Original Article

Survey of External Quality Assessment Scheme for Blood Bank Laboratories in Taiwan

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To evaluate the competences of medical laboratories of blood banks in Taiwan, the long term surveillance of External Quality Assessment Scheme (EQAS) on blood bank laboratories from 1998 to 2005 in Taiwan were performed and analyzed. The participation in EQAS is not mandatory, so the proficiency samples were only delivered to the laboratories that agreed to participate in the scheme. All the participants were requested to perform the testing with routine protocol. The items of proficiency tests composed of ABO grouping, RhD typing, antibody screening and identification as an option. Correct rates of different test items, varied scales of laboratories and test methods were compared. The results indicated that the correct rates of ABO grouping range from 93.9% to 100 %, and 98.7% as average. As for RhD typing, it ranges from 90.6% to 100%, averagely 97.5%. Average correct rate of antibody screening and antibody identification were 88.6% and 97.1% respectively. The use of multiple methods for antibody screening achieved higher correct rates than using single method only. The error rate of antibody screening in the district hospitals and the private laboratories was higher than in the medical centers and the regional hospitals. The blood bank performance in Taiwan has achieved high competence by using EQAS and the laboratories can keep continuous quality improvement in blood transfusion service. For equivocal samples, blood bank laboratories are recommended to use more than one method for antibody screening to elevate their correct rates. EQAS is beneficial for quality control of blood bank laboratories and the continuous improvement of their competences.

Key words*: *ABO grouping, antibody screening, antibody identification, EQAS

Introduction

The primary purposes of the External Quality Assessment Scheme (EQAS) carried out in Taiwan is to examine the quality performance of the laboratories of four different scales, including medical centers, regional hospitals, district hospitals, and private laboratories. Furthermore, EQAS can be used as a monitor and lead to the establishment of a database of laboratory quality performance and testing accuracy comparisons. This database provides valuable assistance in evaluations and the laboratory inspections in Taiwan [1-4].

Continual improvement of blood bank laboratories performance can be achieved by internal quality control and external proficiency scheme. Because of the improving of medical laboratory technology and instrumentation as well as the standardization of blood banks testing protocols, the accuracy and quality of blood bank advanced dramatically worldwide [5-7]. Taiwan Society of Laboratories Medicine (TSLM) has conducted Qual-

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ity Assurance Surveillance Program on clinical laboratories (including blood bank) in Taiwan granted by Department of Health, Taiwan since 1994. However, the government subsidy for blood bank was discontinued from 2003; the participants attended the program at their expense ever since. In spite of the halt of funding, TSLM continued to set up the Committee of Proficiency Test in Blood Bank Laboratory which aims to establish correct concept of quality control and to improve the performance of blood bank laboratory in Taiwan. Based on the findings from EQAS, the conferences for continuous education can be held to improve the competence of blood banks.

This paper collected the data of EQAS for blood bank laboratory in Taiwan from 1998 to 2005, and discussed the competence of blood bank laboratories of different scales.

Materials and Methods

The proficiency testing samples obtained from the Taiwan Blood Service Foundation were prepared and sent along with an instruction manual after stability and uniformity validation by the blood bank laboratories of medical centers located in different areas. All enrolled test items were routine pre-transfusion examinations of blood banks in Taiwan, including ABO and RhD typing, antibody screening and identification. Antibody identification was not included in EQAS until 2000. ABO grouping and RhD typing were categories as "required items" while antibody screening and antibody identification were "optional items." Exercise materials basically included six tubes of 3-5% red blood cell suspensions and six tubes of plasma, except that 3-5% red blood cell suspensions had been replaced by whole blood samples during 2000-2002. Exercise materials became 4 tubes of 3-5% red blood cell and 4 tubes of plasma, and sent to participants twice per year after 2003. The exercise materials were delivered by certified express company at 4℃ and required to store at the same temperature during the entire time period prior to testing.

The participants were required to treat the proficiency specimens as routine samples, and all the tests had to be run by the receiving laboratory only. Because the participation in EQAS was not mandatory, the proficiency samples were only delivered to the laboratories that agreed to participate in the scheme. Participants were divided into two groups by their ranking: medical center, regional hospital and blood center were categorized as group 1 because their high specimen numbers and strictly demands of accuracy; Group 2 was composed of district hospitals and private laboratories.

