



Topic Exploration Report

Topic explorations are designed to provide a high-level briefing on new topics submitted for consideration by Health Technology Wales. The main objectives of this report are to:

1. Determine the quantity and quality of evidence available for a technology of interest.
2. Identify any gaps in the evidence/ongoing evidence collection.
3. Inform decisions on topics that warrant fuller assessment by Health Technology Wales.

Topic:	Point of care haemolysis detection
Topic exploration report number:	TER123

Introduction and aims

Haemolysis is the most common cause for blood samples being deemed unfit for laboratory analysis. Point of care (POC) haemolysis detection may result in a reduction in clinical error and/or delayed treatments. The population includes any patient undergoing a blood test within a hospital setting.

Summary of findings

No evidence-based guidelines or guidance, or systematic reviews of POC haemolysis testing were identified from a search of the literature.

We identified a single clinical study that evaluated the accuracy of POC haemolysis testing compared to laboratory methods. The technology developer also provided a cost-benefit analysis (unpublished) of POC haemolysis.

Evidence

Clinical evidence:

Duhalde et al. (2019) assessed the diagnostic accuracy of POC testing in 1,270 blood samples with laboratory analysis as the reference standard. 7.9% were assessed as haemolysis, which was defined as more than 50ml/dL free haemoglobin in plasma. The POC method identified haemolytic samples with a sensitivity of 80%, and a specificity of 99%. The POC positive and negative predictive values were 89% and 98% respectively.

Health economic evidence:

Submitted documentation included a cost benefit analysis. The structure of the analysis focuses on the balance between initial higher costs of intervention of a Helge v-test (POC) versus the reduction in secondary costs due to haemolysed samples. The POC test is offered on a monthly subscription fee basis. Micro based costing has been undertaken to reflect the additional clinical processes required to implement POC. Processes and costs were applied to the range of true and false negatives and true and false negatives. A reduction in haemolysed blood samples being sent to testing was associated with reduced costs and lower waiting times.

There is a sufficiently detailed HE structure to adapt within a rapid review process. There are some uncertainties within the cost model that would need to be explored within any more detailed assessment.

Conclusions

Evidence exists about the diagnostic accuracy of POC haemolysis testing; however, this initial exploration only identified a single clinical study and fuller exploration of the evidence is warranted. Health economic modelling by the technology developer suggests that POC haemolysis could reduce NHS costs associated with hospital based blood tests due to a reduction in haemolysed samples being sent for testing, but fuller analysis of costs is required in order to draw firm conclusions.

Brief literature search results

Resource	Results
HTA organisations	
Healthcare Improvement Scotland:	We did not identify any relevant evidence
Health Technology Assessment Group	We did not identify any relevant evidence
Health Information and Quality Authority	We did not identify any relevant evidence
UK guidelines and guidance	
SIGN	We did not identify any relevant evidence
NICE	We did not identify any relevant evidence
Secondary literature and economic evaluations	
ECRI	We did not identify any relevant evidence
Cochrane library	We did not identify any relevant evidence
Medline	We did not identify any relevant evidence
Primary studies	
Medline	We did not identify any relevant evidence
Cochrane library	We did not identify any relevant evidence
Other	
Evidence submitted by topic proposer	Company cost benefit analysis (unpublished) Duhalde H, Skogö J, Karlsson M. Point-of-care hemolysis detection in blood gas specimens directly at the emergency department. Scand J Clin Lab Invest. 2019 Sep;79(5):283-287. doi: 10.1080/00365513.2019.1612089

Date of search:	October 2019
Concepts used:	Point of care: Point-of-care: hemolysis: haemolysis