NICE National Institute for Health and Care Excellence

Vision Amniotic Leak Detector to assess unexplained vaginal wetness in pregnancy

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NICE medical technology guidance 15

guidance.nice.org.uk/mtg15

Contents

1 Recommendations

NICE medical technologies guidance addresses specific technologies notified to NICE by sponsors. The 'case for adoption' is based on the claimed advantages of introducing the specific technology compared with current management of the condition. This case is reviewed against the evidence submitted and expert advice. If the case for adopting the technology is supported, then the technology has been found to offer advantages to patients and the NHS. The specific recommendations on individual technologies are not intended to limit use of other relevant technologies which may offer similar advantages.

1.1 The case for adopting the Vision Amniotic Leak Detector (ALD), when issued by a midwife or other healthcare worker, is supported by the evidence. The available evidence suggests that the device can reliably exclude amniotic fluid leak as a cause of vaginal wetness in pregnancy, avoiding the need for a speculum examination and its associated discomforts. Using the device in the community could prevent unnecessary referrals to secondary care antenatal day units or maternity triage services for speculum examinations, releasing clinical time.

1.2 The Vision ALD should be considered for use in pregnant women with unexplained vaginal wetness.

1.3 Based on cost modelling, using the Vision ALD is estimated to be cost saving in scenarios considered to be clinically likely, by avoiding the need for referral to an antenatal day unit. When issued by a midwife or other healthcare worker in a primary care setting, cost savings per woman of up to £24.01 (for prelabour rupture of membranes; PROM) and £18.25 (for preterm prelabour rupture of membranes; PPROM) could be achieved. When issued by a community midwife in a woman's home, Vision ALD is associated with an estimated cost saving of up to £21.01 per woman for PROM and £15.25 per woman for PPROM.

2 The technology

Description of the technology

2.1 The Vision Amniotic Leak Detector (ALD; CommonSense Ltd) is a non-invasive diagnostic panty liner that can be attached to underwear. The panty liner has a central polymer-embedded strip that turns blue-green on contact with fluid that has a pH higher than 5.2 (normal vaginal pH is 3.5 to 4.5 and amniotic fluid has a pH of 6.5 or above). The device can distinguish between amniotic fluid and urine (which contains ammonia) because the polymer strip contains reagents that react differently depending on the pH and whether ammonia is present. The presence of vaginal infection, including bacterial vaginosis, trichomoniasis or desquamative inflammatory vaginitis, can also produce a positive result because infection can raise vaginal pH. The Vision ALD is supplied in individually sealed packs, each containing a liner, a plastic drying unit and an instruction leaflet.

2.2 The liner should be worn until it is sufficiently wet for a result to be read, and for no longer than 12 hours. The indicator strip is then removed and placed in the drying unit for 30 minutes. If the indicator strip is yellow after drying, then the leak is unlikely to be amniotic fluid and a speculum examination can be avoided. If the indicator strip is blue-green after drying, this indicates the wetness is likely to be amniotic fluid or infection, which can be confirmed by a speculum examination and a vaginal swab.

2.3 The Vision ALD is intended for use by women with normal pregnancies experiencing unexplained vaginal wetness as well as by those at high risk of premature rupture of membranes.

2.4 The cost of the Vision ALD stated in the sponsor's submission is £1.60 per test.

2.5 The claimed benefits of Vision ALD in the case for adoption presented by the sponsor are:

- A reduction in unnecessary speculum examinations.

- A reduction in the time spent in hospital. Those who currently undergo a speculum examination need to remain in hospital for approximately 30 minutes pre-procedure and 45–60 minutes in total. Women using the Vision ALD will not require a hospital bed and can undergo the test as an outpatient or in a community setting; there is no requirement for them to lie down whilst wearing the liner.
- A reduced risk of infection from speculum examination, particularly if repeat examinations are required.
- The incidental detection of possible vaginal infection.
- A reduction in the costs associated with the avoidance of speculum examination.
- A reduction in staff time and hospital bed use.