The data showed in this survey were collected during the period of 1998 to 2005. Correct rates of exercise items were calculated after receiving the reports. Comparison results of exercise items, and laboratory scales were evaluated by Excel.

Results

The numbers of the participants of laboratories in each year varied during the eight years, ranging from 99 to 501 since all participants were volunteers, with some enrolling while others withdrawing over the years. Due to the discontinuance of government's grants, the number of participant decreased dramatically in 2003.After then the number of participated laboratories increased again in 2004 and 2005.

ABO grouping and RhD typing

The average correct rate of ABO grouping was 98.7% (Table.1), ranging from 93.9 % to 100 %(Table. 2) Before 2003, a high percentage of laboratories in Taiwan only performed cell typing. The ratio increased from 73.6% in 2000 to 95.3% in 2005, showing a tendency toward the use of both cell typing and serum typing methods (Figure I).

For RhD typing item, the average correct rate was 97.5% (Table 1), increasing from 90.6% in 1998 to 100 % in 2000 and 2005 (Table 2).

Antibody screening and antibody identification

The total average correct rate of antibody screening was 88.6% (Table 1), ranging from 77.2% to 97.9% (Table 3). The correct rate was 95.6% and 91.0% in 1998 and 1999 respectively. However, the average correct rate was decreased to 77.2% in 2000 when an irregular antibody anti-E sample was included in testing samples for the first time, and increased to 97.9% in 2003. In 2001, the correct rate of antibody screening was 87.8%, and increased to 94.4% in 2004 with anti-Mi^a sample. Furthermore, when the exercise materials contained more than one irregular antibody sample (anti-E, anti-Mi^a, or anti-D) in 2002 and 2005, and the correct rate was 85.0% and 91.3%, respectively.

Antibody identification was a respectively new item

Table 1 Average correct rates of four exercise items from 1998 to 2005

Exercise items	No. of participants*	Correct rates
ABO grouping	2611	98.7%
RhD typing	2611	97.5%
Antibody screening	1742	88.6%
Antibody identification	587	97.5%

*Times of number of participants, twice a year and years.

Table 2 Number of participants and correct rates of ABO grouping and RhD typing from 1998 to 2005

Year	No. of participants	Correct rates of ABO grouping	Correct rates of RhD typing
1998	409	98.6%	90.6%
1999	383	96.9%	96.2%
2000	501	100 %	100 %
2001	389	99.2%	97.1%
2002	365	99.8%	99.9%
2003	99	93.9%	99.7%
2004	211	98.1%	99.8%
2005	254	99.5%	100 %

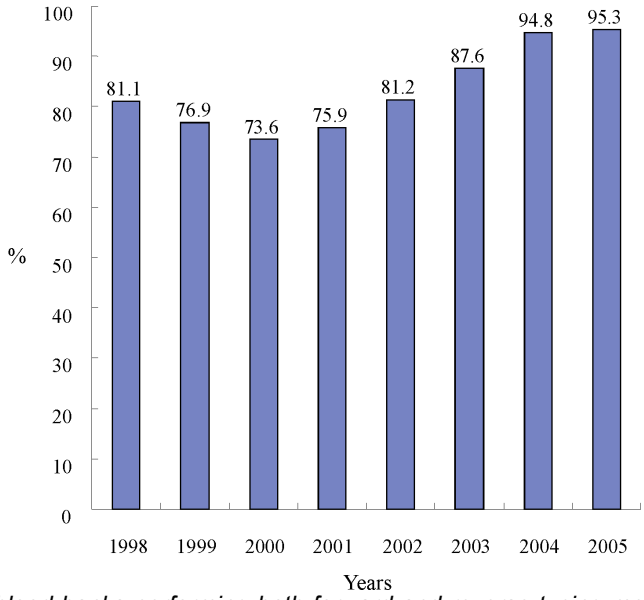

Fig.1 *The frequency of blood banks performing both forward and reverse typing methods for ABO grouping in Taiwan, 1998 to 2005.*

started by TSLM in 2000. For the participants who had the ability to execute antibody identification, the average correct rate of antibody identification was 97.5% (Table 1), ranging from 93.9% to 99.5% (Table 3)

