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Titel des Beitrags: Performance evaluation of the new CoaguChek XS system compared with the established CoaguChek system by patients experienced in INR-self management.

Abstract: The aim of the study was to analyze the concordance of INR values obtained by educated lay users with those obtained by professionals and to determine the imprecision of the new system. The new CoaguChek XS system was tested in a user study over six weeks at four study centres in Austria, Denmark and Germany. Seventy-five patients receiving oral anticoagulant therapy were enrolled in the study. The INR results in capillary whole blood taken by professionals and by patients using the CoaguChek XS system were similar, and the mean relative bias was <1%. The imprecision of the CoaguChek XS system calculated from duplicate testing is low (<6%) and slightly better than for the established CoaguChek S system. The INR results measured during the home testing phase correlated quite well between the established CoaguChek S system and the new CoaguChek XS system with a mean bias of 0.14 INR. This is a remarkably low bias taking into consideration that more than 30 different test strip lots were applied. A questionnaire was filled out by all patients to assess their personal impression. It revealed that patients were very satisfied with the new system and found it easy to operate. The results demonstrate that the agreement between professional and patient INR results for the new CoaguChek XS system was excellent and that INR values can be
determined by lay users as well as by professionals. The instrument is very well accepted by the patients and their satisfaction even increased after four weeks practice at home.

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