



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. Inform discussions on new topics received by HTW.
2. Determine the quantity and type of evidence available on a topic.
3. Assess the topic against HTW selection criteria.

Topic:	Amniotic fluid lactate measurement to predict response to syntocinon in slow labour
Topic exploration report number:	TER010
Referrer:	Mrs A Kumar
Topic exploration undertaken by:	Cedar Researchers on behalf of Health Technology Wales

Aim of Search

On behalf of Health Technology Wales, Cedar Researchers searched for evidence on the clinical and cost effectiveness of amniotic fluid lactate measurement to predict response to syntocinon in slow labour, compared to standard care (i.e. no testing).

Summary of Findings

Clinical effectiveness

No secondary evidence (systematic reviews, technology assessments or guidelines) was identified. Approximately 10 primary studies were identified which were of potential relevance to this topic. However, the focus of these studies was confirming the association between amniotic fluid lactate levels and delivery outcomes (i.e. amniotic fluid lactate was measured and then retrospectively analysed to evaluate an association with delivery outcomes). No studies were identified which used amniotic fluid lactate levels to guide actual clinical decision-making. Therefore, the potential of this test as a diagnostic tool has not been evaluated in the current literature. The impact of this test on patient outcomes has not been reported.

The following device was used in some of the identified studies and appears to be CE marked for the indication of interest: AFL Measurement Unit (LMU 061) manufactured by ObsteCare.

Cost effectiveness

No evidence relating to the cost effectiveness of this intervention was identified.

Ongoing studies

No relevant ongoing studies were identified.

Conclusions

Evidence exists which demonstrates an association between amniotic fluid lactate levels and delivery outcomes. However, no evidence was identified which reported outcomes relevant to the clinical or cost effectiveness of amniotic fluid lactate to predict patients' response to syntocinon in a slow labour.

Areas of Uncertainty

It is unclear how the test would be used to guide clinical decision making and which device would be used in NHS Wales.

Feasibility of Technology Assessment

It is unclear whether there are additional health benefits from the use of this technology. Potential benefits may include more appropriate management of women in slow labour (e.g. avoidance of unnecessary caesarean deliveries, or avoidance of unnecessary long and painful parturition, with avoidance of associated perinatal morbidity). However, the available evidence does not support these outcomes; furthermore it does not report outcomes directly relevant to clinical or cost effectiveness.

The technology is not currently used in NHS Wales and it is unclear whether it will have a major impact on NHS Wales, although there is potential to improve patient care. There is also the potential to release resources through more appropriate management of women in slow labour; however, the available evidence does not support this. It is unlikely that assessment of this technology at this time will result in quality improvement.

Whilst it is likely that one or more focussed technology assessment questions can be prepared, it is unlikely that there will be sufficient published research findings available upon which to base a technology assessment. The initial search identified no secondary evidence. No economic studies were identified. The current evidence (<10 primary studies) shows an association between raised amniotic fluid lactate and delivery outcomes, however no studies were identified where the test has been used to guide clinical decision making. It is unlikely that sufficient evidence exists to inform decision making.

HTW's Assessment Group concluded not to progress this topic further.

Brief literature search results

Resource	Results
UK guidelines and guidance	
SIGN	We did not identify any relevant evidence from this source.
NICE	We did not identify any relevant evidence from this source.
Secondary literature and economic evaluations	
BMJ Best Practice	We did not identify any relevant evidence from this source.
Cochrane library	We did not identify any relevant evidence from this source.
CRD database	Two NIHR Horizon Scanning Centre reports were identified (2011 and 2012).
Primary studies	
Medline	<ol style="list-style-type: none"> 1. Wiberg-Itzel E, Pembe AB, Jarnbert-Pettersson H, et al. Lactate in Amniotic Fluid: Predictor of Labor Outcome in Oxytocin-Augmented Primiparas' Deliveries. PLoS ONE. 2016;11(10):e0161546. doi:10.1371/journal.pone.0161546. 2. Murphy M, Butler M, Coughlan B, Brennan D, O'Herlihy C, Robson M. Elevated amniotic fluid lactate predicts labor disorders and cesarean delivery in nulliparous women at term. Am J Obstet Gynecol. 2015;213(5):673.e1-8. doi:10.1016/j.ajog.2015.06.035. 3. Hall B, Wong DD, Rawlinson WD, Tracy MB, Tracy SK. A validation study: assessing the reliability of the hand held StatStripXPress lactate meter to test lactate in amniotic fluid. BMC Res Notes. 2014;7:935. doi:10.1186/1756-0500-7-935. 4. Ulfsdottir H, Nissen E, Ryding EL, Lund-Egloff D, Wiberg-Itzel E. The association between labour variables and primiparous women's experience of childbirth; a prospective cohort study. BMC Pregnancy Childbirth. 2014;14:208. doi:10.1186/1471-2393-14-208. 5. Wiberg-Itzel E, Pembe AB, Wray S, et al. Level of lactate in amniotic fluid and its relation to the use of oxytocin and adverse neonatal outcome. Acta Obstet Gynecol Scand. 2014;93(1):80-5. doi:10.1111/aogs.12261. 6. Hall B, Iwasenko J, Moriatis M, Rawlinson WD, Tracy MB, Tracy SK. A pilot study to determine the feasibility of collecting amniotic fluid samples from women during labour and measuring amniotic fluid lactate at point of care. BMC Res Notes. 2013;6:112. doi:10.1186/1756-0500-6-112. 7. Wiberg-Itzel E, Akerud H, Andolf E, Hellstrom-Westas L, Winbladh B, Wennerholm UB. Association between adverse neonatal outcome and lactate concentration in amniotic fluid. Obstet Gynecol. 2011;118(1):135-42. doi:10.1097/AOG.0b013e318220c0d4. 8. Wiberg-Itzel E, Pettersson H, Andolf E, Hansson A, Winbladh B, Akerud H. Lactate concentration in amniotic fluid: a good predictor of labor outcome. Eur J Obstet Gynecol Reprod Biol. 2010;152(1):34-8. doi:10.1016/j.ejogrb.2010.05.005. 9. Wiberg-Itzel E, Pettersson H, Cnattingius S, Nordstrom L. Association between lactate concentration in amniotic fluid and dysfunctional labor. Acta Obstet Gynecol Scand. 2008;87(9):924-8. doi:10.1080/00016340802295636.
Ongoing secondary research	
ClinicalTrials.gov	We did not identify any relevant evidence from this source.

Date of search:	April 2018
Concepts used:	Amniotic; amniotic fluid; lactate; labo*r