External quality assessment scheme in red blood cell serology: a 5-year experience in Thailand

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From 2000 to 2004, 36, 58, 72, 78, and 86 laboratories participated in an external quality assessment scheme (EQAS) organized by the Department of Transfusion Medicine, Faculty of Medicine Siriraj Hospital. Each year the staff was requested to perform ABO grouping, D typing, antibody screening, antibody identification, and DATs on eight blood samples. Each participant received information on the correct test results and a coded summary. Regarding ABO grouping, the error rate ranged from 0.3 to 1.3 percent, mostly due to human errors. Error rates in D typing ranged from 0.7 to 5.7 percent, the most problematic being weak D phenotype interpretation. Although every sample was negative by the DAT, error rates due to false positive test results were determined to be 0.4 to 2.1 percent. Antibody screening errors were also found; however, errors steadily decreased from 4.2 percent in 2000 to 0.3 percent in 2004. Only 69.4 to 87.2 percent of laboratories performed antibody identification; however, correct results increased from 78.4 to 91.0 percent. In conclusion, an EQAS in RBC serology should be used to compare results from different laboratories and to identify those laboratories that need improvement in testing procedures. ***Immunohematology* 2006;22:1–5.**

Key Words: RBC serology, external quality assessment, Thailand

Quality assurance in transfusion medicine includes the use of and participation in internal and external quality programs. Quality management is essential to ensure that laboratory performance is reliable and accurate on a daily basis. However, an external quality assessment scheme (EQAS) that compares results from different laboratories is essential to verify the accuracy and reliability of laboratory results.[1-5] This study was undertaken to evaluate RBC serology testing services among hospital blood banks in Thailand.

Among Thai hospital laboratories, the quality assurance program for blood transfusion services was established in 1988. From 1994 to 1997, the Bureau of Laboratory Quality Standards, Department of Medical Sciences, Ministry of Public Health, in cooperation with the Subcommittee on Transfusion Medicine, set up the first proficiency test on RBC serology for hospital blood banks throughout the country. The proficiency testing samples obtained from the National Blood Centre, Thai Red Cross Society, were sent to every member three times per year without charge. At first, all members were requested to perform only ABO grouping and antibody screening tests. Eleven serum samples were sent to 127 blood banks, revealing an overall accuracy of 94.15 percent.[6] Beginning in 2002, D typing and antibody identification tests were also performed. The results of the tests performed were evaluated using target values. Additionally, from November 1996 to August 1997, 20 blood banks in Bangkok were asked to participate in an external quality control study in immunohematology that was organized by the Department of Transfusion Medicine, Faculty of Medicine Siriraj Hospital, Mahidol University. Each blood bank was requested to perform ABO and D typing, antibody screening, antibody identification, and direct antiglobulin tests (DAT) on eight blood samples. Surprisingly, only three public hospital blood banks reported correct results for all tests on every blood sample.

The second external quality assessment program from the Department of Transfusion Medicine, Faculty of Medicine Siriraj Hospital, Mahidol University, started in 2000. In the beginning, 36 laboratories joined the program, with only 13.9 percent of them reporting 100 percent correct results for tests on eight blood samples.[7] Over time, more blood banks joined the program. The number of blood banks participating was 58, 72, 78, and 86 in 2001, 2002, 2003, and 2004, respectively. At the end of each year, our laboratory prepared a list of the errors made by each blood bank and the results were discussed at our annual meeting.

The purpose of the 2000 to 2004 EQAS was to evaluate the efficiency of the blood bank staff who perform routine laboratory tests, such as compatibility

testing, antibody screening, and antibody identification. Analysis of the study results could help blood banks consider more appropriate policies for increasing staff efficiency, performance, and accuracy.

Materials and Methods

Blood samples

For each year in the study (2000 to 2004), eight blood samples were distributed to participating blood banks. The Department of Transfusion Medicine prepared four blood samples and four were prepared by DiaMed AG, Switzerland. Samples were distributed four times per year. Each time, two unknown samples, consisting of 5 ml serum and 5 ml RBC suspension in Alsever's solution, were shipped to participants, packed in wet ice. The samples were distributed by the supplier and each participant received them within 3 days. The participants were instructed to handle these samples as part of their routine work, to have these tests performed by a technician on duty within 3 days after receipt, and to return the results by surface mail or fax within 2 weeks. Late results were not included in the analysis.