Current management

2.6 Intrapartum care (NICE clinical guideline 55) indicates that a speculum examination should be used to detect ruptured amniotic membranes when any uncertainty exists. Expert advice suggests that the woman needs to lie down for up to 30 minutes before the procedure, so that any leaking amniotic fluid can collect in the vagina. After this time, a doctor or midwife will use a speculum to examine the vagina for pooling of amniotic fluid. If pooling is seen, the woman is diagnosed with ruptured membranes and her condition managed accordingly. If there is no pooling, it is assumed that the membranes are still intact and the woman may be discharged. Nitrazine (pH) testing, amniotic fluid crystallisation (fern testing), biomarker testing or ultrasound examination of the uterus may be used to confirm the diagnosis, but none of these are used routinely in the NHS as standard practice.

2.7 If membrane rupture is confirmed in women with pregnancies over 37 weeks' gestation (prelabour rupture of membranes [PROM]), the NICE clinical guideline on intrapartum care recommends that women should be given advice on the increased risk of neonatal infection and the probability of progression to labour. Induction is advised if labour has not started within 24 hours. Women can choose to continue with expectant management in hospital or at home. The fetus should be monitored every 24 hours and women asked to look for any signs of infection or changes in fetal movement. Intravenous antibiotics

should be administered if signs of infection are present. After labour, women are asked to look for any signs of infection in their baby.

2.8 In the case of pregnancies under 37 weeks' gestation (preterm prelabour rupture of membranes [PPROM]), guidance from the Royal College of Obstetricians and Gynaecologists (2006) recommends that women should be monitored in hospital for at least 48 hours for signs of chorioamnionitis. Corticosteroids and erythromycin should be given. Some women can be monitored at home after 48 hours in hospital, but this decision depends on the individual woman's level of risk. Women are asked to monitor themselves for any signs of infection and return to hospital if this is suspected. Induction of labour should be considered after 34 weeks' gestation.

3 Clinical evidence

Summary of clinical evidence

3.1 The key clinical outcomes for Vision Amniotic Leak Detector (ALD) presented in the decision problem were:

- incidence of speculum examinations
- diagnostic accuracy for the detection of amniotic fluid leak and premature rupture of membranes
- identification of vaginal infection
- incidence of speculum-associated cross-infection
- bed utilisation and staff time
- device-related adverse events.

3.2 The clinical evidence for the Vision ALD was based on 3 comparative diagnostic studies, evaluating the non-inferiority of the Vision ALD to speculum examination. In 2 of the studies (Bornstein et al. 2006 and Bornstein et al. 2009), the comparator was speculum examination or a positive nitrazine (pH) and fern test. In addition, the External Assessment Centre extrapolated unpublished data from these studies (supplied by the sponsor) to provide a comparison against speculum examination alone. As part of this analysis, the External Assessment Centre redesignated false positives as true positives if infection was detected or if ruptured membranes were subsequently diagnosed. Published data from a study by Mulhair et al. (2009) were also included to calculate overall mean sensitivity, specificity and predictive values for the Vision ALD.

3.3 Bornstein et al. (2006) carried out a prospective, single-centre study evaluating the diagnostic efficacy of the Vision ALD (under an alternative brand name, AL-SENSE) involving 103 pregnant women attending a labour and delivery ward at a hospital in Israel. Women were enrolled in 3 groups: a negative control group of women showing no signs of fluid leakage (n=27), a positive control

