Upsala Journal of Medical Sciences

ISSN: 0300-9734 (Print) 2000-1967 (Online) Journal homepage: https://www.tandfonline.com/loi/iups20

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To cite this article: Erik Magid (1993) 6.3.1 Some Concepts and Principles of Clinical Test Evaluation. Classification, Analytical Performance, Monitoring and Clinical Interpretation, Upsala Journal of Medical Sciences, 98:3, 413-414, DOI: 10.3109/03009739309179341

To link to this article: https://doi.org/10.3109/03009739309179341

Published online: 18 Jan 2010.

Upsala J Med Sci 98: 413–414, 1993

6.3.1 Some Concepts and Principles of Clinical Test Evaluation. Classification, Analytical Performance, Monitoring and Clinical Interpretation

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ABSTRACT

A NORDKEM working group consisting of two clinicians (Mogens Christensen and Jens Møller-Petersen) and three clinical chemists (Per Hyltoft Petersen, Per Winkel and myself) have recently completed a monograph with the above title published by NORDKEM in the Scandinavian Journal of Clinical and Laboratory Investigation vol. 52, suppl. 208, 1992. A brief summary is provided below with particular emphasis on specifications of relevance to the clinical use of tests.

Clinical tests are performed in order to reduce uncertainty in preparation of medical decisions. Depending on local circumstances the clinician selects in each situation one or several examinations ranging from questioning and looking for physical signs to complex procedures involving various specialized laboratory or other diagnostic services.

For the clinical chemist a test is usually a measurement of a quantity and the result is expressed as a numerical value multiplied by a unit. Such results can be ranked on an ordinal, interval or ratio scale and are amenable to formal decision analysis and many different types of statistical procedures.

The selection of an appropriate repertoire of tests is the responsibility of the clinical chemists at the level of the individual institutions. Progress with respect to optimization of the repertoire must rely on systematic evaluations of the clinical properties of tests in their actual clinical setting. There are many difficulties inherent in clinical test evaluation. Obstacles must be overcomed through extensive cooperation with the clinicians and with colleagues from other fields of laboratory medicine. It is also necessary to further develop

the theory of test evaluation and to implement the concepts into clinical practice.

An essential function of clinical chemical tests is to classify: into disease or non disease, into degree of function, into poor or good prognosis, into change or no change in a time series, etc. High clinical utility is linked to the ability of the test to classify with minimal uncertainty. Quantitative data characterising this function should be made more readily available and incorporated into routine diagnostic procedures.

It is important to realize that the ability of clinical chemistry measurements to contribute to clinical decision making is dependent on 1) the analytical quality of the measurement procedure, 2) the clinical target population, 3) the choice of discrimination values and 4) the "gold standards" according to which true classifications can be realized and used as references. Specifications for clinical chemistry tests must comprise all of these variables in order to be complete.

The monograph comprises a detailed description of basic terms in clinical test evaluation. The design and phases in test evaluation are discussed. A separate chapter deals with the influence of analytical quality on the interpretation of test results. Finally some of the problems involved in interpreting serial measurements are addressed.

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