Tests performed

Each hospital blood bank was requested to perform five tests using their routine reagents and methods, such as the conventional tube technique or gel test. These tests included ABO grouping, D typing, antibody screening and identification, and a DAT. A result form was developed and used to record the individual hospital test results and the testing method used. The results from all blood banks were compiled and assessed and the correct test results, the individual laboratory performance, and a coded summary of the results of all participants were shared with all participants. This enabled them to have interlaboratory comparison. Additionally, at the end of the year, a summary of each laboratory's performance was reported to the head of the blood bank laboratory and hospital director for each facility. This allowed them to be aware of capacity building needed for laboratory personnel as well as equipment, reagents, and methods used.

Moreover, to educate and increase the awareness of all members, a workshop was set up at the end of each year. Every participant was invited free of charge and a lecture on relevant topics was given. Causes of discrepant results, challenges, and any difficulties occurring during the program were discussed and resolved with an organizing team.

Results

Details of the samples with or without antibody identification distributed in 2000 to 2004 are summarized in Table 1. The number of blood bank laboratories participating in the EQAS on RBC serology from 2000 to 2004 was 36, 58, 72, 78, and 86 for each year, respectively (Table 2). Causes of errors in ABO grouping, D typing, DAT, and antibody screening tests are summarized in Table 3. For ABO grouping, all participants performed both RBC and serum grouping but some errors in reporting still occurred. The error rates for the 5 years were 0.7, 1.3, 0.9, 0.6, and 0.3 percent, respectively (Table 2). Errors in ABO grouping tests were classified as human, misinterpretation, and technical. Human errors included those that occurred because of failure to interpret or record correct test results, inadequate identification of blood specimens such as testing old EQAS samples instead of the current ones, and sample mixups. Errors classified as misinterpretation included those that occurred because of the inability to interpret results because of ABO discrepancies caused by antibodies that went undetected because antibody identification was not performed. Technical errors included those that occurred because of the failure to detect antibodies of the ABO system; positive results were missed. Regarding D typing, error rates were 0.7, 5.7, 2.3, 4.8, and 3.2 percent, respectively (Table 2). The high error rates in the year 2001 and 2003 were due to variation in the reporting of RBC samples with a weak D phenotype as either D– or D+ (Table 3). These errors were classified as those caused by misinterpretation. Again, human errors in this category were caused by a mixup of specimens. Errors classified as reagent errors occurred because some commercial reagents gave strong positive results in the immediate spin phase while others gave negative results. Technical errors included those caused by D– RBCs that were interpreted as D+ or as a weak D phenotype.

Negative DAT results were correctly ascertained; however, error rates due to false positive test results were found to be 2.1, 1.1, 0.4, 1.6, and 1.2 percent, respectively (Table 2). The misinterpretation error that occurred in one laboratory was caused by a mixup between DAT and antibody screening tests results (Table 3). They reported positive DAT results instead of antibody screening results. Errors caused by improper testing procedures that resulted in the reporting of DAT negative samples as DAT positive were classified as technical.