group (n=42) including 32 women with overt spontaneous prelabour rupture of membranes [PROM]) and 10 with artificially ruptured membranes and an intervention group of women with vaginal wetness of unknown cause (n=34). Women were included in the study if they were aged between 18 and 45 years with pregnancies of at least 20 weeks' gestation. Women were given an AL-SENSE liner to wear for 1 hour and asked to record any colour change. After 10 minutes drying time, the colour was read by the attending midwife or obstetrician and the study coordinator, who were all blinded to the participant-recorded result. Another clinician, blinded to the results of the AL-SENSE test, subsequently made a clinical diagnosis based on a speculum examination to look for pooling of amniotic fluid, or by a nitrazine and fern test if no pooling was visible. The sensitivity and specificity of the AL-SENSE liner were calculated by comparing the clinical diagnosis with the final reading of the liner colour. The sensitivity of the device was 100% in the intervention group (10/10, 95% confidence interval [CI] 69.15 to 100%) and the specificity was 75% (18/24, 95% CI 53.29 to 90.23%). It is important to note that device colour change caused by vaginal infection was classed as a false positive; 4 of the 6 false positives were subsequently found to be caused by bacterial vaginosis. The device correctly diagnosed ruptured membranes in all 42 women in the positive control group. In the negative control group, 23 women were confirmed as having intact membranes and 2 women did in fact have ruptured membranes that were identified by the device. The remaining 2 results in this group were false positives.

3.4 Bornstein et al. (2009) carried out a prospective multicentre trial evaluating the non-inferiority of the Vision ALD (under an alternative brand name, AmniScreen) to a nitrazine swab test (AmnioTest, Pro-Lab Diagnostics), which had a reported sensitivity of 91% and specificity of 73% in detecting amniotic fluid. Women aged between 18 and 45, with pregnancies of 16 weeks' gestation or more, presenting at labour and delivery triage with unexplained vaginal wetness were included in the study. Women were recruited from 2 centres in Israel (n=110, n=179) and 1 in the USA (n=50) making a total of 339 women. Data from 309 women were analysed; 10 women were excluded for protocol violations and 20 did not have a complete set of tests. Women were given an AmniScreen liner to wear until wetness was felt and asked to read the result after 30 minutes drying time. The result was subsequently read

by a healthcare provider, blinded to the participant-recorded result. Another healthcare provider, blinded to the AmniScreen results, made a clinical diagnosis using a speculum examination to look for pooling of amniotic fluid, or by a nitrazine and fern test if no pooling was visible. If the AmniScreen result was positive and clinical diagnosis negative, testing for vaginal infection was carried out, followed by further clinical assessment within 48 hours to obtain a final clinical diagnosis. Analysis was carried out by comparing the woman's reading of the device with the clinical diagnosis. The healthcare provider's reading of the device was also compared with the clinical diagnosis. The sensitivity of the test was found to be 95.8% (158/165) and the specificity 86.8% (125/144) based on the comparison between women's readings and final clinical diagnosis. The authors concluded that the sensitivity and specificity of the AmniScreen test were significantly higher ($p=0.02$ and $p<0.0001$ respectively) than that of the AmnioTest nitrazine swab. Comparison of the healthcare provider's device readings and the final clinical diagnosis indicated that the sensitivity of AmniScreen was 95.8% and the specificity was 88.1%. Comparison of the healthcare provider's and the women's device readings led the authors to conclude that overall agreement between them was above 90%.

3.5 Mulhair et al. (2009) carried out a prospective single-centre study comparing the diagnostic performance of the Vision ALD (under an alternative brand name, AmnioSense) with speculum examination in identifying amniotic fluid leak. The study involved 157 women, with pregnancies between 18 and 42 weeks' gestation, presenting to an antenatal day unit in the UK with suspected rupture of membranes. Women were given AmnioSense to wear for 20 minutes or until wetness was felt. A midwife read the result of the test after 10 minutes drying time. Another midwife, blinded to the AmnioSense results, carried out a speculum examination to obtain a clinical diagnosis. Data from 139 women were analysed after exclusions for protocol violations or clinical circumstances. A high vaginal swab was taken in 103 of these women to test for infection. Results of the AmnioSense test were compared with the clinical diagnosis, revealing a sensitivity of 98.0% (58/59, 95% CI 91 to 100%) and a specificity of 65.0% (52/80, 95% CI 54 to 75%). Of 28 AmnioSense results deemed to be false positives by clinical diagnosis, 7 were associated with infection determined by the vaginal swab. A further 2 women were

subsequently identified as having ruptured membranes on further clinical examination, and 7 gave birth within 3 days of having the test. The positive predictive value was 67.4% (95% CI 56.5 to 77.2%) and the negative predictive value was 98.1% (95% CI 89.9 to 100.0%).

