

대한진단검사의학회 우수검사실 신임인증의 도입과 분석(1999년-2006년)

신보문¹ · 채석래² · 민원기³ · 이위교⁴ · 임영애⁴ · 이도훈⁵ · 임환섭⁶ · 이유경⁷ · 차영주⁸ · 서순팔⁹ · 이갑노¹⁰ · 곽연식¹¹

인제대학교 상계백병원 진단검사의학과¹, 동국대학교 의과대학 진단검사의학교실², 울산대학교 의과대학 진단검사의학교실³, 아주대학교 의과대학 진단검사의학교실⁴, 국립암센터 진단검사의학과⁵, 관동대학교 의과대학 진단검사의학교실⁶, 순천향대학교 의과대학 진단검사의학교실⁷, 중앙대학교 의과대학 진단검사의학교실⁸, 전남대학교 의과대학 진단검사의학교실⁹, 고려대학교 의과대학 진단검사의학교실¹⁰, 경북대학교 의과대학 의료정보학교실¹¹

The Implementation and Effects of a Clinical Laboratory Accreditation Program in Korea from 1999 to 2006

Bo-Moon Shin, M.D.¹, Seok-Lae Chae, M.D.², Won-Ki Min, M.D.³, Wee Gyo Lee, M.D.⁴, Young Ae Lim, M.D.⁴, Do Hoon Lee, M.D.⁵, Hwan Sub Lim, M.D.⁶, You Kyoung Lee, M.D.⁷, Young-Joo Cha, M.D.⁸, Soon-Pal Suh, M.D.⁹, Kap No Lee, M.D.¹⁰, and Yun Sik Kwak, M.D.¹¹

Department of Laboratory Medicine, Sanggye Paik Hospital, Inje University¹, Seoul; College of Medicine, Dongguk University², Goyang; University of Ulsan College of Medicine³, Seoul; Ajou University⁴, Suwon; National Cancer Institute⁵, Goyang; Kwandong University⁶, Goyang; Soonchunhyang University⁷, Bucheon; Chung-Ang University⁸, Seoul; Chonnam National University⁹, Gwangju; Korea University¹⁰, Seoul; Department of Medical Informatics, Kyungpook National University¹¹, Daegu, Korea

Background : The Korean Laboratory Accreditation Program (KLAP) by the Korean Society of Laboratory Medicine (KSLM) was started in 1999. We summarized history and achievement of KLAP for the last 8 yr.

Methods : We analyzed 8 yr data (1999-2006) of historical events, trends of participating laboratories, and scores according to the impact of the question to the outcome of the tests. Inspection check lists are for 'laboratory management', 'clinical chemistry', 'diagnostic hematology', 'clinical microbiology', 'diagnostic immunology', 'transfusion medicine', 'cytogenetics', 'molecular genetics', 'histocompatibility', 'flow cytometry', and 'comprehensive laboratory test verification report'. The laboratories with score 90 or higher got 2-yr certificate and laboratories with score between 60 and 89 got 1-yr certificate. The laboratories with score below 60 failed accreditation.

Results : The number of accredited laboratories was 2.4 times higher in 2006 (n=227) than in 1999 (n=96). Inspection check lists have been revised 5 times till 2006. The average accreditation rate was 99.6% during these periods and the 2-yr accreditation rate was 32.4% in 2000, 45.6% in 2001, 53.3% in 2002, 47.3% in 2003, 68.5% in 2004, 37.7% in 2005, and 47.7% in 2006. Number of participants in inspector training workshops increased from 89 in 2000 to 766 in 2006.

Conclusions : The KLAP has been in place successfully and stabilized over the past 8 yr. It seemed to enhance the laboratory quality. Efforts for improvement of quality control and inspector training workshops appeared to be in the main contributing factors. (*Korean J Lab Med* 2009;29:163-70)

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Corresponding author : Seok-Lae Chae, Ph.D.

Department of Laboratory Medicine, College of Medicine, Dongguk University, 814 Siksa-dong, Ilsan-gu, Goyang 411-773, Korea
Tel : +82-31-961-7890, Fax : +82-31-961-7902
E-mail : rocky@duih.org

INTRODUCTION

The Korean Laboratory Accreditation Program (KLAP) began in 1999 by the Korean Society of Laboratory Medicine (KSLM) with the establishment of the Laboratory Accredi-

tation Committee.

