# Have international standards in haemostasis improved comparability of laboratory results?

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Coagulation factors and inhibitors are complex biologicals, the activity of which, cannot be easily defined or quantified by physico-chemical analysis. Similarly, the majority of therapeutics for the prevention and treatment of haemostasis related disorders are biological medicines, either extracted from animal sources or fractionated from plasma or produced by recombinant technology. Activity and potency assignments of these biologicals present different challenges to the estimation of concentrations of chemical entities. The activity of coagulation factors/inhibitors and potencies of these therapeutics can only be accurately measured by bioassays in which the concentration of the analyte is determined by the effect or response it illicits relative to a reference standard. In the haemostasis field, the amount of activity of a coagulation factor or inhibitor is defined as the amount of activity found in normal plasma and can be measured relative to local pooled normal plasma. However, the variability of local normal plasma makes it difficult to compare activity between laboratories and it may also be difficult within a laboratory when different donors are used for the production of different batches of normal pooled plasma. In addition, since there are no established reference methods, assay discrepancies often occur. The World Health Organisation (WHO) establishes International Standards for coagulation factors and inhibitors, value assigned against a large number of local pooled normal plasmas, using multiple methods in multiple centres. The existence of WHO international standards provides a framework for traceability of all secondary and working standards. These internationally recognised common standards have proven to be invaluable in improving the agreement of measurement of haemostasis related analytes within and between laboratories.