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ICSH/ICTH recommendations for reporting prothrombin time in oral anticoagulant control

International Committee for Standardization in Haematology and International Committee on Thrombosis and Haemostasis

To achieve harmonisation in prothrombin time (PT) testing for oral anticoagulant control and thus to ensure reliable oral anticoagulant therapy, the International Committee for Standardization in Haematology (ICSH) and the International Committee on Thrombosis and Haemostasis (ICTH) have agreed on recommendations which are based on the results of international collaborative studies, published in the scientific medical journals[1 2] and in the proceedings of a workshop on thromboplastin calibration.[3] The recommendations are in agreement with those made by the World Health Organization using reference thromboplastins[4 5] based on the primary international reference preparation BCT/253.[6]

It is proposed that manufacturers of thromboplastins used in oral anticoagulant control should indicate the relation of each batch of their material to the WHO international reference preparation by a number which describes the comparative slope (c). This is, at present, referred to by the WHO as the international sensitivity index (ISI).[4] They should also provide a table or graph showing the relation between the conventional terms of expression of results of the PT test and the international normalised ratio (INR). The INR is calculated by the equation: $INR = R^c$, where R is the PT ratio (patient PT: mean normal PT) and c is the comparative slope of the thromboplastin used. Examples of how to present the relation are given in Figs. 1 and 2.

This does not preclude the development or implementation of plasma, synthetic substrates, or other methods of PT standardisation for oral anticoagulant control in the future. In calculating the INR it is important to consider the effect(s) of pretest variables and the type of instrumentation used in the PT determination.

Users of commercially available thromboplastin preparations are urged to follow the manufacturers' recommendations for use of the slope (c) of the thromboplastin to calculate the INR and in patients receiving oral anticoagulant treatment to include this measurement along with their traditional measurement in their reports. This is especially important for the safety of any patient who is likely to be referred to another laboratory where a different modification of the PT test may be used for anticoagulant

ISI = 2·3

Prothrombin time ratio	PT index	Percent activity	INR
1·0	100	100	1·0
1·1	91	74	1·2
1·2	83	57	1·5
1·3	77	48	1·8
1·4	71	41	2·2
▶1·5	67	35	2·5
1·6	62	31	2·9
1·7	59	28	3·4
1·8	56	25	3·9
1·9	53	23	4·4
2·0	50	21	4·9
2·1	48	20	5·5
2·2	45	18·5	6·1
2·3	43	17·4	6·8
2·4	42	16·4	7·5
2·5	40	15·4	8·2
2·6	38	14·6	9·0
2·7	37	13·9	9·8
2·8	36	13·2	10·7
2·9	34	12·6	11·6
3·0	33	12·0	12·5

Patient's prothrombin time: 18s
Normal prothrombin: 12s

Fig. 1 *Example of a manufacturer's table for translating a patient's prothrombin time (PT) into international normalised ratio (INR). The PT index is defined as* $\frac{100}{PT\ ratio.}$ *Percent activity is defined as the concentration (in %) of normal plasma diluted in physiological saline. In this example the INR is obtained by* $INR = (PT\ ratio)^{2·3}$. *Note that this example is valid only for one particular batch of thromboplastin. Different values will be found for other batches and brands.*

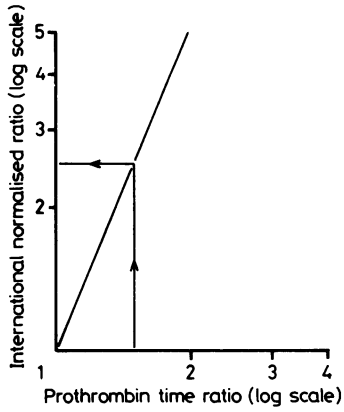

Fig. 2 *Example of a manufacturer's graph for translating a patient's prothrombin time ratio into international normalised ratio. In this example the value of the comparative slope c is 2·3. The straight line represents the equation log INR = log (PT ratio) × 2·3, which is equivalent to INR = antilog [(log PT ratio) × 2·3] or (PT ratio)$^{2·3}$. Note comment in Fig. 1.*

control. The referring laboratory or physician should provide such patients with the INR value of their tested plasma and also, for the present, with the usual measurement (seconds, ratio, index, percentage activity) used in each laboratory where their plasma is tested.

Clinicians and investigators are urged to take into consideration INRs when dealing with intensity of oral anticoagulation. Editors and reviewers of scientific papers are urged not to accept the expression of PT given only in traditional terms.

References

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Requests for reprints to: Dr SM Lewis, Royal Postgraduate Medical School, Ducane Road, London W12 0HS, England.