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Consistent accuracy: a goal for thrombosis and hemostasis testing is accomplished using an external quality assurance program

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Editorial

Consistent accuracy: a goal for thrombosis and hemostasis testing is accomplished using an external quality assurance program

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Accuracy of laboratory testing used in the diagnosis and management of thrombotic and hemostatic disorders can be very troublesome. Hemostatic testing has many pitfalls that are common to all sections of the laboratory, as well as a number of issues unique to hemostasis testing that are not seen in other laboratory disciplines (1,2). All aspects of laboratory testing have issues associated with analytical and post-analytical variables but hemostasis has many more issues pertaining to the preanalytical aspects of sample procurement and processing. Another major complexity is in the actual measurement of the end-product (a fibrin clot) which can be ascertained using different analytical endpoints, calculations and technical methods, thus generating different criteria for the clotting endpoint (3). The process of forming a clot includes many enzymatic reactions and potential interfering components that can contribute to an inaccurate result (3). In addition, the results are usually based on arbitrary endpoint units such as time (seconds) or a percent of a local population that can differ in various countries or even regions of a country (3,4). Many results are determined based on secondary endpoints that can also contribute to the cause of a significant error. With all of these variables taken together, it becomes more difficult to assess the result accuracy by individual laboratories with nothing to compare with their result and must assume a consistent and accurate diagnostic and therapeutic result to care for their patient. The lack of internationally accepted reference methods for most tests of hemostasis compounds this difficulty.

Since thrombosis and hemostasis testing is a very difficult arena for the clinical laboratory to maintain consistently accurate results, it requires a concerted effort to maintain a long-term and quality individual laboratory program. Individual laboratories must band together regionally or nationally to ensure their results accurately assess the diagnosis and management of their patients (4). External quality assessment [EQA; or proficiency testing (PT)] portion of a quality laboratory program is directed toward the accuracy of the test result (4-6). Having a good EQA program in thrombosis and hemostasis is paramount to ensuring consistent and accurate results allowing for appropriate diagnosis and treatment of patients. It is extremely important that an External Quality Assessment Scheme (EQAS) be in-place at least regionally (but better if national or even international) to evaluate all of the assays performed in the thrombosis and hemostasis laboratory (7). An EQA program must be available for all laboratories to guarantee the accurate result for the correct diagnosis. If an EQAS program is not available to the local/regional thrombosis and hemostasis laboratories, then developing, implementing and maintaining an EQAS program must be considered.

Developing a new EQAS system in thrombosis and hemostasis can be daunting especially if done from the

Table 1 Reference organizations involved in the development of the guidance document

1. External Quality Assurance in Thrombosis and Hemostasis (EQATH): EQATH.org
2. North American Specialized Coagulation Laboratory Association (NASCOLA): NASCOLA.com
3. External quality Control of diagnostic Assays and Tests (ECAT): ECAT.nl
4. UK National External Quality Assessment Scheme for Blood Coagulation (NEQASCoag): NEQASCOAG.org
5. Royal College of Pathologists of Australasia Haematology Quality Assurance Program (RCPAQAP)
6. Institute for Quality Management in Healthcare (IQMH)
7. College of American Pathologists (CAP)
8. Laboratorio de Evaluacion Externa de la Calidad en Hematologia (LEECH)
9. Indian Society of Haematology and Transfusion Medicine—Christian Medical College EQAS (ISHTM-CMC)
10. Association ProBioqual (The English version of this page is still being developed) ProBioQual
11. Institute for Standardization and Documentation in Medical Laboratories e.V., ehemals Haemometerprüfstelle INSTAND e.V.

ground up. Currently the only guidance documents for establishing an EQAS program are general EQA guidance documents that are not specific for the unique issues associated with thrombosis and hemostasis (7,8). Therefore, since a guidance document for development and implementation of an EQAS program for thrombosis and hemostasis was not available, the External Quality Assessment in Thrombosis and Hemostasis (EQATH) organization has developed one such guidance document specific for clinical laboratory testing in thrombosis and hemostasis (9). The objective of this document is to provide guidance for implementing and operating a regional or national EQAS program specifically for thrombosis and hemostasis testing. This Thrombosis and Hemostasis guidance document is presented as a freestanding article in this journal (9), and can also be found as an internet link embedded in other EQAS organizations specific for thrombosis and hemostasis (see *Table 1*—reference organizations below). The guidance document outlines the major requirements for an EQAS program in thrombosis and hemostasis testing. Specific elements of this EQA Guidance document include: (I) setting up the EQA program; (II) preparation of samples, including plasma selection, pre-testing, aliquoting and packaging; (III) specimen distribution; (IV) data collection; (V) initial analysis of data for quality; (VI) data analysis for acceptability or failure of the participating laboratory's results; and (VII) final report with follow up support and education. Also included in the document are the major components necessary for the operation of the program (personnel, equipment and methods for obtaining and processing samples) and basic methods of data evaluation and result reporting.

The EQATH sub-committee members listed in the document wrote the bulk of the document. Each committee member brings expertise to the document from the perspective of actually overseeing EQA programs while other users are very involved in EQA program utilization or operation. The document was written in alignment with the Clinical Laboratory and Standards Institute (CLSI) and International Standards Organization (ISO) documents with deviations added specific to thrombosis and hemostasis testing (*Table 2*). The document was also reviewed with the opportunity to comment on by numerous other EQA organizations and individuals (*Table 1*).

Regional or national groups interested in starting a thrombosis and hemostasis EQA program can use this document as the basis for establishing a new program. Individuals with questions, issues or needing further help in establishing a program can contact the authors of this commentary or any of the different EQA programs listed in *Table 1*.

Accurate results in clinical testing for thrombosis and hemostasis analytes can be a difficult goal; here, ensuring accuracy of testing relies on a good EQAS. Having access to a reliable program may not be readily available to all laboratories that perform thrombosis and hemostasis testing. As well, accreditation organizations and government regulations may require participation at various levels in an EQAS program. If an EQAS program does not exist or is

Table 2 A summary of other consolatory processes undertaken for development of the guidance document

Document number	Document title
ISO 9000: 2015	Quality management systems—fundamentals and vocabulary
ISO 15189:2012C	Medical laboratories—requirements for quality and competence.
ISO/IEC 17043: 2010	Conformity assessment—general requirements for PT
ISO 13528: 2015	Statistical methods for use in PT by interlaboratory comparison
GP27-A	Using PT to improve the clinical laboratory; approved guideline
MM14-A	Proficiency testing (EQA) for molecular methods; approved guideline

PT, proficiency testing; EQA, external quality assessment.

not available to the laboratories in a region or country, then one may need to be developed. This guidance document (9) provides the background to develop and implement such a program.

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