

Title HbA1C Point of Care (POC) Analyzer

Agency MaHTAS, Health Technology Assessment Section, Medical Development Division, Ministry of Health Malaysia,

Level 4, Block E1, Parcel E, Presint 1, Federal Government Administrative Center, 62590 Putrajaya, Malaysia

Tel: +603 88831229, Fax: +603 88831230; <a href="mailto:https://https:

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Aim

To review evidence on the safety, efficacy/effectiveness and cost-effectiveness of using HbA1c POCT analyzer, LabonaCheck™ compared with the laboratory method in the monitoring of patients with diabetes mellitus.

Conclusions and results

Most of the POCT analyzers for HbA1c showed good correlation with the laboratory method (Pearson's correlation, r between 0.884 and 0.999) and acceptable precision (coefficient of variations, CVs < 5% to ensure that clinically significant changes in serial HbA1c concentrations can be detected). One study revealed that the sensitivity and specificity of the POCT method was 81.8% and 93.2%, respectively. In addition, the POCT had a short turn-around time (TAT), which varies between two to six minutes per test. LabonaCheck™ (a cartridge-based analyzer that utilizes boronate affinity chromatography method) did not show interference or affected by the presence of the haemoglobin variants S, E, C, D, and elevated fetal haemoglobin (HbF).

Recommendations

HbA1c POCT analyzer, LabonaCheck™ can be used in the monitoring of patients with diabetes mellitus in MOH clinics.

Methods

Literatures were searched through electronic databases specifically PubMed, Medline, Cochrane, Ovid, Horizon scanning databases, other websites; US FDA, MHRA and from non scientific database - Google search engine. In addition, a cross-referencing of the articles retrieved was also carried out accordingly to the topic. Relevant articles were critically appraised and evidence graded using US/Canadian Preventive Services Task Force.

Further research/reviews required

Demand for POCT in general practice is increasing; however, evidence about its benefits, particularly relating to clinical outcomes is yet to be determined.

Written by

Syful AMF, MaHTAS, Malaysia