The comparison of correct rates for antibody screening among different scale of hospitals was shown in Table 4. The better correct rates were found in hospitals with higher scales (medical centers and regional hospitals) than in the lower scales hospitals (district hospitals and private laboratories). The most commonly used screening method in Taiwan was manual polybrene (MP). The correct rate was 91.4% when used MP alone (Table 5). Noteworthily, the correct rates were 100% when more than one method was used for the tests (Table 5). Those methods used for double-checking include Saline-AHG (Anti-Human Globulin), Albumin—AHG, LISS—AHG, (Low Ionic Strength), PEG—AHG (Polyethylene glycerol), and Column Agglutination Testing [8, 9].

Table 3 Correct rates of antibody screening and antibody identification from 1998 to 2005

Year	No of Participants		Correct Rates		*Sample number				
	Antibody screening	Antibody identification	Antibody screening	Antibody identification	Antibody screening		Antibody identification		
					positive	negative	anti-E	anti-Mi[a]	anti-D
1998	203	NA**	95.6%	NA	0	2	0	0	0
1999	234	NA	91.0%	NA	2	0	0	0	0
2000	284	88	77.2%	94.3%	1	1	1	0	0
2001	288	185	87.8%	99.5%	0	5	0	0	0
2002	251	82	85.0%	93.9%	2	3	1	1	0
2003	84	62	97.9%	98.4%	1	7	1	0	0
2004	186	82	94.4%	98.6%	1	7	0	1	0
2005	212	88	91.3%	98.0%	3	5	1	1	1

* The positive samples of antibody screening were included for antibody identification exercise after 2000.

**NA: not available

Table 4 Correct rates of antibody screening among different scales of medical laboratories from 1998 to 2005

Year	Medical Centers	Regional Hospitals	District Hospitals	Private Laboratories
1998	100.0%	100.0%	93.3%	100.0%
1999	100.0%	93.3%	89.0%	94.5%
2000	100.0%	97.9%	69.3%	83.3%
2001	94.1%	98.4%	84.1%	82.4%
2002	100.0%	93.0%	81.2%	66.7%
2003	100.0%	100.0%	94.1%	91.7%
2004	100.0%	95.2%	91.7%	100.0%
2005	100.0%	100.0%	84.6%	90.0%
Average	99.3%	97.2%	85.9%	88.6%

Table 5 Correct rates of antibody screening by different detection methods during 2004 and 2005

	Test formats							
	Single	Double					Triple	
Methods*	1	1+2	1+3	1+4	1+5	1+6	1+2+6	1+4+6
No. of Lab**	603	16	13	9	1	32	1	1
No. of Correct	551	16	13	9	1	32	1	1
Correct rate	91.4%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

*Methods include: 1) Manual Polybrene; 2) Saline – AHG; (3) Albumin – AHG; (4) LISS – AHG; (5) PEG – AHG; (6) Column Agglutination Testing

**62 incomplete reply forms were omitted

Discussion

The present data has shown a continuous improvement of blood bank laboratories in Taiwan from 1998 to 2005. In addition to the external quality scheme, the technical improvement and continue education for EQAS participant each year also help greatly in the amelioration of testing quality in Taiwan. For ABO blood grouping, some participants didn't perform serum typing which might be the reason for them failed to meet the expectation in EQAS. Before 2000, there were some laboratories using polyclonal anti-D reagents to test RhD. After then, the participants had all been using monoclonal blend IgG+IgM anti-D reagents to perform RhD typing, which was the main cause of the better accuracy. By using both cell typing and serum typing for ABO blood grouping and replacing the polyclonal antibody to monoclonal antibody for RhD typing, correct rates were

remained high for these years.

