Point-of-care testing for patients with diabetes, hyperlipidaemia or coagulation disorders in the general practice setting: a systematic review

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CRD summary
The review assessed the clinical effectiveness of point-of-care testing for monitoring patients with diabetes, hyperlipidaemia or coagulation disorders in general practice; it concluded that there was no robust evidence that point-of-care testing in general practice improved patient health outcomes. The authors' cautious conclusions reflected the limited evidence presented and are likely to be reliable.

Authors' objectives
To assess the clinical effectiveness of point-of-care testing for monitoring patients with diabetes, hyperlipidaemia or coagulation disorders in general practice.

Searching
The following databases were searched without language restrictions from 1966 to 2007: PubMed, EMBASE, CINAHL, Current Contents, BIDS and the Cochrane Library. Search terms were reported. The following journals were handsearched from January 2007 to November 2007: British Medical Journal, Clinical Chemistry, Journal of Near Patient Testing and Technology, and British Journal of General Practice. Reference lists of relevant publications were screened. References of a previous systematic review and relevant book were also screened. The study authors were contacted for additional studies. Conference abstracts were excluded.

Study selection
Randomised controlled trials (RCTs) or quasi-randomised trials that compared point-of-care testing with usual care (defined as testing in a conventional pathology laboratory setting) in adults (at least 18 years old) that were treated for diabetes, hyperlipidaemia or were receiving anticoagulant therapy, in a general practice setting, were eligible for inclusion.

The review outcomes included improvement in health outcomes, change in patient management as a result of the immediate information provided by point-of-care testing, analytical performance (accuracy of point-of-care versus the equivalent laboratory test), patient satisfaction, and health professional satisfaction.

Half of the included trials evaluated the point-of-care testing in patients receiving anticoagulant therapy. Most of the included trials assessed point-of-care testing in combination with another intervention (e.g., education or computer decision support). The mean age of patients in included trials ranged from 61 to 70.2 years (where reported). The included trials were conducted in the UK, USA and Belgium.

Two reviewers independently assessed studies for inclusion.

Assessment of study quality
The quality of trials was assessed using criteria on bias (selection bias, performance bias, attrition bias and detection bias), and internal/external validity and relevance. The trial quality was classified as low risk of bias (met all the above criteria), moderate risk of bias (one or more criteria moderately met) or high risk of bias (one or more criteria not met).

Two reviewers independently performed validity assessment, with any discrepancies resolved by discussion.

Data extraction
The authors did not specify what data were extracted.

Two reviewers independently performed data extraction.
Methods of synthesis
The trials were combined in a narrative synthesis, supported by accompanying data tables.

Results of the review
Six trials, detailing nine publications (n=3,885 patients), were included in the review; eight publications were RCTs. All the trials were classified as having moderate risk of bias. The follow-up duration ranged from 188 days to 12 months (where reported).

Clinical effectiveness
Patients receiving anticoagulant therapy (three trials): One trial showed no significant difference of the time spent in the target range of the international normalised ratio (INR) between the point-of-care testing and control groups. Two trials reported that there was a significant improvement in the time spent in the target range of INR in the point-of-care testing group at the end of the trial (within-group analysis), but there was no significant difference for this outcome between the intervention and control groups.

Patients with diabetes (two trials): Two trials reported that there were no significant differences in the glycated haemoglobin (HbA₁c) values between the point-of-care testing and control groups. One trial reported a significant improvement in the mean HbA₁c value within the point-of-care testing group; the general practice significantly intensified diabetes therapy in the point-of-care testing group compared with the control group.

Patients with hyperlipidaemia (one trial): One trial reported that, compared with the control group, point-of-care testing significantly impacted on clinical decisions with more coronary heart disease interventions in the intervention group.

Analytical performance
One trial showed that point-of-care testing overestimated the INR result from the point-of-care testing compared with the pathology laboratory testing. The Bland-Altman plots revealed that the agreement between point-of-care testing and pathology laboratory testing was clinically acceptable.

Results of patient satisfaction and health professional satisfaction with point-of-care testing were also reported.

Cost information
One RCT reported that point-of-care testing in combination with education resulted in net savings and quality improvement. The cost per test was reduced to €14.13 and accounted for €36.74 per patient per month. The incremental cost-effectiveness ratios for point-of-care testing in combination with education were dominant over usual care. One RCT reported that the cost of point-of-care testing was 170 UK pounds sterling (95% CI 149 to 190) versus £69 (95% CI 57 to 81) in primary care (P<0.01). One RCT reported a non-significant difference in cost of care between the intervention and control groups.

Authors’ conclusions
There was no robust evidence that point-of-care testing for monitoring patients with diabetes, hyperlipidaemia or coagulation disorders in general practice improved patient health outcomes. Point-of-care testing had comparable analytical quality to pathology laboratory testing.

CRD commentary
The inclusion criteria of the review were clear. Relevant databases were searched. Unpublished studies, such as conference abstracts, were excluded, so the potential for publication bias was introduced. No language restriction was applied to the search, minimising the possibility of language bias. Sufficient attempts were made to minimise error and bias in the review process.

It appeared that appropriate criteria were used to assess the trial quality, although no details of the checklist were provided. A narrative synthesis was appropriate given the diversity of the included trials, but there was a lack of clarity in the synthesis.
The authors’ cautious conclusions reflected the limited evidence presented and are likely to be reliable.

**Implications of the review for practice and research**

*Practice*: The authors did not state any implications for practice.

*Research*: The authors stated that further research is required to inform policy decisions on whether point-of-care testing should be implemented in the general practice setting. Further non-inferiority trials are required to determine the safety and clinical effectiveness of point-of-care testing.

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This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.