Table 1. Distribution of proficiency testing samples from 2000 to 2004*

	Number of samples				
	2000	**2001**	**2002**	**2003**	**2004**
ABO grouping					
A (12)	2	3	2	3	2
B (9)	1	2	3	1	2
AB (2)	1	0	0	0	1
O (17)	4	3	3	4	3
D typing					
D+ (21)	5	5	4	3	4
D– (12)	2	1	3	3	3
Weak D phenotype (7)	1	2	1	2	1
DAT					
Positive (0)	0	0	0	0	0
Negative (40)	8	8	8	8	8
Antibody screening					
Positive (33)	7	5	8	7	6
Negative (7)	1	3	0	1	2
Antibody identification (33/40)					
Single antibody (20)					
Inhouse (Siriraj)					
anti-E (2)	1	0	1	0	0
anti-P1 (3)	0	1	1	1	0
anti-Mi^a (2)	1	0	1	0	0
anti-M (1)	0	0	0	0	1
anti-D (1)	0	0	0	0	1
Import (DiaMed)					
anti-D (1)	0	0	1	0	0
anti-c (3)	0	1	1	0	1
anti-e (2)	1	0	0	1	0
anti-K (3)	1	0	1	1	0
anti-E (2)	0	0	0	1	1
Mixture of antibodies (13)					
Inhouse (Siriraj)					
anti-D, -Mi^a (1)	0	0	0	1	0
anti-D, -C (1)	1	0	0	0	0
anti-D, -E (1)	0	0	1	0	0
anti-E, -Mi^a (3)	0	1	0	1	1
anti-P1, -Mi^a (1)	0	1	0	0	0
Import (DiaMed)					
anti-D, -Fy^a (1)	0	1	0	0	0
anti-c, -K (2)	1	0	1	0	0
anti-C, -D, -E (1)	1	0	0	0	0
anti-D, -E (1)	0	0	0	1	0
anti-D, -K (1)	0	0	0	0	1

*Number in parentheses is total number of samples from 2000 to 2004.

Errors in antibody screening were also found. Errors rates were 4.2, 1.1, 1.4, 0.8, and 0.3 percent, respectively (Table 2). Errors caused by reagents occurred because inappropriate locally made screening RBCs, which lacked some antigens such as Mi^a, E, K, P1, or M, were used. Therefore, such antibodies could not be detected. Technical errors again included those caused by improper testing techniques that resulted in the reporting of negative antibody screening test results as positive. On the contrary, some positive antibody screening test results were reported as negative even though their screening RBCs contained the specific antigens.

Antibody identification was not routinely performed in all blood bank laboratories participating from 2000 to 2004. In the first year, only 25 out of 36 laboratories (69.4%) performed this procedure. Routinely, the other blood bank laboratories, which did not perform antibody identification, sent the blood samples with positive antibody screening results to the National Blood Centre of the Thai Red Cross Society for investigation and crossmatching. Because of the explanations and recommendations given at the workshop, the number of participating laboratories performing antibody identification increased from 79.3 to 87.2 percent.

The results of antibody identification testing were the most striking. In 2000, among 36 participants, only 78.4 percent reported correct results for all eight blood samples. The correct results increased to 79.1 percent in 2001, 90.7 percent in 2002, 91.0 percent in 2003, and 91.0 percent in 2004, as shown in Table 2. Moreover, due to the workshop discussions on how to decrease errors, the number of participants reporting correct results for all tests on the eight blood samples each year gradually increased: 5 of 36 (13.9%) in 2000, 8 of 58 (13.8%) in 2001, 29 of 72 (40.3%) in 2002, 21 of 78 (26.9%) in 2003, and 37 of 86 (43.0%) in 2004.

Every blood bank laboratory sent one or two members of its staff to attend the end-of-year workshop and each received a certificate of attendance. In addition, an award was given to the blood bank laboratories that reported all results correctly.

Discussion

External proficiency testing programs 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. The proficiency testing samples must be tested with the laboratory's regular patient workload, using routine testing methods. In this study, the organizing team also reported the laboratory performance to the chief of laboratories as well as hospital directors. Therefore, these EQAS help evaluate the performance of procedures, equipment, materials, and personnel of the individual blood bank or transfusion service and suggest areas for improvement.[1-5]

The results of this study indicated that only 13.9 to 43.0 percent of the participating hospitals reported 100 percent correct results for all tests on eight blood samples in each year, which is similar to previous studies' results.[7] ABO grouping errors occurred because of human error in the interpretation of results.

