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| Manuscript – Letter to the editor  |
| Accuracy of the point-of-care coagulometer CoaguChek XS in the hands of patients  |
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| Financial support | none |
| Conflict of Interest | none |
| Word count | 1189/ 1500 |
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| Running Title | Accuracy of CoaguChek XS in the hands of patients |
| Keywords | point-of-care, diagnostic accuracy, international-normalised ratio |

Dear Editor,

In a recent systematic review published in the Journal, Christensen et al. found no high-quality papers assessing the diagnostic value of point of care testing (POCT) coagulometers when used by patients, and they concluded that the question of accuracy remains open in this setting [[1](#_ENREF_1" \o "Christensen, 2012 #2024)]. Stimulated by this excellent report, we present the results of an investigator-initiated, non-sponsored diagnostic study investigating the concordance of INR values determined by patients using the POCT coagulometer CoaguChek XS® (Roche Diagnostics, Basel, Switzerland) and determined by certified laboratories using an established reference method.

In this paper we defined precision as the extent of reproducibility of a test result (influenced by analytical precision, biological variation and pre-analytical factors) and accuracy as the extent of agreement between an index test and a reference test (analytical accuracy) or the true illness state (diagnostic accuracy) [[1-4](#_ENREF_1" \o "Christensen, 2012 #2024)]. To assess whether diagnostic accuracy was sufficient, we applied the trade-offs proposed earlier [[1](#_ENREF_1" \o "Christensen, 2012 #2024), [5](#_ENREF_5" \o "Anderson, 1993 #2045)].

We analysed data of all patients who had received training and were performing patient self-management (PSM) within the "Coagulationcare" initiative in Switzerland between 2006 and 2009 (about 90% of PSM patients in Switzerland) [[6](#_ENREF_6), [7](#_ENREF_7)]. At the check-up visit one to three months after the PSM training, patients tested their INR value themselves. Second, venous blood samples were taken within one hour and the prothrombin time was determined in the laboratory of each training centre (the tertiary care hospitals of Lucerne, Berne, Basel and Zurich), using a one-stage clotting assay employing the reagent Innovin® (Siemens Healthcare Diagnostics AG, Zurich, Switzerland; ISI 0.96—0.99) on STA-R® coagulation analyser (Roche diagnostics AG, Rotkreuz, Switzerland), BCS® or BCS-XP® coagulation analyser (Siemens Healthcare Diagnostics AG, Zurich, Switzerland). Calibration to ISI standards was done with each batch of the Innovin® reagent using the InnoCal Set (Siemens Healthcare Diagnostics AG, Zurich, Switzerland). Standard measures of agreement were used to examine the extent of concordance [[1](#_ENREF_1" \o "Christensen, 2012 #2024), [5](#_ENREF_5" \o "Anderson, 1993 #2045), [8](#_ENREF_8" \o "Douketis, 1998 #2047)]. Statistical analysis was performed with the MedCalc software (Version 12.2.1.0, Mariakerke, Belgium).

INR data on 534 out of 657 patients trained were available; 21 (3.2%) had not yet started PSM, and 102 (15.5%) did the check-up visit with the family physician. Median age was 54.1 years (range 16.2 – 85.1), and 169 were women (31.6%). Indications for oral anticoagulation (OAC; almost exclusively phenprocoumon) were: venous thromboembolism (n=219; 41.1%), prosthetic heart valve/aortic graft (n=154; 28.9%), atrial fibrillation (n=112; 21.0%), arterial thromboembolism (n=21; 3.9%) and others (n=28; 5.2%). All applied measures revealed a good level of agreement with regard to mean difference, limits of agreement, magnitude of difference, and concordance (Fig. 1). Based on high-quality criteria established before [[1](#_ENREF_1), [5](#_ENREF_5)] – a large number of measurements, controlled laboratory as comparator, use of reputable accuracy criteria, not industry-sponsored – our investigation shows that the accuracy of CoaguChek XS is adequate for clinical use if used by patients to determine their INR value by themselves.

This report closes a relevant gap in evidence that has been identified in a recent review published in the Journal [[1](#_ENREF_1)]. Our results are in line with previous investigations that found a good to acceptable, but somewhat inconsistent accuracy of CoaguChek XS [[1](#_ENREF_1), [9-15](#_ENREF_9)] in the hands of medical staff. In conclusion, the CoaguChek XS is a reliable instrument in POCT and of value in patient self-management of oral anticoagulation.

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Legend to the figure:

**Accuracy of the POCT coagulometer CoaguChek® XS if used by patients to determine their INR values by themselves. (A)** Accuracy criteria and corresponding results. Criteria for concordance (narrow) are fulfilled if both measurements are within the target range, or if both are above the range and the difference is maximal 0.8 units, or if both are below the range and the difference is maximal 0.4 units, or if one measurement is within the range and the difference is maximal 0.5 units (\*). Criteria for concordance (expanded) are fulfilled if both measurements are within the target range, or if both are below the target range, or if both are above the target range, or if one measurement is within the target range and the difference is maximal 0,5 units (+). **(B)** Scatter diagram with Passing & Bablok regression line (solid line) and identity line (dotted line). **(C)** Bland-Altman difference plot. Horizontal lines are drawn at the mean differences and the limits of agreement (± 1.96 standard deviation).