The manual polybrene technique is a rapid, simple and sensitive method for red blood cell antibody detection which has been adopted to perform antibody screening in Taiwan for decades. The procedure includes three phases; the first part is takes place in low ionic solution with antigen-antibody reaction; then add polybrene, a positively charged synthetic polymer, to induce nonspecific aggregation between erythrocytes; at last a salt solution is used to resuspend the aggregates produced by polybrene. The presence of an antibody is recognized by the persistence of agglutination after polybrene effects have been reversed [10, 11]. The method has been used for pretransfusion testing which consists of ABO grouping, antibody screening and cross-matching in Taiwan since 1983. Due to the rapid (about 3 min), easy performance, economical cost, and reliable results, manual ploybrene method is widely accepted and performed by blood bank laboratories in Taiwan. However, the lack of adequate sensitivity for Kell system antibodies has prevented it from becoming a ubiquitous test in the countries where Kell-incompatibility is relatively common. On the contrary, manual ploybrene is a common blood bank test in Taiwan because Taiwanese people rarely have K-antigens [12]. However, the medical technologists need to be experienced and well-trained to use manual polybrene properly and correctly [13, 14]. Thus, to refer the query positive antibody screening results, additional methods for antibody screening used in Taiwan such as Saline-AHG, Albumin-AHG, PEG-AHG, LISS-AHG, and column agglutination testing are recommended to prevent missing positive antibody screening and confirm the results. Based on the data collected, the use of double methods elevated the correct rate to 100% while that of using manual polybrene method alone was 91.4%. This is in accordance with Melo's investigation result, "when multiple methods were used, the correct rate of antibody screening rose up to 100%" [6]. Thus, it is highly recommended to have the performance of double methods as the protocol of antibody screening when equivocal sample tested [15].

Because Anti-E and anti-Mi^a are two of the most frequently irregular antibodies in Taiwan, the Technical Committee has decided to add irregular antibodies to the exercise materials afterwards since 2000. At first, the anti-E was added in the exercise materials in 2000, the correct rate of antibody screening dropped to 77.2%. After then, through the peer group learning and continue education conference, the correct rates elevated when each type of irregular antibodies sample was included in the exercise materials for the second time. The correct rates were from 77.2% to 97.9%, and from 87.6% to 94.4% for anti-E and anti-Mi^a respectively (Table.3).

The correct rate of antibody identification had improved over the eight years. It was 94.3% in 2000, increased to 99.5% in 2001(Table 3) but dropped to 93.9% in 2002 because both anti-E sample and anti-Mi^a sample were added to the exercise materials and made the identification more difficult for participants. Interestingly, the correct rate reached 98.0% in 2005 with the testing samples of anti-E, anti-Mia, anti-D. This indicated that the participants had become capable of dealing with complicated cases of antibody identification, and even though the incidence of anti-D is very low in Taiwan, most of the blood banks still have the ability to identify it.

All of the hospitals were ranked into four scales according to the hospital accredited by Taiwan Joint Commission of Hospital Accreditation. The four scales were medical centers, regional hospitals, district hospitals, and private laboratories. Medical centers provide 500 beds or above and comprise the departments of transfusion medicine or the division of blood bank. There were more technologists and clinical laboratory specialist working for the blood banks and being fully responsible for transfusion services. The laboratories of these medical centers used multiple methods and many of them were equipped with fully automated instruments. There are 250 to 499 beds in a regional hospital and the capacity of blood banks is lower since there are only a few technologists in service. District hospitals provide less than 249 beds and have no independent divisions of blood bank or full-time blood bank technologists.

More of the private laboratories are operated by only one medical technologist. When performing ABO grouping, some of the private laboratories use slide method because they do not have instruments such as blood bank centrifuges available. There were different regulations and guidelines for clinical laboratories in the hospitals of different scales to obey and fallow. As a result, the numbers of clinical lab professionals and availability of instruments vary from scale to scale. These factors related to the competence and quality performance of a laboratory. In this study, the participants were further divided into two groups. Group 1 was composed of medical centers and regional hospitals and group 2 was composed of district hospitals and private laboratories. The results of irregular antibody screening showed that group 1 had a higher correct rate and there was a significant difference between the correct rates of group 1 and group 2. Take together, the fact that the blood bank

laboratories in the hospitals with more beds, such as medical centers and regional hospitals, had performed better than those in the district hospitals and private laboratories, which were of lower scales (data not shown).