Proficiency Testing (external QC) program was run by the Korean Association of Quality Assurance for Clinical Pathology. But as an agreement was reached on the limitations of the Proficiency Testing program for improving quality of clinical laboratory and the need for accreditation and inspection program, the Ministry for Health and Welfare (currently Ministry of Health, Welfare and Family Affairs) asked the KSLM to develop an accreditation and inspection program.

KLAP bought out with a "A Study of a Standardized Clinical Laboratory Inspection and Accreditation Program" initially by Dr. Yun Sik Kwak in June 1998 and in June 1999 by Dr. Wee Gyo Lee at Ajou University School of Medicine as one of the sub-projects of "an Inspection and Quality Certification Program for Improving and Managing the Quality of Clinical Laboratory Tests" by Kap No Lee at Korea University School of Medicine (final report in May 2001) for the Ministry of Health and Welfare [1, 2].

The laboratory inspection checklists designed to be used in Korea were developed from this research project, referenced to the LAP of the College of American Pathologists (CAP) [3, 4].

Under the leadership of the Korean Society of Clinical Pathology (KSCP; currently KSLM), a pilot project of voluntary KLAP was launched in 1999.

Now in 2008, the tenth year of KLAP, we retrospectively reviewed the outcome and achievements of our own inspection and accreditation program.

This study summarized the history of the KLAP, the content of the inspection check lists, and the activities of the Laboratory Accreditation Committee. The results of the KLAP were examined according to the participating institutions and the type of accreditation. We also analyzed results of survey for the impact of KLAP on the accredited institutions.

METHODS AND RESULTS

1. The early ages of KLAP (1998-1999)

KLAP in Korea was initiated as an outcome of projects

initiated by Lee WG, Kwak YS, and Lee DH et al. [1, 2]. The Laboratory Accreditation Committee was organized as a standing committee of the KSCP (October 15, 1998), and 24 clinical pathologists including the chairman were appointed as committee members. A subcommittee was organized within the Laboratory Accreditation Committee to carry out detailed work related to inspection of laboratories.

In January 1999, KLAP was established with following standards; the qualifications and duties of responsible laboratory personnel, laboratory facilities and safety, quality control and quality improvement, and requirements for participation of the program as in the LAP of CAP. The inspection check lists were drawn up for 11 areas based on the specialties of laboratory medicine [1, 2].

The inspection check lists included 2,486 questions, with 203 questions on laboratory management, 146 on diagnostic hematology, 409 on clinical chemistry (including 114 for general chemistry, 210 for special chemistry, and 85 for urinalysis), 282 on clinical microbiology, 246 on transfusion medicine, 70 on diagnostic immunology, 102 on flow cytometry, 117 on histocompatibility, 137 on cytogenetics, 232 on molecular genetics, and 542 on limited function laboratory [1].

Three workshops were held at Ajou University Hospital on February 20, 27 and March 6, 1999. A total of 132 clinical pathologists from institutions that had applied for KLAP participated. The workshops included the need for KLAP, introduction of KLAP inspection check lists, case study for inspection, and the role of inspectors.

In May/June 1999, KLAP was demonstrated at four institutions: Ajou University Hospital (May 1999, Suwon), Samsung Medical Center (May 1999, Seoul), Seoul Medical Science Institute (SCL; June 1999, Seoul), and Kyungpook National University Hospital (June 1999, Daegu). At that time approximately 100 volunteer inspectors carried out hands on experience with on site inspections. Since it had been the first event of KLAP, the results were not scored; only disqualified questions were noted and recommendations were made to be known.

In July 1, 1999, the Ministry of Health and Welfare announced that KLAP accreditation should be mandatory qualification of reference laboratories for reimbursement until

June 30 [3]. However, because of the sudden application of the program, some reference laboratories could not be inspected until June 30, 1999. Therefore, a short-term certificate was issued based on a document inspection on the condition that an on site inspection would be received within the next 3 months.

By September 20, 1999, more than 60 clinical pathologists were recruited as inspectors of KLAP and guidelines for the operation of KLAP for the reference laboratories were prepared and applied. All of the inspected laboratories got scores of 90 or higher and accreditation certificates were issued.

