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Quality Control in Clinical Biochemistry in Developing Countries: Gaps Between Theory and Practice

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Since 1978, the international Federation of Clinical Chemistry (IFCC) has approved several recommendations on "Quality Control in Clinical Chemistry", such as (1) General Principles and Terminology (Clin. Chim. Acta 98, 129F-143F, 1979), (2) Assessment of Analytical Methods for Routine Use (Clin. Chim.Acta 98, 145F-162F, 1979), (3) Internal Quality Control (J. Clin. Chem. Clin. Biochem. 21, 877-884, 1983), and (4) External Quality Control (J. Clin. Chem. Clin. Biochem. 21, 885-892, 1983). But the developing countries were very poorly represented both in the Expert Panel on Nomenclature and Principles of Quality Control in Clinical Chemistry of IFCC, which proposed the recommendation, and the Council of IFCC, which approved it by vote. Should a developing country try to put all the

recommended principles and theories into routine practice, they must expect some problems. Some of the difficulties, but certainly not all of them, are as follows:

(1) Some novel terminology (such as imprecision and inaccuracy) have been recommended. If everyone used such terms, it has some advantage in gaining consistency. However, the more usual terminology may also have the advantage of familiarity. How hard we should try to adopt the newer terminology in full?

(2) According to the recommendation on the "Assessment of Analytical Methods for Routine Use", evaluations of performance should be carried out in all laboratories whenever a new method, instrument or reagent kit is to be adopted for routine use. The full protocol obviously takes much time, skill and resources, which may not be practical for all laboratories in the developing counries. Should there be a simpler approach for laboratories with limited resources? One the other hand, factors other than analytical performance such as the availability of service and spares, stability in high temperatures and humidity, which may be very important in the developing countries, were not considered in the recommendation.

(3) The document on "Internal Quality Control" described the control materials, charting and other techniques in a quite academic approach with little

practical advice on topics such as
(a) how many controls should be run and (b) what levels of control material should be analyzed.
(4) The recommendation on "External Quality Control" also concentrated on academic principles, which may not satisfy the practical needs of a laboratory in the developing countries.

The IFCC is getting aware of the gaps now, and has started to attempt to bridge the gap. In the meantime, the improvement of the quality of clinical biochemistry service in developing countries really depends on the profession within the country. We should very carefully review all the existing documents and recommendations, and make appropiate adjustments, when necessary, before final adoption. And finally, successful advance in quality can be achieved only by "putting theory into practice" with the voluntary consensus of the profession, government, and industry.