Analytical performance, agreement, and user-friendliness of automated POCT urine test strip analysers, and a comparison between man and machine.

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Objective Urine analysis is a widely used diagnostic procedure in general practice, most commonly used for the diagnosis of urine tract infection (UTI). Point of Care testing (POCT) analysers for urine test strip analysis are commercially available for use in general practice. The procedure of automatic reading through POCT analysers is less susceptible for erroneous labelling and registration of test results in the medical record of the patient compared to manual handling and could therefore enhance patient safety. We compared analytical performance, agreement, and user-friendliness of six different automated urine strip POC analysers in a laboratory setting. Subsequently we selected one analyser to study the diagnostic performance of automated versus traditional visual urinalysis in general practice.

Method The following six analysers were evaluated in the laboratory: Uryxxon Relax (Machery Nagel), Urisys 1100 (Roche), Clinitek Status (Siemens), Aution 11 (Menarini), Aution Micro (Menarini) and Urilyzer (Analyticon). Results were compared to a laboratory reference standard urine analyser, the Urisys 2400 (Roche). Analytical performance and agreement with the laboratory standard was analysed and user-friendliness was evaluated. Additionally analytical performance of both automated (Urisys 1100) and visual urinalysis in general practice was compared to the reference laboratory standard.

Results Analytical performance was good for al six urine test strip POCT analysers. Compared to laboratory reference standards, overall agreement was good, but differed per parameter and per analyser. Concerning the nitrite test, the most important test for clinical practice, all but one showed perfect agreement with the laboratory standard. For leucocytes and erythrocytes specificity was high, but sensitivity was considerably lower. First-time users found the different urine test strip POCT analysers easy to use. The susceptibility to flaws was considered low. First-time users were overall positive about the increase in productivity, effectiveness, and accuracy by using a urine test strip POCT analyser. Automated urinalysis by experienced and routinely trained practice assistants in general practice performs as good as visual urinalysis for nitrite, leucocytes, and erythrocytes.

Conclusions The overall performance of all six commercially available urine test strip POCT analysers in the laboratory was sufficient to justify routine use in general practice. First-time users indicate that the analysers are easy to use and expect higher productivity and accuracy when using these analysers in daily practice. Automated urinalysis performed as good as traditional visual urinalysis on reading nitrite, leucocytes, and erythrocytes in routine general practice. Implementation of automated urinalysis in general practice is justified as automation is expected to reduce human errors in patient identification and transcribing of results.