On October 11, 1999, first-edition guidelines for the operation of the KLAP for clinical laboratories were prepared.

On November 15, 1999, the "Standards for the Estimation of Medical Insurance Service Fees and Dispensary Costs" were revised, adding a "fee for comprehensive laboratory test verification report (Code No. B0001)" [4]. In order to get the reimbursement of this fee, it was mandatory to be accredited by the KLAP including 'comprehensive laboratory test verification report'. This area was added to the 11 previously existing areas of inspection check lists. On December 4, 1999, a workshop on laboratory test verification report was held to train those to be inspected and the inspectors.

2. Main changes in the laboratory accreditation program

In February 2000, a working committee to revise inspection check lists was formed. The second generation inspection check lists were completed in March 2000. Revised inspection check lists included 1) revising ambiguous phrases; 2) removing redundant questions; 3) adding criteria and explanations for each question; 4) assigning scores differently according to the impact of the questions to the quality of laboratory testing; and 5) assigning a serial number to questionnaire. Assigning a serial number was instated so that the score of each question could be compared by years. The area of 'limited function laboratory' was abolished due to the disparity in operation and equity among institutions.

In February 2002, the first-edition guidelines for the operation of the KLAP were revised. Changes were made regarding the applications for inspection, the composition of the inspection team, the scoring criteria, the type of certification, and an actual cost reimbursement for inspectors. Also the guidelines include role of Laboratory Accreditation Committee and data processing of inspection results.

For the years 2004 and 2005, based on inspection experiences during the period 1999–2003, the inspected institutions were divided into two groups according to the size of parent hospital (Group A: 400 beds or more, Group B: fewer than 400 beds). Slightly different checklist questions were used for the two groups. Until this point, the same checklist questions were applied to all institutions.

Recognizing the need of an inspection team for reference laboratories exclusively, an inspection team for reference laboratories was formed in March 10, 2003. The initial members were Drs. Yonggoo Kim, Hyeon Ok Kim, Won-Ki Min, Ae Ja Park, Eul-Ju Seo, Kap No Lee, Wee Gyo Lee, Jong Rae Jo, Han-Ik Cho, and Young-Joo Cha. Regardless of the score obtained, all the reference laboratories were to be inspected annually on principle.

In November 2004, the web site of the LAP (www.labsimsa.com) was established. Beginning with 150 medical technologists and clinical pathologists as initial members of the home page, the membership had increased to 984 by December 2006 (656% increase).

The chairmans and executive secretaries of the Laboratory Accreditation Committee were Drs. Yun Sik Kwak and Do Hoon Lee in 1999–2000, Kap No Lee and Chae Seung Lim in 2001, Soo Hwan Pai and Hwan Sub Lim in 2002–2003, Kap No Lee and Seok-Lae Chae in 2004–2005, and Soon-Pal Suh and Bo-Moon Shin in 2006.

3. Survey results of KLAP by the year (Table 1)

Starting with 96 institutions that participated and were inspected and accredited in 1999, the number of institutions inspected increased to 227 in 2006, a 2.4-fold increase in 8 yr. The numbers of institutions who failed to be accredited were 0, 1, 1, 5, 0, 11, and 5 from 2000 to 2006, respec-

Table 1. Distribution of participating laboratories according to the results of inspection scores of each laboratory (N)

	1999	2000	2001	2002	2003	2004	2005	2006
Participating institute	96	178	187	187	188	192	204	226
2-yr accreditation*	0	55	52	65	53	89	49	82
1-yr accreditation†	96	116	62	57	59	41	71	93
Self-inspection	0	0	55	52	65	53	81	47
Non-renewal	0	6	16	13	8	8	3	4
Non-accreditation‡	0	1	2	0	2	1	0	0
Retrial	0	0	1	1	5	0	11	5

*Two-year accreditation is given to the laboratory if the total average inspection score is 90 or higher, Institutions in group B (<400 beds) scoring 80 or higher received 2-yr accreditation only during the period of 2004-2005; †One-year accreditation is given to the laboratory if the total average score is 60 or higher but less than 90; ‡Non-accreditation is given to the laboratory whose inspection score is less than 60.

tively and an average of 0.44% failed for accreditation.

