JMA/%Bias				−2.24	1.93	−0.08	−0.34	0.15	0.19	−0.76	−0.55	−0.21	0.78
	SRL/CV				1.46	2.63	3.65	2.01	1.91	2.34	1.82	2.29	2.26	
	JMA/TE	7.5%		7.5%	5.10	7.08	7.23	4.28	3.89	4.78	4.33	5.04	5.22	
AST (GOT)	JMA/%Bias				3.03	−0.43	0.21	−0.07	1.37	0.59	−0.60	0.25	0.54	0.82
	SRL/CV				1.69	1.83	1.26	1.12	2.09	1.41	1.94	1.53	1.61	
	JMA/TE	10.0%		8.2%	6.34	4.02	2.68	2.27	5.47	3.35	4.40	3.25	3.97	
ALT (GPT)	JMA/%Bias				2.81	−0.22	0.38	−1.43	−0.08	1.48	1.06	−0.64	0.42	1.01
	SRL/CV				1.37	1.73	1.42	1.41	2.26	1.48	2.26	2.17	1.76	
	JMA/TE	10.0%		8.7%	5.50	3.61	3.16	4.19	4.51	4.38	5.49	4.89	4.47	
γ-GT (γ-GTP)	JMA/%Bias				0.74	−0.01	−0.24	0.82	0.37	−0.13	−0.48	−0.83	0.03	0.45
	SRL/CV				1.77	1.79	1.62	1.74	2.27	1.31	2.00	2.14	1.83	
	JMA/TE	7.5%		6.2%	4.21	3.52	3.42	4.23	4.82	2.70	4.40	5.02	4.04	
Glucose	JMA/%Bias				0.42	−0.58	−0.39	−0.31	0.17	−0.06	0.76	0.53	0.07	0.40
	SRL/CV				1.37	0.97	1.67	1.21	1.42	1.36	1.39	1.52	1.36	
	JMA/TE	5.0%		4.6%	3.11	2.48	3.66	2.68	2.95	2.73	3.48	3.51	3.08	

unit: %
JMA, Japan Medical Association
TE, Total Error

(2) The permissible TE range according to analytes obtained from the CAP evaluation criteria was 5.0% for total cholesterol, 15.0% for HDL cholesterol, 12.5% for triglycerides, 4.5% for urea nitrogen, 8.5% for uric acid, 7.5% for creatinine, 10% for AST (GOT), 10% for ALT (GPT), 1.5SD for γ-GTP, and 5.0% for glucose[11]. The permissible range for γ-GTP is expressed as the SD in the CAP survey. However, since our calculation based on results by the CAP peer group showed that a 1.5 SD corresponds to 7.5%, this percentage was considered the permissible range (**Table 1**).

(3) Based on the results of quality control for 8 years, new permissible ranges with a reliability of 80% were obtained. The new permissible range was 4.8% for total cholesterol, 7.8% for HDL cholesterol, 8.8% for triglycerides, 6.7% for urea nitrogen, 5.7% for uric acid, 11.2% for creatinine, 8.2% for AST (GOT),

Table 2. SRL Performance based on Lipid Standardization Program by CDC/CRMLN

Analyte	Performance	CDC Criteria	Year								Average	Average absolute %bias
			1999	2000	2001	2002	2003	2004	2005	2006		
Total Cholesterol	CDC/%Bias	±3%	0.00	−1.30	0.00	−0.90	0.30	−0.10	−0.90	−0.90	−0.48	0.55
	CDC/CV	3.0%	0.50	0.60	0.60	0.50	0.50	0.60	0.40	0.40	0.51	
	CDC/TE	9.0%	0.98	2.48	1.18	1.88	1.28	1.40	1.70	1.70	1.58	
HDL Cholesterol	CDC/%Bias	±5%	0.70	0.70	2.00	2.00	1.00	1.00	1.20	1.20	1.23	1.23
	CDC/CV	4.0%	1.00	1.00	1.30	1.30	1.70	1.70	1.10	1.10	1.28	
	CDC/TE	13.0%	2.70	2.70	4.60	4.60	4.40	4.40	3.40	3.40	3.78	

unit: %
CDC, Centers for Disease Control and Prevention
CRMLN, Cholesterol Reference Method Laboratory Network
TE, Total Error

8.7% for ALT (GPT), 6.2% for γ-GT (γ-GTP), and 4.6% for glucose (**Table 1**). However, when the new permissible range is higher than the CAP-derived permissible range, there is a risk of overestimation, and, therefore, the CAP-derived permissible range was adopted (urea nitrogen, 4.5%; creatinine, 7.5%). The usefulness of the proposed permissible TE ranges should be evaluated for at least the subsequent 5 years.

Discussion

We evaluated the validity of the constituents of a monitoring system for the determination of whether the annual follow-up of results obtained by the National Health and Nutrition Survey is possible.

Validity of the Use of Measurement Values Obtained by the Repeated Cut-Off Correction Method in the EQA as an Index of Accuracy

