

## Creatinine point-of-care testing for detection and monitoring of chronic kidney disease:

primary care diagnostic technology update

### Clinical Question

What is the accuracy and utility of creatinine point-of-care (POC) tests in the detection and monitoring of chronic kidney disease (CKD), compared with standard practice using laboratory blood tests?

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### ADVANTAGES OVER EXISTING TECHNOLOGY

Creatinine point-of-care (POC) testing could facilitate primary care chronic kidney disease (CKD) screening, allowing rapid results and immediate feedback to patients. Up-to-date renal function testing would allow immediate adjustment of medications excreted via the kidneys in patients with renal impairment.<sup>1</sup> Creatinine POC testing allows patients to monitor their renal function at home, facilitating more frequent testing and earlier detection of deterioration.

### DETAILS OF TECHNOLOGY

We identified 10 creatinine POC devices, allowing rapid measurement of creatinine levels from fingerprick blood samples; a summary of these can be found on the Diagnostic Evidence Co-operative Oxford website.<sup>2</sup>

### PATIENT GROUP AND USE

- Screening for CKD in high-risk patients.
- Adjustment of doses of renal-excreted medication and monitoring renal function in patients with CKD.
- Detection of acute kidney injury and acute-on-chronic renal failure.

### IMPORTANCE

CKD has an annual incidence rate of 1701 per million population in the UK and a prevalence of 6%. Incidence increases with age; >2% of the NHS budget is spent on renal replacement therapy. The National Institute for Health and Care Excellence emphasises early detection through screening at-risk groups.<sup>3</sup>

### PREVIOUS RESEARCH

#### Accuracy compared with existing technology

Most studies found creatinine POC devices to be reliable alternatives to laboratory

testing; however, some noted a tendency of devices to underestimate renal impairment,<sup>4–6</sup> as well as poor inter-device concordance.<sup>7</sup>

A study comparing creatinine levels from two Nova StatSensor™ devices against laboratory values in 401 consecutive patients undergoing contrast CT scans showed that correlation between the two POC devices differed between the two study centres (mean  $r=0.93$ ,  $P<0.0001$ ; versus mean  $r=0.84$ ,  $P<0.0001$ ).<sup>8</sup> But there were significant differences between creatinine levels measured by POC and laboratory methods (overall  $r=0.89$ ;  $P<0.0001$ ), with better correlation with normal renal function (venous creatinine level  $<106\ \mu\text{mol/L}$ ,  $r=0.91$ ) compared with impaired renal function (venous creatinine level  $\geq 106\ \mu\text{mol/L}$ ;  $r=0.63$ ).

A study of 100 patients<sup>6</sup> evaluating the Nova StatSensor in community CKD screening found a 13% false negative rate for detecting estimated glomerular filtration rates (eGFRs)  $<60\ \text{mL/min}$  using the Nova StatSensor compared with laboratory methods, meaning these CKD patients would be missed in screening.

The eGFRs calculated from Nova StatSensor creatinine values were compared with laboratory measurements in 113 patients undergoing contrast enhanced radiology scans.<sup>4</sup> The mean POC creatinine value was lower than the laboratory value:  $62.8\pm 17.6\ \mu\text{mol/L}$  (range 30–121) versus  $72.5\pm 21\ \mu\text{mol/L}$  (range 36–142) ( $P<0.0001$ ). Another study<sup>5</sup> comparing Nova StatSensor creatinine values with laboratory analysis in 161 patients (non-, pre-, and post-dialysis) found good concordance ( $R^2=0.9328$ ). Although creatinine POC values were consistently lower than laboratory measures, the authors concluded that the device provided reliable measurement across a clinically relevant range.

Correlation between eGFRs (CKD-EPI formula) calculated from creatinine values generated by the POC i-STAT and

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laboratory values<sup>9</sup> using 40 anonymised samples showed excellent inter-device agreement ( $R^2 = 0.99$ ), with an average bias of  $-2.18 \text{ ml/min/1.73 m}^2$ .

In a radiology department, creatinine values from 31 blood samples were compared using the i-STAT and central laboratory values<sup>10</sup> and showed excellent correlation;  $R^2 = 0.99$ . The authors concluded that i-STAT POC devices could help improve efficiency, providing accurate, up-to-date creatinine/eGFR values in patients presenting for scans requiring contrast media.

### Impact compared with existing technology

In a screening study of individuals at high risk of CKD (previous diagnosis of diabetes or hypertension, age >50 years, first-degree relatives with end-stage kidney disease), using POC creatinine, proteinuria, haematuria, and albuminuria testing, findings suggestive of CKD were identified in 20.4%.<sup>6</sup> Regarding acceptability, 99% found it convenient, and 96% felt immediate results and feedback helped them understand their condition.

In a Dutch community pharmacy setting,<sup>1</sup> 46 older individuals using renal-excreted drugs for diabetes or cardiovascular disease underwent creatinine POC testing, with subsequent dose adjustment of renal-excreted medications when creatinine levels were elevated. Of the 44 patients that underwent creatinine POC testing, 24 were eligible for dose adjustment and acceptability of POC testing by the study population was good.

### WHAT THIS TECHNOLOGY ADDS

Creatinine POC tests could be integrated into a primary care initiative, with an annual (or more frequent) creatinine POC test for high-risk patients, allowing immediate

action on significant results. Creatinine POC testing in primary care could make for safer prescribing, theoretically reducing inappropriate prescription or dosages of medications excreted via the kidneys. However, there is currently no robust evidence that is able to demonstrate the technology's impact on patient outcomes and service delivery, including negative and unforeseen consequences.

### Methodology

Standardised methodology was applied in writing this report, using prioritisation criteria and a comprehensive, standardised search strategy, and critical appraisal. Full details of these are available from: <http://madox.org/sites/default/files/pdf/methods-horizon-scanning-reports.pdf>. The search for this article was conducted in December 2013.

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### Competing interests

The authors have declared no competing interests.

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