4. Accreditation checklists

Accreditation includes laboratory management, clinical chemistry (including special chemistry and urinalysis), diagnostic hematology, clinical microbiology, diagnostic immunology, transfusion medicine, cytogenetics, molecular genetics, flow cytometry, histocompatibility, and comprehensive laboratory test verification report, while the area of limited function laboratory was abolished in the 2000 revision due to disparity in operation and equity among institutions. Excluding the “reference laboratory” area which was introduced in 2005, 11 areas have been inspected continuously.

The inspection checklists of KLAP contained 2,486 questions in 1999. In spite of continuous revisions, the inspection checklists still includes 1,700–1,900 questions. Since the first edition in 1999, four revised versions have been published by teams led by Drs. Do Hoon Lee (2000), Wee Gyo Lee (2002), Hwan Sub Lim (2004), and Do Hoon Lee (2006). To reflect the raised standards of laboratories, the questions have been revised continuously. In particular, the 2006 version was considered a complete revision because many questions and their content were changed. In KLAP, each question has scoring system with the options “Yes,” “No,” and “Not Applicable.” Our scoring system gave scores to each question according to the impact of question to the quality of laboratory testing. The scores were summed and converted to a percent score for each inspected area.

5. Analysis of the accreditation results (Table 2)

In our system, institutions were divided into 1-yr certification and 2-yr certification from 2000. During the period 2000–2003, institutions that scored 90 percent or higher got 2-yr certificate, those scoring 60–90 percent got 1-yr certificate, and those scoring less than 60 were not accredited. Temporarily, during the period 2004–2005, institutions in group B scoring 80 percent or higher got 2-yr certificate. From July 2005, institutions scoring less than 80 percent were not accredited. When an institution failed to be accredited at the first inspection, it was given the opportunity for a re-application.

During the period 2000–2006, the percentage of institutions given a 2-yr certificate was 32.4, 45.6, 53.3, 47.3, 68.5, 37.7, and 47.7%, respectively. Average 48% of the inspected institutions acquired a 2-yr certificate. In 2006, although every institution was inspected using the fully-revised inspection check lists, the percentage of institutions receiving 2-yr certificate kept the same average level. During the period 2000–2006, six institutions (0.44%) failed, most of which were small reference laboratories.

Regarding the mean score by inspection area during the period 2000–2006, the mean scores of core areas such as laboratory management, clinical chemistry, diagnostic hematology, clinical microbiology, diagnostic immunology, and transfusion medicine were over 90 percent, except 88.7% in 2003 of clinical microbiology. In 2003, the scores of clinical chemistry, clinical microbiology, transfusion medicine, and diagnostic immunology were somewhat lower than those

Table 2. The inspection scores of participating institutes by inspection checklist areas (year 2001-2006)

Parameter	2001	2002	2003	2004	2005	2006
Lab. Management (N)*	118	124	117	133	127	178
Mean	91.87	93.64	92.33	93.18	93.48	95.05
SD	7.58	5.18	5.97	6.55	6.52	4.55
Hematology (N)	117	124	116	130	122	174
Mean	92.45	94.98	92.48	94.10	94.36	94.47
SD	6.29	5.06	6.79	5.36	7.03	5.66
Chemistry	117	124	120	131	124	172
Mean	93.74	95.37	90.27	94.93	94.22	95.40
SD	7.87	3.85	13.20	6.82	5.70	4.07
Microbiology	114	121	119	129	118	156
Mean	92.69	94.10	88.73	93.58	92.20	95.15
SD	5.29	5.38	16.29	6.14	7.28	3.95
Blood Bank	114	125	116	129	121	170
Mean	93.69	95.88	92.44	95.26	95.51	96.76
SD	6.45	4.83	11.05	4.90	4.67	3.63
Immunoserology	117	124	118	132	122	172
Mean	93.72	95.20	92.20	94.50	94.40	94.92
SD	5.78	4.97	11.34	6.04	7.38	5.20
Flow cytometry	6	25	9	26	14	33
Mean	97.89	98.05	97.94	98.33	97.87	98.16
SD	2.59	1.71	2.12	1.67	2.03	1.75
HLA	16	42	19	39	29	44
Mean	96.54	97.20	97.92	97.27	97.46	97.79
SD	2.95	3.57	2.43	2.93	2.35	1.75
Cytogenetics	6	25	11	22	19	32
Mean	96.38	98.16	97.48	97.37	97.84	98.09
SD	2.71	1.58	4.06	5.69	2.50	1.90
Molecular biology	18	45	23	48	44	63
Mean	95.09	97.25	97.02	97.40	96.28	97.40
SD	5.67	2.45	3.05	2.69	4.50	2.96
Comprehensive						
Verification of Laboratory test						
Result	97	103	98	105	82	128
Mean	96.81	97.04	97.24	97.52	96.97	97.24
SD	5.08	3.84	3.94	3.17	4.85	3.47
Reference Lab.					42	33
Mean					84.89	95.88
SD					9.27	3.67

