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Standardization in the Laboratory Control of Oral Anticoagulant Therapy

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In collaboration with the International Committee for Standardization in Haematology (ICSH), the European Community Bureau of Reference (BCR) has produced three certified reference materials for the standardization of commercial or laboratory-made human, bovine and rabbit thromboplastins, respectively. These reference materials have been calibrated against the WHO international reference preparation (IRP 67/40). By using the appropriate BCR reference material (human, bovine or rabbit) a sensitivity index can be assigned to any thromboplastin working preparation which will thus be directly related to the WHO primary reference preparation.

In clinical practice a prothrombin ratio obtained by means of a thromboplastin reagent with an assigned sensitivity index can then be converted to an international normalised ratio (INR) by a simple equation: $INR = \text{antilog of } (\log \text{ prothrombin ratio} \times \text{sensitivity index})$.

Manufacturers are being encouraged to establish the sensitivity indices of their thromboplastin reagents and to provide appropriate tables of INRs. A therapeutic range for INR of 2.0-4.0 has been recommended.

Details of the scheme have recently been described by E.A. Loeliger and S.M. Lewis (Progress in laboratory control of oral anticoagulants. Lancet, August 7, 1982). Information of the availability of BCR certified reference materials, a report of the certification protocol and recommended methodology for calibration of working preparations are available from the European Community Bureau of Reference, Rue de la Loi 200, Brussels B-1049, Belgium.