Committee considerations

3.6 The Committee considered that the studies described above indicate that the Vision ALD is sufficiently accurate to reliably exclude amniotic fluid leak as a cause of vaginal wetness in pregnancy.

3.7 The Committee considered that use of the Vision ALD would avoid unnecessary speculum examinations, which may be intrusive and uncomfortable.

3.8 The Committee noted that 2 studies included additional comparators that were outside the scope, but the External Assessment Centre reanalysed the study data to address this issue and to provide clear comparative data for the Vision ALD against NHS standard practice.

3.9 The Committee noted that the clinical outcome evidence was limited, because all women participating in the studies received a separate clinical diagnosis and their vaginal wetness was not managed solely on the basis of the Vision ALD result.

4 NHS considerations

System impact

4.1 The sponsor claimed that use of the Vision Amniotic Leak Detector (ALD) would reduce time spent in hospital and associated staff time and bed use.

Committee considerations

4.2 The Committee considered the setting in which the Vision ALD would be used. The Committee concluded that the most likely benefit would arise from using the Vision ALD in community health services to avoid unnecessary referrals to secondary care, such as an antenatal day unit or maternity triage service, releasing resources and clinical time in these departments. The Committee heard advice from clinical experts confirming that use of the Vision ALD by a midwife based in a GP practice, or by a community midwife visiting the woman's home, would be the most likely scenarios for use of the device in the community.

4.3 The Committee also noted that women contacting an antenatal day unit or maternity triage service by telephone, with concerns over unexplained wetness, could be advised to contact a community or primary care-based midwife to be given the Vision ALD, potentially avoiding unnecessary visits to secondary care services.

4.4 The Committee heard expert clinical advice that such a change in practice, aimed at reducing referrals to secondary care through the use of the Vision ALD, was realisable and was likely to be acceptable to clinicians involved in the current care pathway.

4.5 The Committee was advised by a clinical expert that the Vision ALD could be issued by a healthcare worker to women presenting at a GP practice with unexplained wetness. The Vision ALD could be worn by the woman while sitting in the waiting room and the results read by a midwife or GP.

4.6 The Committee heard clinical expert advice that a further possible scenario was self-administration of the Vision ALD by women in their own homes, and noted that this was outside the scope of the evaluation.

5 Cost considerations

Cost evidence

5.1 The sponsor submitted a de novo cost analysis evaluating the cost consequences of using the Vision Amniotic Leak Detector (ALD) compared with speculum examination alone. The population was pregnant women with unexplained vaginal wetness that could be leaking amniotic fluid caused by ruptured membranes. The model was a simple decision tree comparing 2 pathways:

- use of speculum examination in the entire population presenting to an antenatal day unit with unexplained wetness
- use of the Vision ALD to provide an initial diagnosis, followed by speculum examination in women with a positive Vision ALD result and discharge for women with a negative result.

The sponsor did not specify a time horizon because consequences were not considered beyond initial examination and diagnosis in the day unit. The sponsor included base-case, worst-case and best-case scenarios in their sensitivity analysis.

5.2 The key assumptions used in the model were:

- The Vision ALD had 100% sensitivity.
- Speculum examination had 100% sensitivity and specificity.
- All women receiving speculum examination would need cardiotocography (CTG; fetal heart rate monitoring), but women in the Vision ALD arm with a negative result would not receive CTG.
- Women needing speculum examination would wait on a bed.
- Women would not wait on a bed before using the Vision ALD.
- The Vision ALD would be used as the sole diagnostic test to rule out ruptured membranes.

5.3 Clinical parameters from the study by Mulhair et al. (2009) were used to inform the model, including the reported percentage of women with a negative Vision ALD result (38%, n=53/139); however, this was wrongly transcribed as 42%, which was the reported prevalence. The model did not account for false positive Vision ALD results; the study by Mulhair et al. (2009) identified 12 false positives (9%) that could not be attributed to infection or subsequent delivery.

