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Diagnostic accuracy of clinical judgement versus PAMG-1 biomarker test for PROM: Single centre study

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INTRODUCTION

AmniSure, which has a sensitivity of 98.9% and specificity of 100%, is a rapid non-invasive diagnostic tool which detects the placental alpha microglobulin-1 protein (PAMG-1) using specific monoclonal antibodies. The rationale for the audit is to reduce misdiagnosis of PROM/PPROM as research shows 47% of clinicians are uncertain when diagnosing ROM using a speculum examination alone.

METHODS

Compare the results of clinical judgement and the diagnostic test kit AmniSure when the speculum examination is equivocal for 3 months.

- Record data and results of all patients an AmniSure test is used on for 3 months from 14.4.23 – 14.7.23.
- Follow up on results after 14.7.23 for each patient AmniSure is used on to see if test is disputed by looking at the delivery records to check ROM - Delivery date.
- Compare all AmniSure data results used in the ADU setting only for the said 3 months to the attendees seen in the ADU setting only from 14.4.22 – 14.7.22 with a query of PROM/PPROM and diagnosing using the then current methods of speculum examination only.
- Gain feedback from health professionals using AmniSure to determine if confidence is increased by communicating verbally

RESULTS

During the 3-month data collection study, 121 AmniSure tests were used on women who attended with a query of PROM/PPROM when the health professional's clinical judgement of diagnostic accuracy using speculum examination alone was questionable.

Out of the 121 AmniSure diagnostic tests used 91 tests were negative,

30 tests were positive and only 1 test result was disputed

CONCLUSIONS

Our results show clinical judgement when using a speculum examination alone is not accurate and clinical uncertainty reported in our single-centre study supports the existing literature of a high incidence of uncertainty when diagnosing PROM using clinical judgement alone.

False negatives and false positives both can have serious consequences for mum & baby and due to the use of AmniSure during the 3 months data collection period, we can safely say that the 121 women tested received appropriate follow up plans of care. Furthermore, our analysis showed that monetary and time related costs for staff and the hospital have been reduced as a result of AmniSure testing. In view of this, AmniSure has now been implemented into current practice for use when speculum examinations are equivocal and health professionals have reported feeling more confident with their diagnosis. AmniSure use will be audited again in 2024.