Current practice in the pre-analytical phase

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In cooperation with EQALM (European Organisation for External Quality Assurance Providers in Laboratory Medicine), a questionnaire regarding pre-analytical practices on routine coagulation testing (APTT, PT-INR, PT-sec and fibrinogen) was sent by email to European laboratories during the autumn 2013/spring 2014. The aim of the study was to investigate practices in the pre-analytical phase for routine coagulation assays in European countries, to investigate whether the CLSI H21-A5 guideline (2008) was followed and to investigate whether there were other guidelines or studies affecting the routines.
Results: A total of 662 laboratories from 28 different countries responded. The median response rate was 12%, but ranged from 3 – 88%. The response to each question was generally 95-99%. The largest group of responders was non-private hospital laboratories (63%). Of the responders, 55% did only routine coagulation analyses (APTT, PT/INR, Fibrinogen, D-dimer, Thrombin time), while the rest did additional coagulation tests. Citrated tubes of 3.2% were used by 74% of the laboratories. The variation in centrifugation force and duration was very large. Most laboratories had requirements for tube fill volume for regular tubes, and 75% of the laboratories accepted only tube fill volumes ≥ 90%, while about 20% accepted ≥80% and about 5% accepted ≥70%. In contrast, about 40% did not have tube fill requirements for pediatric tubes. More than 80% stated to ask for a new sample if under-filled tubes were received. The requirements for sample stability for citrated blood in room temperature varied significantly for all the parameters studied, and 76% (APTT), 83% (INR) and 50% (fibrinogen) had stability requirements according to the CLSI guidelines of 4 hours, 24 hours and 4 hours, respectively. 70% would reject the samples if not received within the time requirements.
Only a few countries (France and The Netherlands) seem to have a national guideline known by several laboratories. Most laboratories mentioned the CLSI guideline (international). In addition, a few laboratories mentioned recommendations from the British Committee of Standards in Haematology or the WHO guideline from 2002. The content of some of these guidelines do not deal with the issues studied in sufficient detail to be useful in everyday practice in the laboratory.
Conclusion: Large variations in the pre-analytical routines were seen for some of the issues studied. The CLSI guideline from 2008 was not followed by many laboratories in Europe. Several studies have been done since 2008. Should the CLSI guideline be updated on some points? There are a few national guidelines available.