5.4 The cost of the Vision ALD was £1.60 and the cost of a disposable speculum was £0.84 (provided by the sponsor). The cost of bed use in the antenatal unit was estimated to be £364, taken from the healthcare resource group for antenatal false labour including prelabour rupture of membranes (PROM) (NZ23Z; excess bed day cost of £364). The total cost of bed use in the antenatal day unit for speculum examination (a total of 35 minutes) was £8.90, based on 30 minutes pooling time plus the examination. The costs of infection identification and treatment were not included in the model.

5.5 The cost per minute of midwife time was estimated as £1.37, extrapolated from £82.00 per hour (Personal Social Services Research Unit [PSSRU] 2011). The sponsor estimated the times for administering the Vision ALD and a speculum examination to be 5 minutes each, with a total cost of £6.85 for midwife time for each test. The total cost per use of the Vision ALD was therefore estimated to be £8.45 and for speculum examination, the total cost per use was estimated to be £43.99. The cost of CTG was added to the cost of the speculum examination, amounting to an estimated 20 minutes of midwife time (£27.40).

5.6 The sponsor carried out one-way and multi-way deterministic sensitivity analyses to produce base-case, worst-case and best-case cost scenarios. The costs of the Vision ALD and a disposable speculum were fixed. Bed day cost was varied according to a published range. All other variables were adjusted to plus or minus 50% of the base case.

5.7 The sponsor carried out a threshold analysis to determine at what point the Vision ALD became cost neutral, by varying midwife time to conduct a speculum examination and CTG, and midwife time to administer the Vision ALD, as well as the cost of the Vision ALD.

5.8 The sponsor's base-case analysis showed that the cost per woman of using the Vision ALD, followed by speculum examination in the event of a positive result, was £33.93. The cost per woman of using speculum examination alone was £43.94, thus generating a cost saving per woman of £10.01. The results of the one-way sensitivity analysis carried out by the sponsor showed that the Vision ALD remained cost saving for each of the varied parameters. Cost savings ranged from £0.78 to £19.23, the broadest variation being related to the percentage of negative Vision ALD tests (63% to 21%).

5.9 The sponsor's best- and worst-case scenarios for the Vision ALD generated, respectively, a cost saving of £54.60 and an additional cost of £3.52 per woman. The threshold analysis showed that the Vision ALD would no longer be cost saving if the time taken to perform a speculum examination and CTG was reduced to 7.6 minutes or less, the time taken to administer the Vision ALD was increased to 12.3 minutes, the cost of the Vision ALD was increased to £11.60 or the percentage of women with a negative result was reduced to 19%.

5.10 The External Assessment Centre considered that the sponsor's de novo analysis was limited in that it did not include the cost consequences of using the Vision ALD in a community setting and it did not explore the full diagnostic pathway. The External Assessment Centre carried out additional modelling to address these limitations.

5.11 The External Assessment Centre's model consisted of a decision tree with 2 main arms, comparing standard care for diagnosing unexplained vaginal wetness (speculum examination), with use of the Vision ALD, followed by speculum examination in the event of a positive result. In the Vision ALD arm, women with a negative test result would be sent home with no further intervention. Each arm of the model was populated separately for PROM or preterm prelabour rupture of membranes (PPROM) to account for the differences in management and the prevalence of infection in these 2 groups.

5.12 The standard care arm included 3 usage scenarios based on a cohort of 1000 women, in which speculum examination was carried out by a GP, a midwife based in a GP practice or a clinician in an antenatal day unit. In the

Vision ALD arm, women were given the Vision ALD test in the same clinical settings and, in addition, by a community midwife in the woman's home.

5.13 The health outcomes considered in the model were:

- diagnosis of ruptured membranes
- diagnosis of ruptured membranes with infection
- diagnosis of infection without ruptured membranes
- no infection or ruptured membranes.