Thus, it is recommended that blood banks of district hospitals and private laboratories use two or more methods to confirm the equivocal antibody screening testing results due to the difficulties of detecting all clinically significant antibodies with one single technique [16-18]. Besides original testing item, DAT may useful and should be considered to include in the future EQAS program. Also, brief discussion of educational subject may help, educational materials such as cause of ABO discrepancies, false positive and negative Rh(D) results, reagent storage, incubation temperature, centrifugation speed etc. may also benefit to the improvement of blood bank laboratories. Furthermore, the standardization is the tendency of other clinical laboratories. Through the standard operation procedure and reliable automatic system, the workflow efficiency and accuracy can be increased remarkably.

In conclusion, External Quality Assessment Scheme offer a valuable management tool because they enable laboratory personnel to compare their laboratory results with those obtained in other laboratories when the same material is examined. In addition, EQAS program can help participants to detect their potential problems. The information collected in the long term surveillance, EQAS, is an essential reference for the design of good training courses and continuing education of the quality improvement [7, 19].

References

1. Sciacovelli L, Secchiero S, Zardo L, et al. External quality assessment: an effective tool for clinical governance in laboratory medicine. Clin Chem Lab Med 2006;44(6):740--9.
2. Menitove JE. Process control. Standard for blood banks and transfusion services. 22nd ed. Bethesda: American Association of Blood Banks 2003;11--69.
3. Menitove JE. Assessments: internal and external. Standard for blood banks and transfusion services. 22nd ed. Bethesda: American Association of Blood Banks 2003;93.
4. Holburn AM, Prior D, Whitton CM. The UK national external quality assessment scheme in blood group serology. ABO and D grouping, antibody screening, direct antiglobulin test and antibody identification. Clinical and Laboratory Haematology 1988;10:73--85.
5. Knowles SM, Milkins CE, Chapman JF, et al. The United Kingdom national external quality assessment scheme. Blood transfusion laboratory practice: trends in proficiency and practice between 1985 and 2000. Transfus Med 2002;12: 11--23.
6. Melo L, Pellegrino J Jr, Bianco C, et al. Twelve years of the Brazilian external quality assessment program in immunohematology: benefits of the program. J Clin Lab Anal 2005;19:209--18.
7. Bejrachandra S, Saipin J, Nathalang O, et al. External quality assessment scheme in red blood cell serology: a 5--year experience in Thailand. Immunohematol 2006; 22:1--5.
8. Mintz PD, Anderson G. Comparison of a manual hexadimethrine bromide--antiglobulin test with saline- and albumin-antiglobulin tests for pretransfusion testing. Transfusion 1987; 27:134--7.
9. Fisher GA. Use of the manual polybrene test in the routine hospital laboratory. Transfusion 1983; 23:152--4.
10. Mintz PD, Anderson G. Comparison of a manual hexadimethrine bromide-- antiglobulin test with saline--and albumin--antiglobulin tests for pretransfusion testing. Transfusion 1987 Mar--Apr; 27(2):134--7.
11. Lalezari P, Jiang A.F. The manual polybrene test: a simple and rapid procedure for detection of red cell antibodies. Transfusion 1980 Mar--Apr; 20(2):206--11.
12. Lin M. Compatibility testing without a centrifuge: the slide polybrene method. Transfusion 2004; 44:410--3.
13. Chang JB, Wu TL, Tsao KC,et al. Accreditation of medical laboratories by using ISO15189 in Taiwan: a report of fitness investigation. J Biomed Lab Sci 2007; 19(2):47--55.
14. Brecher ME, Combs MR,, Drew MJ,et al. Initial detection and identification of alloantibodies to red cell antigens. AABB Technical Manual 2002; 411
15. Mina A. A new quality control model using performance goals based on biological variation in external quality assurance scheme. Clin Chem Lab Med 2006;44(1):86--91.
16. Castilho LM, Pellegrino J, Bechelli APP, et al. Evaluation of recent techniques for detection of red blood cell antibodies in sera of reference samples, patients, pregnant women, and blood donors. J Clin Lab Anal 1996; 10:250--256.
17. Engelfriet CP, Reesink HW. What is the best technique for the detection of red cell alloantibodies. Vox Sanguinis 1995; 69:292--300.
18. Knight RC, Silva M. New technologies for red cell serology. Blood Rev 1996;10:101--110.
19. Parham DM. External quality assessment slide schemes: pathologists' experiences and perceptions. J Clin Pathol 2006 May; 59(5): 530--2. Epub 2006 Mar 8.