6. Summary

Introduction

Results of laboratory examination are an essential, integral part of all areas of modern medicine. Data provided by Medical Diagnostic Laboratories are necessary in diagnosing diseases, monitoring the effectiveness of applied therapies and carrying out effective and comprehensive preventive programs. The diagnostic usefulness of the results of laboratory examination is strictly dependent on their possibility to distinguishing between health and disease condition and evaluation of the intended effects of therapeutic interventions. For this purpose, it is necessary to compare the obtained laboratory results to values that are taken as reference (characteristic) intervals. The main difficulty in obtaining a reference value is the physiological biological variability of all laboratory parameters.

Therefore, it is necessary to conduct research aimed at characterizing the distribution of values for diagnostically important components of body fluids and tissues in various patient populations. The tool for this purpose is the evaluation of the characteristic values of laboratory parameter and determining the intervals in which a given value occurs with a certain probability.

The knowledge of the variability of the values (distribution) of the studied parameters in specific populations is used not only to distinguish between health and disease, but also to identify risk factors for the development of diseases in the future. Continuous determination and monitoring of changes in parameters describing the distribution of laboratory parameter values is the basis for the progress and development of laboratory methods.

Objectives

The aim of the study was the evaluation of the variability of selected laboratory parameters in the population of patients hospitalized at the University Clinical Hospital in Wroclaw. For this purpose patients' non-selected laboratory examination results from approximately 4 years of laboratory work were assessed, taking into account sex and age. The characteristic values were estimated using the indirect modified Hoffman method.

The aim of the study has been achieved by searching for answers to the following research questions :

1) Can the indirect methods of statistical analysis of laboratory test results, regardless of the reason for patient's hospitalization, be used to characterize and evaluate the variability of these parameters without additional financial and organizational costs ?

2) Are the obtained values defining lower and upper ranges of characteristic results comparable with the values reference intervals provided by the manufacturers of reagent kits and data from the literature?

3) Can the results of determinations of routine laboratory parameters be used to assess the stability of laboratory measuring systems over a long period of observation ?

Material and Methods

Almost 800,000 values of test results from the Laboratory Information System of the Department of Laboratory Diagnostics University Clinical Hospital in Wrocław were included in the study. Retrospective analysis included the numerical values of non-selected results of TSH, fT3, fT4, LDH,

uric acid, AST, ALT, along with information on the age and sex of patients and the date of the analysis. For most parameters, the data collected from the Laboratory Information System came from the period of 45 months - from September 2015 to May 2019.

Results

No significant differences were found between the values characteristic for individual age groups determined by the Hoffman method and in relation to the values provided by the manufacturer of the reagents for 2 out of 7 analyzed parameters: fT4 and ALT. Differences only in relation to individual age groups were observed for TSH and AST, while significant differences in relation to both: age groups and the values provided by the manufacturer of reagents were revealed for fT3, LDH and uric acid. In the analysis taking into account subsequent age groups, significant changes occurred most often in the pubertal period, i.e. from 12 years of age (LDH, uric acid, AST). The ranges of the characteristic values for subsequent age groups showed a decrease for TSH, fT3 and LDH, while the values of the characteristic ranges for uric acid systematically increased with the age of the patients. The ranges of values characteristic for fT4 were characterized by no changes in subsequent age groups, while for ALT higher values were observed in the youngest and oldest age groups. The analysis of the moving average control charts showed the complete absence of alarm signals for fT3 (in the 14-month observation period) and ALT (throughout the observation period). Single significant deviations were found for moving averages of parameters such as TSH, AST, LDH, which were not accompanied by alarm signals for the precision of the method. The highest number of alarm signals was observed for fT4 and uric acid.

Conclusions

The variability of the values distribution determined by the Hoffman's indirect method for most of the analyzed parameters shows significant differences compered to values supplied by the manufacturers and the values determined by indirect methods available in the literature.

The variability of characteristic values was demonstrated for all analyzed parameters in individual age groups and by sex.

Ranges of characteristic values determined by the Hoffman's indirect method may constitute the basis for determining the reference intervals dedicated to the Department of Laboratory Diagnostics the University Clinical Hospital in Wrocław.