5.14 The proportion of positive and negative speculum and Vision ALD tests were taken from the External Assessment Centre's additional analysis of the published studies by Bornstein et al. (2006 and 2009) and Mulhair et al. (2009), described in sections 3.2–3.5. A weighted mean rate of positive tests was calculated. The weighted mean positive predictive value of the Vision ALD was also used to determine the number of positive PROM or infection diagnoses after a speculum examination in the Vision ALD arm.

5.15 The infection rates for PROM (1%) and for pregnant women in general (0.5%) were taken from the NICE clinical guideline on intrapartum care. For PPROM, a rate of 28% was taken from the Royal College of Obstetricians and Gynaecologists' guidance (2006).

5.16 Key assumptions used in the model were:

- Antibiotic therapy would be given for 24 hours, based on the assumption that delivery would occur within 24 hours in most women with PROM. The External Assessment Centre noted that for PPROM, delivery could occur after 24 hours, but opted to use the same antibiotic costs for both conditions to simplify the model.
- Each usage scenario would follow a like-for-like pattern with care being provided in the same setting throughout the pathway. The only exception to this would be in the community midwife scenario for the Vision ALD, when the woman would be referred to a midwife in a GP practice for the speculum examination.

- The clinical times for administering the Vision ALD (10 minutes) and carrying out a speculum examination (15 minutes) included time for consultation and discussion.
- False negatives were not included in the model, because the rate of false negative results calculated by the External Assessment Centre (around 4%) was similar for both tests.
- The cost of CTG was not included in the model because this would only be available in an antenatal day unit and would most likely be accounted for in a referral cost.

5.17 Costs were estimated for clinical time and resource use, as well the treatment and monitoring of infection and PROM or PPROM. The costs for the Vision ALD (£1.60) and a disposable speculum (£0.84) were taken from the sponsor's model. Clinical time costs were taken from PSSRU 2012 unit costs, giving a per minute rate of £3.68 for a GP, £0.88 for a midwife based in a GP practice and £1.18 for a community midwife. No costs were applied for resource use (for example, a bed or consultation room) for speculum examination in the GP practice. The External Assessment Centre stated that the cost for this was most likely to be negligible, based on calculations using GP cost elements (PSSRU 2012, section 10.8a) and would not significantly affect the outcomes in the model. The External Assessment Centre also stated that availability of unused space would vary considerably between practices and so generalisation would be difficult to include in the model.

5.18 The costs of treating infection consisted of microbiology laboratory costs of £8.00, taken from NHS reference costs, and broad spectrum antibiotic costs of £41.72 for 24 hours, based on published evidence. A small cost was applied for temperature monitoring to identify potential infection after a diagnosis of PROM or PPROM, based on NHS supply chain costs for a Tempa-dot thermometer at £0.90 for 10. The External Assessment Centre's sensitivity analysis also included costs for a 24-hour course of antibiotics specifically for group B streptococcus at a cost of £22.71; this was added on the basis of clinical advice. Costs for managing PPROM consisted of corticosteroids at a cost of £4.98 and a course of prophylactic antibiotics (if no infection was diagnosed) at £2.41. A cost of £696.00 was applied for inpatient observation after a diagnosis of infection and/or PPROM. The cost for referral to an

antenatal day unit was £81.00; both figures were taken from NHS reference costs. The External Assessment Centre assumed that the cost of an antenatal day unit referral would cover clinical time and resource use.

5.19 The External Assessment Centre found that use of the Vision ALD was cost-incurring compared with standard care, for both PROM and PPROM, in all the clinical usage scenarios described in section 5.12. The cost of the Vision ALD device and the additional clinical time taken to administer it were not outweighed by the savings from avoided speculum examinations across the 1000-woman cohort. Administration of the Vision ALD by a GP would incur the greatest cost (£14.85 per woman) and the least cost-incurring scenario would be its use in the antenatal day unit (£1.28 per woman).

