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Update article

Are the review criteria for automated complete blood counts of the International Society of Laboratory Hematology suitable for all hematology laboratories?

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ABSTRACT

Objective: to verify whether the review criteria for automated blood counts suggested by the International Consensus Group for Hematology Review of the International Society for Laboratory Hematology are suitable for the Hematology Laboratory of Hospital de Clinicas, Universidade Federal do Paraná.

Methods: initially, the review criteria of the International Society for Laboratory Hematology were adapted due to limitations in the Institution's electronic hospital records and interfacing systems. The adapted review criteria were tested using 1977 samples. After this first assessment, an additional 180 inpatient samples were analyzed to evaluate the screening criteria of the review criteria in conjunction with positive smear findings established by the institution. The performance of the review criteria was verified by determining false positive, false negative, true positive and true negative rates, sensitivity, specificity, positive predictive value, negative predictive value, microscopic review rate and efficiency.

Results: initial analysis showed false negatives = 6.73%, false positives = 23.27%, microscopic review rate = 46.03% and efficiency = 70.0%. An evaluation of the screening criteria adapted from the review criteria together with the positive smear findings of the institution showed false negatives = 15.5%, false positives = 10.5%, microscopic review rate = 37.3% and efficiency = 73.8%. In both situations the safety limit (false negative <5%) recommended by the review criteria was exceeded.

Conclusions: the review criteria adapted from the International Society for Laboratory Hematology are neither suitable nor safe for use in the hematology laboratory of the Hospital de Clinicas. This implies a need to develop and validate institution-specific review criteria in order to decrease false negative results to an acceptable and safe rate for patients.

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Introduction

In 2005, the International Society for Laboratory Hematology (ISLH) through the International Consensus Group for Hematology Reviews, founded by hematologist Berend Houwen, published a set of 41 rules applicable as criteria for the review of automated complete blood counts (CBCs) and leukocyte differential results of automated hematology analyzers, i.e., review criteria for automated complete blood counts (RC).[1] These guidelines were formulated with the aims of reducing costs and the turnaround time of the results without sacrificing their quality, and justifying the performance and skills of the multiparametric hematology analyzers.[2–4] Since then, the rules suggested by the ISLH[2] have been considered the international standard to indicate situations requiring a blood smear review (BSR). They take into account the age and gender of patients, whether the request for CBC is the initial or a subsequent one to monitor CBCs, or whether there are significant differences between the current results, and previously validated and released results.[2,4] In practice, they are based on the set of screening thresholds for the results given by the analyzers and in the presence or absence of suspect flags. The aim is to distinguish samples with a high probability of containing relevant morphological alterations for the diagnosis and treatment of patients. When the CBC results do not meet the screening criteria, there are recommended procedures to follow, specifically to prepare an adequate peripheral blood smear for microscopic analysis.[2]

Hospital de Clínicas of the Universidade Federal do Paraná (HC-UFPR) is a general Class IV hospital according to the hospital classification system of Brazil's publically funded healthcare system (SUS); it is the largest provider of government healthcare services in the State of Paraná with 510 beds. Moderately to highly complex procedures are carried out in 59 departments. Approximately 61,000 consultations are made per month. The clinical hematology laboratory is located in the Diagnosis Support Service and contains two types of hematology analyzers: the Sysmex XE-2100D and XT-2000i (Sysmex Corporation, Kobe, Japan). Approximately 500 samples are sent for CBCs daily. Prior to the development of the RC, 100% of CBCs were analyzed microscopically, which led to delays in the release of the results even when performed by experienced professionals.

According to Bain[5] because BSRs and manual differential leukocyte counts (MDLCs) are laborious and expensive, they should be based on the RC. Thus, all hematology laboratories must be encouraged to establish locally valid protocols indicating when a BSR and MDLC should be performed. The guidelines suggested by the ISLH can be the starting point as long as they are interpreted in consideration of the experience of the laboratory staff, sophistication of the hematology analyzers and the laboratory's electronic records system, and incidences of abnormalities and variations in reference values of the population being tested.[6,7] Thus, this study evaluated the implementation of the RC suggested by the ISLH in the HC-UFPR Hematology Laboratory in order to determine automated thresholds such that microscopic analyses are performed only under special circumstances. In addition, the study aimed to define whether such guidelines could be tailored to the population served or whether there is a need to establish and evaluate specific RC for this Institution.

Methods

Study site and sample preparation

The investigation was conducted in the Hematology Laboratory of HC-UFPR after approval by the local Ethics Committee. The samples were obtained in two stages. First, for five consecutive days, all laboratory samples were collected after the release of the results into the electronic hospital records system. A total of 1977 whole-blood samples in ethylenediaminetetraacetic acid (EDTA)-K_2 (1.8 mg/mL) were analyzed within 3 h of collection. Of these, 1573 and 404 were analyzed using the XE-2100D and XT-2000i hematology analyzers, respectively. Furthermore, to evaluate the screening criteria adapted from the ISLH together with positive smear findings (PSFs) of the HC-UFPR, an additional 180 inpatient samples were collected randomly and analyzed using the XT-2000i device; these samples were more likely to have PSFs because they also had abnormal CBC results. The PSFs elaborated by the HC-UFPR were intended to ensure clinically significant abnormalities were not omitted from the results, thereby establishing a minimum threshold of information that should be reported in the CBC results according to local consensus. All numerical data and information from suspect flags and blood smear findings were recorded. Approximately 70% of the samples tested were from outpatients, many of whom were having their first blood count. The other 30% were from inpatients from various hospital units (e.g., hematology, chemotherapy, infectious diseases, intensive care units, emergency care), many of whom had their blood counts monitored daily.

Adaptation of the review criteria of the International Society for Laboratory Hematology according to local requirements

In order to determine whether the performance of these RC met local requirements or indicated the need to develop specific RC, the screening criteria and PSFs suggested by the ISLH were initially evaluated. However, changes were made to tailor the ISLH screening criteria to the hematology analyzers used in this study and particularly to adapt them to the electronic hospital records system. The main adaptations were associated with Delta Check rules, which were not possible to implement because of limitations of the institution's electronic hospital records and interfacing systems. The adapted ISLH screening criteria concerning the possibility of local implementation are shown in Table 1. Table 2 shows the PSFs recommended by the ISLH.[2] PSFs that differ from those recommended by the ISLH were also created for the HC-UFPR (Table 3) in an attempt to meet local requirements.

Sample classification criteria

The criteria followed to select samples for review were compared with the findings of the peripheral BSR. A sample was classified as true positive (TP) if it was positive for a particular