

Comments on the participation in proficiency programs and promotion of quality in transfusion services of Minas Gerais

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Conflict-of-interest disclosure:
The author declares no competing
financial interest

Submitted: 1/26/2012
Accepted: 1/27/2012

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DOI: 10.5581/1516-8484.20120005

The paper by Ferreira et al. published in this issue of the *Revista Brasileira de Hematologia e Hemoterapia*⁽¹⁾ provides one of the rare quantitative assessments of the value of test results in external proficiency programs as indicators of quality in transfusion services. Essentially, services that participated in proficiency programs in Minas Gerais had significantly better performance on important immunohematology procedures than services that did not participate. Furthermore, a comparison of general parameters of quality compliance showed better attention to quality practices in the group participating in external proficiency programs than among those who did not participate. Unfortunately, a significant number of blood banks in both groups, participants and non-participants, had performance failures in the proficiency programs.

Historically, external quality control programs in immunohematology, also referred to as proficiency programs, evolved from the initial desire of laboratory scientists to refine the accuracy and precision of their assays. They started sharing and exchanging blood specimens, discussed results at meetings, carried out "wet" and "dry" workshops, participated in working groups and committees, and ultimately defined the quality requirements adopted by standard setting organizations. The organizations established criteria, nomenclature and best practices for the identification of blood group antigens and antibodies that served as the basis for the assurance of immunologically safe blood transfusions.

Despite progress, hemolytic transfusion reactions with tragic consequences continued to occur. Attempting to address this issue, strong willed blood banking leaders developed minimum standards and created voluntary accreditation programs based on inspections to assess compliance of blood banks with these standards. These accreditation programs were implemented in the United States in 1978, when the American Association of Blood Banks added the requirement for an external quality control program to its Standard.⁽²⁾

All blood banks and transfusion services shall utilize a program of quality control that is sufficiently comprehensive to ensure that reagents and equipment perform as expected, and that there is compliance with these Standards. Each blood bank and transfusion service shall participate in a proficiency testing program.

Thus, in order to receive accreditation, blood banks had to correctly identify red cell antigens and antibodies in blind specimens provided by an approved organization. Testing was performed according to the blood bank protocols and results submitted to the agency preparing the specimens. Results were fed back to the blood banks being tested. Unfortunately, as mentioned earlier, there are little published data measuring quantitatively the impact of introduction of accreditation and proficiency programs in the quality of transfusions and prevention of adverse reactions.

The creation and expansion of regulatory agencies by local and federal governments around the world and the common-sense perception that accreditation and proficiency programs improved patient safety, led to the gradual change of these programs from voluntary to obligatory requirements for the operation of a blood bank and transfusion service. In the United States, this became a formal requirement with the approval of the Clinical Laboratory Improvement act of 1988 as part of the Public Health Law. The law essentially determined that clinical laboratories and blood bank laboratories had to be registered with the U.S. Department of Health and Human Services, had to comply with various regulations and could only perform complex tests and be paid if they were registered and passed inspections by the government or by deemed organizations. The successful performance of proficiency tests, e.g., obtaining accurate results on specimens provided by an approved organization became a fundamental requirement. Gone were the days when one blood bank physician could call another blood bank physician to discuss what was wrong with their results and what could be done to improve performance. Every blood bank had to participate in a proficiency program. Failure would mean no reimbursement for services performed and, in extreme cases, loss of the license to operate.

There have been revisions of the law and of regulations over the years,⁽³⁾ but the fundamental requirement for proficiency remains, and certainly the financial penalty of

no reimbursement constitutes an important incentive for compliance.

We all recognize that there has been a substantial improvement in the quality of testing and a reduction of fatal hemolytic reactions over the years and that many factors, including better management systems, computers, training and regulatory actions have contributed to that improvement.

The data presented in the paper by Ferreira et al.⁽¹⁾ clearly shows the value of proficiency programs. However, it is surprising to verify that a large number of laboratories were able to operate despite erroneous results in proficiency testing. Even more surprising is the fact that a large proportion of blood banks failed to participate in the program despite the Brazilian regulatory requirements. The finding that one third of the non-participants obtained inaccurate results in antibody screening and 14.7%, or one in six, had inaccurate results on compatibility testing, the last step in the chain of measures that ensures transfusion safety is very concerning.

I strongly believe that the publication of this manuscript will have a healthy impact on practitioners and regulators inside and outside Brazil. It will contribute to the improvement of transfusion practice in Brazil and will confirm quantitatively the value that good quality systems, good laboratory practices and participation in proficiency programs bring to the safety of transfusion recipients.

References

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