5.20 The External Assessment Centre carried out a one-way sensitivity analysis, altering each clinical time and treatment cost. Costs were estimated for 'lowest' and 'highest' ranges. The 2 variables with the greatest impact on both arms of the model were clinician time taken to administer the Vision ALD and to carry out speculum examination (by a GP or midwife). Threshold analysis on these 2 variables was carried out to determine at what level the Vision ALD would become cost saving. For PROM, the time taken to carry out speculum examination would need to be around 30 minutes and the time taken to administer the Vision ALD would need to be 6 minutes or less, both varying depending on the clinician carrying out the test. Similar figures were found for PPROM.

5.21 The External Assessment Centre then explored the cost consequences, using their existing model, of additional scenarios for the Vision ALD in which women attended 2 different facilities. The scenarios modelled were a GP or midwife issuing the Vision ALD in a GP practice, or a community midwife issuing the Vision ALD in the woman's home, followed by referral to either a practice-based midwife or GP, or an antenatal day unit, for a speculum examination. For the standard care arm, all women would have a speculum examination by a practice-based midwife or GP, or at an antenatal day unit. The setting for the speculum examination would be the same in both arms for each scenario compared.

5.22 Base-case results indicated that cost savings could be achieved if the clinician issuing the Vision ALD is of lower cost than the clinician carrying out the speculum examination, because the cost saving was driven by avoided speculum examinations in high-cost settings. A GP issuing the Vision ALD, followed by referral to a practice-based midwife or antenatal day unit for a speculum examination, incurred costs of between £3.99 per woman in the PROM arm and £38.28 per woman in the PPROM arm. A practice-based midwife issuing the Vision ALD and referring women to an antenatal day unit for speculum examination was associated with estimated cost savings of £24.01 per woman for PROM and £18.25 per woman for PPROM. A practice-based midwife issuing the Vision ALD followed, if required, by speculum examination by a GP, could generate estimated cost savings of £13.15 per woman for PROM and £7.40 per woman for PPROM. The scenario of a community midwife issuing the Vision ALD in the home and referring women to an antenatal day unit for speculum examination could generate cost savings of £21.01 and £15.25 per woman for PROM and PPROM respectively; referral to a GP could generate savings of £10.15 per woman for PROM and £4.40 for PPROM.

Committee considerations

5.23 The Committee considered the scenarios and findings from the sponsor's model and the additional analyses carried out by the External Assessment Centre. The Committee heard advice from clinical experts regarding which scenarios were likely to reflect a realistic care pathway. The advice indicated that the most likely scenarios in the community were use of the Vision ALD by a practice-based or community midwife, followed by referral to an antenatal day unit in the event of a positive Vision ALD result. The Committee noted that in these scenarios, use of the Vision ALD was cost saving in the External Assessment Centre's analysis.

5.24 The Committee noted that the observed cost savings were largely a result of avoiding speculum examinations in women with a negative Vision ALD test. It also noted that a significant factor in the analysis was the cost of the healthcare provider administering the test.

5.25 The Committee noted that use of the Vision ALD in an antenatal day unit was a likely scenario based on current practice, and that this had been shown to be cost-incurring in the External Assessment Centre's model. The Committee considered that use in this setting would become cost neutral if the consumable costs of the Vision ALD and disposable speculums were included in the reference cost of a referral.

6 Conclusions

6.1 The Committee concluded that the Vision Amniotic Leak Detector (ALD) test is sufficiently accurate to exclude amniotic fluid leak as a cause of wetness in pregnancy and that its use in the correct clinical setting would avoid unnecessary speculum examinations.

6.2 The Committee considered that use of the Vision ALD in the community could generate cost savings and avoid the discomfort and inconvenience of unnecessary speculum examinations in some pregnant women.

6.3 The Committee concluded that the adoption of the Vision ALD, with appropriate changes to clinical practice in the community, should be encouraged.

7 Committee members and NICE lead team

Medical Technologies Advisory Committee members

The Medical Technologies Advisory Committee is a standing advisory committee of NICE. A list of the Committee members who took part in the discussions for this guidance appears below.