Table 2. Summary of ABO, D, DAT, antibody screening, and antibody identification test results (2000–2004)

Year	N	ABO		D		DAT		Antibody screening		Antibody identification	
		✔	✘	✔	✘	✔	✘	✔	✘	✔	✘
2000	36	93.3	0.7	99.3	0.7	97.9	2.1	95.8	4.2	78.4	21.6
2001	58	98.7	1.3	94.3	5.7	98.9	1.1	98.9	1.1	79.1	20.9
2002	72	99.1	0.9	97.7	2.3	99.6	0.4	98.6	1.4	90.7	9.2
2003	78	99.4	0.6	95.2	4.8	98.4	1.6	99.2	0.8	91.0	9.0
2004	86	99.7	0.3	96.8	3.2	98.8	1.2	99.7	0.3	91.0	9.0

N = number of blood bank laboratories ✔ = correct results (%) ✘ = wrong results (%)

If a patient receives mistyped blood, especially an ABO mismatch, this can result in a life-threatening event. RBC samples that were D– as well as those of the weak D phenotype were also mistyped because of technical errors and result misinterpretation. Moreover, some commercial monoclonal anti-D reagents gave strong agglutination with RBCs of the weak D phenotype. This should be noted because patients with an apparent weak D phenotype who may have a partial D phenotype may be considered D+ and if D+ RBCs are given, anti-D could be made. On the other hand, donor RBCs of the weak D phenotype must be identified as such. RBC products from these donors should be labeled as D+ and given to D+ patients in order to prevent the production of anti-D.[8] Even though some reduction in the number of ABO and D typing test result errors were found, the error rates were still higher than those found in the previous studies in the United Kingdom.[9-10]

The false positive results in the DAT should lead some blood banks to reevaluate their reagents and testing procedures. Because anti-E is one of the common Rh antibodies and anti-K is uncommon among the Thai population, the use of locally made screening RBCs, which lack these antigens, might explain the errors in antibody screening tests and why these antibodies were not identified.[11-14] When the appropriate screening RBCs, which included all clinically significant antigens, and methods, such as saline IAT, enzyme, and LISS IAT, were used, these blood bank laboratories could identify antibodies in other samples containing a mixture of antibodies such as anti-c, -K and anti-E, -Mi[a].

Moreover, for antibody identification of two or three antibodies, such as anti-c, -K, anti-C, -D, and anti-C, -D, -E, only 40 to 80 percent of the hospitals could report the correct antibody specificity. When appropriate panel RBCs and second panel RBCs together with different methods were used, the hospitals could identify these antibody specificities. In Thailand, in addition to inhouse screening and panel RBCs, laboratories can obtain these from the National Blood Centre at a reasonable price. The study showed that errors in antibody identification could not be attributed to the reagents and the reason some laboratories did not perform this test may be due to the policy of those laboratories. However, to differentiate whether there is another antibody in the serum sample or not, extra RBCs of known rare phenotypes are needed. In addition, antigen typing of the patient's RBCs should be performed before reaching any conclusion. Moreover, staff who are experienced with appropriate testing procedures are needed to identify more complex samples.[3,4]

Our results showed the same pattern as that of the National External Quality Assessment Scheme in Blood Group Serology, organized by the Bureau of Laboratory Quality Standards, which sent unknown samples to various blood banks in the country (622 in 2002 and 653 in 2003). They found that among 285 blood banks (51%) who continuously reported test results, 5

Table 3. Summary of the nature of the errors in ABO grouping, D typing, DAT, and antibody screening tests (2000–2004)

	Number of blood banks reporting incorrect results				
	2000	2001	2002	2003	2004
ABO grouping					
Human errors	2	4	1	2	1
Misrepresentation	0	1	2	1	0
Technical errors	0	0	0	0	0
D typing					
Human errors	0	2	0	1	0
Misrepresentation	0	8	4	14	1
Reagents	0	9	2	3	1
Technical errors	2	3	6	7	20
DAT					
Misrepresentation	1	0	0	0	0
Technical errors	4	4	1	7	5
Antibody screening					
Reagents (screening RBCs)	4	0	5	3	2
Technical errors	7	3	2	1	1

percent (15 of 285) and 0.3 percent (1 of 254) had unacceptable results for ABO and D typing tests, respectively. In addition, of the 57.2 percent (163 of 285) and 16.8 percent (48 of 285) of blood banks that reported the results of antibody screening and antibody identification tests, 27 percent (44 of 163) and 73 percent (35 of 48) had excellent results.[15]

In conclusion, internal and external quality assessment programs should be maintained in order to ensure effective transfusion service and safety of patients. In addition to hospital accreditation, the hospital administration should support training and continuing education to improve the ability of the blood bank staff to perform all tests and evaluate their results.

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