*Number of participating institutes.

in other years. In every year, the mean scores of special areas such as flow cytometry, histocompatibility, cytogenetics, and molecular genetics, were over 95 percent.

6. Workshops

Since the first workshop in 1999, one to four workshops were held every year, except in 2003 and 2005. In most of the workshops, clinical pathologists and medical technologists participated together and workshops only for the clinical pathologists were also held. The number of participants

was 132 in 1999 (3 workshop), 89 in 2000 (1 workshop), 92 in 2001 (1 workshop), 43 in 2002 (1 workshop), 744 in 2004 (4 workshops), and 766 in 2006 (3 workshops), showing an increasingly favorable response.

7. Composition and education of inspectors

The inspection team consisted of four to eight inspectors depending on the size of the institution and the team leader of the inspection team organized them. There were seven training courses for inspectors before 2006, with 539 par-

Table 3. The result of questionnaire survey on the effects of laboratory accreditation program and its training workshops (% , n=274)

Effects of accreditation programs	Strongly disagree	Disagree	Uncertain	Agree	Strongly agree	No response
We could improve equipments functions	6.5	15.0	32.0	39.7	4.5	2.4
We could improve instrumentations	6.9	15.0	44.5	27.9	3.2	2.4
We could implement laboratory information system	10.1	17.0	34.8	27.9	5.7	4.5
We could improve the qualities of tests	2.0	2.4	21.1	56.3	15.8	2.4
We could increase the numbers of medical technologist	32.4	28.3	27.5	8.1	1.2	2.4
We could intensify the internal quality control systems	1.2	1.2	13.4	58.7	23.9	1.6
We recognized the importance of documentations	0.8	1.6	6.9	55.5	33.6	1.6
We became more aware of importance of laboratory safety	1.6	4.5	25.5	53.4	13.4	1.6
We became more interested in qualities of tests	0.4	2.0	10.5	59.1	26.7	1.2
We have pride through laboratory accreditation	2.4	8.5	37.3	36.0	14.2	1.6
Inspectors cited deficiencies and provided corrective measures	0.8	5.3	23.9	52.2	15.8	2.0
Inspectors were courteous and not nitpicking	0.8	2.4	21.5	59.9	13.8	1.6
I expressed my opinion in case of disagreement	1.2	11.3	39.7	38.9	6.9	2.0
I am aware there is KLAP homepage	18.2	15.0	16.6	22.7	25.5	2.0
I frequently visit KLAP homepage	30.0	25.1	30.8	7.3	4.5	2.4
I will use homepage in case of unsolved problems	4.1	7.7	23.9	43.3	19.8	1.2
The workshops were useful	0.8	0.8	21.1	53.0	23.5	0.8
I recommend my colleagues to attend the workshop	1.2	3.6	19.9	50.2	24.3	0.8

ticipants in total. The number of inspectors registered by 2006 was 396. A total of 357 inspectors had served more than once and 161 inspectors had served more than 10 times until 2006.

8. Benefits for accredited institutions

If a laboratory is accredited by KLAP, the laboratory receives a certificate of accreditation with remark of excellence in providing high quality services. The Laboratory Accreditation Committee provides the outcome of the laboratory inspection to the Health Insurance Review Agency (HIRA). Then HIRA reimburses the fee for the 'comprehensive laboratory test verification report' to the hospital when it is requested and the fee for the laboratory test to the reference laboratory from insurance funds.

