Quality assurance of the entire diagnostic process: a multi-center study using a case with an acquired Factor VIII Inhibitor

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Objective
External quality assurance programs are essential in guarantying high quality performance of diagnostic laboratories. Until now, the focus of all these programs has been mainly on the analytical performance. The total diagnostic process of patient samples also includes steps that are performed by the clinician, such as diagnosing the patient, choosing the tests and interpreting the results from the laboratory. This phase is mainly not included in external quality assurance programs.
The aim of this study was to study the total testing process, including both medical doctors and laboratories using a patient case with a acquired Factor VIII inhibitor.
Methods
This study was performed in 34 hospitals in the Netherlands, including medical doctors and laboratories. The medical doctor was presented a patient case, filled in a questionnaire and requested laboratory testing. A plasma sample belonging to this patient case was provided to the laboratory. The test results were reported back, and this process was repeated twice, or until the final diagnosis was made.
Results
Thirty hospitals completed the whole study. A variety of laboratory tests was ordered by the physicians, mainly including APTT, APTT mixing study, Intrinsic clotting factors, Factor VIII inhibitor testing, lupus anticoagulant and Von Willebrand Factor. All participants obtained a prolonged APTT in the plasma sample (mean APTT ratio: 2.5). Twenty-four laboratories measured a positive Factor VIII inhibitor. Twenty-eight physicians gave the correct final diagnosis, one physician gave a wrong diagnosis (Von Willebrand Disease) and one physician had even after three cycles not sufficient information to make the final diagnosis.
Conclusion
In conclusion, integrated diagnostic EQA, based on real case scenario's and focussing on the entire diagnostic process, may be an important addition to the current EQA approaches which mainly focus on analytical quality or separate parts of the pre- and post-analytical phase.