In standardization, which is the most developed system in quality control assessments, target values are obtained by the globally accepted definitive or reference method. Therefore, there is almost no doubt over its accuracy. However, in the EQA by the JMA, unlike the CAP program in which peer groups have the responsibility of providing target values, adjusted mean values statistically obtained from measurement values from all participating laboratories are used as target values. A similar data-processing method is also used in external quality control assurance programs in Western countries. This method statistically excludes extreme outliers and missing reports due to mistakes, improving the reliability of target values. Such adjusted means do not represent accuracy itself but are often adopted as consensus values in surveys[17]. Consensus values are often used instead of target values when there is no established reference method, or a reference method has been established but not used. In this respect, the use of consensus values in many laboratories such as 2,800 laboratories in the EQA by the JMA instead of accuracy presents no major problems. However, the disadvantage of this method is the influence of the routine analysis method frequently used in each period on measurement values. When an analysis method based on new measurement principles is developed and commonly used by laboratories due to its convenience and economy, changes in the mean value are sometimes observed. For example, the HDL cholesterol method changed from the precipitation method using polyanions and cations to the homogeneous method employing a surfactant, and began to be used by many laboratories. Changes in mean HDL cholesterol values according to age since this switch to the new method have been reported[18]. These changes are due to differences in measurement principles. Such cases cause discontinuity with previously obtained results in surveys such as retrospective case control studies, markedly affecting annual follow-up. When consensus values are used as a substitute for accuracy, attention should be paid to changes in measurement methods and automatic analyzers. In this study, when the measurement method was changed, whether or not the switch from the old to new measurement method was smooth was determined by observing the presence or absence of changes in correlations and quality control sera.

Validity of the Use of 50% of the CAP Evaluation Limit on One Side as the Permissible TE Range

Our survey on the criteria for the establishment of the permissible range of measurement values when results are evaluated in external quality control assur-

ance programs highlighted the following 3 methods: (1) The CAP method in which permissible ranges are determined based on target values established by a peer group[5], (2) The JMA method in which evaluation is performed in terms of SD[8], and (3) the NCEP method[19] in which the coefficient is corrected for evaluation criteria, and the permissible range is established. The EQA by the JMA showed the following evaluation system for each analyte: A, ≤ adjusted mean ± 1 SD; B, ≤ adjusted mean ± 2 SD; C ≤ adjusted mean ± 3 SD; and D, > adjusted mean ± 3 SD. This system only allows relative evaluation, unlike standardization by which accuracy is numerically expressed centering on the target value obtained by the standard analysis method. Relative evaluation is simple and easy to understand, but does not allow quantification, and lacks international compatibility. Therefore, we compared 3 types of numerically expressed evaluation criteria provided by the CAP, EQALM, and Clinical Laboratory Improvement Amendments (CLIA) as a clinical laboratory regulation in the U.S.[19, 20] As a result, the CAP evaluation limits included those for both accuracy and precision, aiming at the inclusion of 80% of participating laboratories based on the SD of the results of previous measurements performed by the CAP according to the CLIA evaluation criteria in the U.S. The CLIA evaluation limits were not adopted because they were 2-3 times wider than those established by the CAP. Assuming that the bias relative to the target value by the peer group is 0%, and the CV is 2-3%, the evaluation limit in a single laboratory is calculated to be 60-50%[21]. Therefore, using 50% as the permissible range of the TE, evaluation was initiated. We also considered that overestimation can be avoided using the 50% level, which is stricter than the 60% level, for SRL based on precision according to examination analytes by the peer group obtained from data derived from the Chemistry Resource Committee of the CAP, results obtained through Japan-U.S. meetings at AACC concerning lipid standardization, and consistency with standardization by the CDC.

Theoretical and Observed Values of the Permissible TE Range

Presuming that both accuracy and precision show nearly a constant t-distribution every year, and assuming that the maximum accuracy and precision (CV) are 3% and 2%, respectively, for each examination analyte at a statistical power of 80% and bilateral significant level of 0.05, the theoretical TE calculated is 6.9%. On the other hand, assessment was performed by establishing the following equation for the calculation of the permissible TE range based on the results of accuracy and precision for the 10 analytes during the 8-year period: (the mean of the absolute value of JMA/%Bias during the 8-year period + its SD × 3) + 1.96 × (Mean SRL/CV during the 8-year period + its SD × 2)[14]. Here, according to statistical methods, the confidence limit of accuracy was determined to be 3 times the SD and that of precision to be twice the SD. Under these conditions, the permissible range of the TE was 4.8% for total cholesterol, 7.8% for HDL cholesterol, 8.8% for neutral fat, 6.7% for urea nitrogen, 5.7% for uric acid, 11.2% for creatinine, 8.2% for AST (GOT), 8.7% for ALT (GPT), 6.2% for γ-GT (γ-GTP), and 4.6% for glucose (**Table 1**). Since the permissible ranges for urea nitrogen and creatinine obtained by this method were wider than those obtained by the CAP, the CAP-derived values were used for these analytes as the new permissible ranges.

Urea Nitrogen

The TE for urea nitrogen exceeded the permissible range (4.5%) by 0.61% in 2002. Therefore, caution was considered necessary for the evaluation of annual changes in urea nitrogen. To overcome this problem, improving the measurement precision for urea nitrogen in SRL would be most effective. As a target value, 1.47% or below as the mean during the 8-year period was considered appropriate (**Table 1**).

Results of LSP and their Interpretation

In the LSP during the 8-year period, the accuracy, precision, and TE for total cholesterol and HDL cholesterol met the CDC evaluation criteria (**Table 2**). Therefore, results for these analytes in the National Health and Nutrition Survey in Japan can be compared with those in Western countries[4, 15].

Conclusions

In this study, TE was calculated based on two types of the EQA by the JMA and the LSP by the CDC/CRMLN. By comparing this TE with the CAP-derived permissible range, we established a monitoring system for the determination of whether blood chemistry data obtained by the National Health and Nutrition Survey in Japan can be annually followed up. Based on the results during the previous 8-year period, the TE for 9 analytes other than urea nitrogen fell within the permissible range, showing that the follow-up of annual changes is possible. Annual changes in urea nitrogen were considered to require caution. Follow-up of urea nitrogen may become possible by maintaining the CV in SRL at ≤ 1.47%. Based on the results of quality control during the 8-year period, we

proposed a new permissible TE range for each analyte.

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