Certification of accreditation by KLAP is frequently requested for clinical research conducted by the medical institutions [7].

9. Evaluation of the KLAP (Table 3)

The Laboratory Accreditation Committee conducted a questionnaire survey with 247 respondents who participated in workshops held in January and February 2006. Accord-

ing to the survey, LAP had a strong influence in implementation of laboratory information system (LIS) and improved the laboratory facilities, quality, and staffing. The respondents replied positively regarding the inspection process, workshops, and related education [8].

DISCUSSION

The KLAP was started in 1999 to enhance the capacity of laboratory medicine and promote quality improvement. In 2006, after operating the program for 8 yr, there seems to be no objection that KLAP has made a great contribution to the substantiation of quality improvement. In 1961, the LAP of CAP, which has been recognized worldwide as the best, started LAP as a joint on site survey of laboratories with the Canadian Society of Pathologists. In Korea, eight laboratories, including four university hospital laboratories have been accredited by the CAP LAP until 2006 [5, 6], however, the number increased to 11 today. While it has been 45 yr since CAP LAP was started, it has been 10 yr since the Korean LAP has been implemented due thanks to the development of inspection checklists similar to those of CAP LAP, its unique scoring system, the voluntary and enthusiastic participation of clinical pathologists, and the strong interest of medical institutions.

Over the last 8 yr, the rates of re-application and failure were 1.8% and 0.04%, respectively. As a whole, most institutions were accredited as 'superb laboratories'.

Average 48% of the inspected institutions received a 2-yr certificate. This suggests that because the inspection was conducted by a peer group, the inspectors tried to conduct the inspection objectively and fairly, establishing the inspectors' evenhandedness and ethics.

Remarkably, although the inspection check lists were fully revised and applied in 2006, the rate of 2-yr accreditation remained at the similar level. This suggests that despite the different questions in the revised version, each institution had improved its own capacity in quality improvement through several years of LAP experience and acquired know-how on inspection from workshops and education programs.

Between 1999 and 2003, much effort was made to enhance participation in KLAP, and the quality of inspection was improved by supplementing and revising the checklist questions [1, 2]. As practical experience accumulated during this period, it was believed that the composition of checklist questions for small and medium size hospital laboratories should be different from those for large hospitals. Considering this opinion, the institutions were divided into two groups according to the size of the institution for the years 2004 and 2005. As each hospital laboratory increased its capacity annually based on KLAP, the quality of laboratory services was upgraded even in small and medium size hospitals until they became confident in quality improvement. Consequently, all institutions were inspected using the same inspection checklists in the fifth revision in 2006.

While the mean scores in core laboratory areas such as diagnostic hematology, clinical chemistry, diagnostic immunology, and clinical microbiology exceeded 90 percent, the mean scores in special laboratory areas such as flow cytometry, histocompatibility, cytogenetics, and molecular genetics averaged over 95 percent every year. This is because such special laboratory services are conducted mostly at tertiary care hospitals and large reference laboratories having a basic infrastructure that enables having a high score for facilities, instruments, and personnel.

According to a 2006 questionnaire survey, the 8-yr accreditation effort was evaluated very positively in terms of laboratory facilities and instruments, implementation of LIS, practical improvement in inspection quality, thorough internal quality control, recognition of the importance of documentations, the pride as a laboratory medical technologist, the inspectors' sincerity and fairness during the inspection, and the value of workshops [8].

While 6.6 times more members joined the membership on the home page at the end of 2006 compared to those when the home page was made available initially, which suggests the LAP will be widely known through homepage in the future.

Multi-institutional and multinational clinical research also require a certificate of KLAP, which is a good opportunity to advertise the validity of KLAP [7].

For further development, it is necessary to educate new inspectors systematically. In addition, because the KLAP is operated by peer-group review, it is necessary to consider ongoing supplementary education for the quality and ethics of inspectors in order to minimize inter-observer variability. The Korean Institute of Genetic Testing Evaluation (KIGTE) and the Korean Society of Blood Transfusion (KSBT) also have the legal authority to perform LAP. Although the framework for accreditation and inspection by the KIGTE and the KSBT were modeled after the KLAP, it would be advisable to minimize reduplication of laboratory accreditation programs that are executed by various professional organizations [9, 10].

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