題名:Study on Establishing the Criteria and Parameters for Autoverification of Numerical Clinical Laboratory Test Results
數值型檢驗報告自動驗證判斷準則參數之研究

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摘要:檢驗結果自動驗證(Autoverification)是指利用電腦來執行臨床實驗室判斷準則與邏輯自動核發檢驗結果報告。目前台灣大部分的醫院臨床檢驗部門均已建置檢驗資訊系統，且與檢驗儀器完成雙向連線，大幅增進檢測分析能力和加速完成檢驗結果。然而，檢驗結果報告的發放速度卻一直無法隨著資訊化的腳步獲得改善。究其原因主要在於檢驗結果的發放仍需依賴檢驗師逐筆人工閱覽驗證後核放，既耗時又費力。而且，臨床檢驗部門又面臨著經費減少、醫檢人力緊縮和檢驗業務量日益增加的壓力；爲了降低實驗室檢驗報告的錯誤百分比及提升臨床醫療服務品質，檢驗結果驗證自動化勢在必行。檢驗結果報告自動驗證不僅可改善報告核放速度，且可降低報告錯誤百分比和縮短報告完成時間(Turnaround Time)。本文主要提出方法，針對生化檢驗項目，利用病人檢驗歷史資料和實驗室品質管理規範，來建立數值型檢驗報告自動驗證判斷準則參數的設定，包括自動驗證範圍值(Autovalidation range)、差值比對範圍值(Delta check range)、差值絕對值基準值、以及高、低差值百分比係數等。本文並以鈉離子(Sodium, Na(上標 +))爲例，採用Excel(上標 TM)進行試算決策，展示自動驗證判斷準則參數的設定方法，建立參數組合。本研究所建立的各項驗證判斷準則參數，不但考慮了實驗室服務病患的族群特性，而且也納入實驗室本身品質管理的差異性，因此，可以讓實驗室主管對各項設定的參數更有信心，對於推動檢驗結果報告自動驗證的上線作業也將更爲容易。
Autoverification or automated verification of clinical laboratory test results means to use a computer system to implement the established criteria and logic for clinical laboratory practice to release the test results to medical records automatically. In nowadays Taiwan, most clinical laboratory departments of hospitals have developed their laboratory information systems (LISs),

and established two-way communications between the LISs and analytical instruments. It has largely enhanced the analysis capability and speeded up test result productivity. However, the speed of release of the test results has not followed the speed of improvement in LISs because the release of test results still relies on medical technologist manually, which is time consuming and needs lots of effort. Moreover, the clinical laboratory departments face the problems of spending cut-down, shrinking of medical laboratory manpower, and increasing the test volume. Hence, autoverification would be a good choice to speed up the release of test results, and lower the percentage of mistake of the released results. This paper presents methodologies to establish criteria and parameters for auto-verification of test results with numerical type for a clinical laboratory by using the historical patient population patterns and standards of quality management of the laboratory. The criteria and parameters include autovalidation range, delta check range, the baselines of delta difference check, Delta absolute value and the high and low coefficients of delta percent change. In this paper, we present examples, and use Excel(superscript TM) as a tool to demonstrate the establishment of criteria and parameters for autoverification of Sodium (Na(superscript +)) test results. In our approach, we consider not only the patient population characteristics but also the standards of quality management of a laboratory to establish autoverification criteria and parameters for a test item. Therefore, the established autoverification criteria and parameters should be easy to understand, and this can encourage the laboratory managers to implement autoverification online in release of test results.