Committee members are asked to declare any interests in the technology to be evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The minutes of each Medical Technologies Advisory Committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

Professor Bruce Campbell (Chair)
Consultant Vascular Surgeon, Exeter

Dr Peter Groves (Vice Chair)
Consultant Cardiologist, Cardiff and Vale NHS Trust

Professor Dilly Anumba
Chair of Obstetrics and Gynaecology/Honorary Consultant Obstetrician and Gynaecologist, University of Sheffield

Ms Susan Bennett
Lay member

Professor Bipin Bhakta (until April 2013)
Charterhouse Professor in Rehabilitation Medicine and NHS Consultant Physician, University of Leeds

Dr Keith Blanshard
Consultant Interventional Radiologist, University Hospitals of Leicester NHS Trust

Professor Daniel Clark
Head of Clinical Engineering, Nottingham University Hospitals NHS Trust

Professor Tony Freemont
Professor of Osteoarticular Pathology, University of Manchester

Professor Peter Gaines
Consultant Interventional Radiologist, Sheffield Vascular Institute and Sheffield Hallam University

Professor Shaheen Hamdy
Professor of Neurogastroenterology, University of Manchester

Mr Matthew Campbell-Hill
Lay member

Dr Jerry Hutchinson
Independent Medical Technology Adviser

Dr Cynthia Iglesias
Health Economist, University of York

Dr Greg Irving
General Practitioner, University of Liverpool

Professor Mohammad Ilyas
Professor of Pathology, University of Nottingham

Dr Eva Kaltenthaler
Reader in Health Technology Assessment, ScHARR, University of Sheffield

Dr Paul Knox
Reader in Vision Science, University of Liverpool

Mrs Jacqui Nettleton
Programme Director, Commissioning, Western Sussex Hospitals NHS Trust

Professor Brian J Pollard
Professor of Anaesthesia, University of Manchester
Consultant Anaesthetist, Central Manchester University Hospitals

Mr Brian Selman
Managing Director, Selman & Co

Professor Wendy Tindale
Scientific Director, Sheffield Teaching Hospitals NHS Foundation Trust

Professor Allan Wailoo
Professor of Health Economics, School of Health and Related Research (ScHARR), University of Sheffield

Dr Janelle Yorke
Lecturer and Researcher in Nursing, University of Manchester

NICE lead team

Each medical technology assessment is assigned a lead team of a NICE technical analyst and technical adviser, an expert adviser, a non-expert member of the Medical Technologies Advisory Committee (MTAC) and a representative of the External Assessment Centre.

Joanne Higgins
Technical Analyst

Sally Doss
Technical Adviser

Jenny Carter
Lead Expert Adviser

Julie Orford
Patient Expert

Daniel Clark
Non-Expert MTAC Member

Alistair Ray
External Assessment Centre Representative

Sue Peirce
External Assessment Centre Representative

8 Sources of evidence considered by the Committee

The External Assessment Centre report for this assessment was prepared by Cedar:

- Ray A, Peirce S, Cleves A et al. Vision Amniotic Leak Detector (ALD) to eliminate amniotic fluid leakage as a cause of vaginal wetness in pregnancy, January 2013

Submissions from the following sponsor:

- CommonSense Ltd (manufacturer)

The following individuals gave their expert personal view on the Vision ALD by providing their expert comments on the draft scope and assessment report.

- Ms Jenny Carter, ratified by the Royal College of Midwives – clinical expert
- Professor Alan Cameron, ratified by the British Maternal and Fetal Medicine Society – clinical expert
- Dr Devender Roberts, nominated/ratified by the Royal College of Obstetrics and Gynaecology – clinical expert

The following individuals gave their expert personal view on the Vision ALD in writing by completing a patient questionnaire or expert adviser questionnaire provided to the Committee.

- Ms Jenny Carter, ratified by the Royal College of Midwives – clinical expert
- Ms Julie Orford, nominated by the Birth Trauma Association – patient expert
- Professor Alan Cameron, ratified by the British Maternal and Fetal Medicine Society – clinical expert
- Ms Melanie Woolman, nominated/ratified by the Royal College of Midwives – clinical expert
- Ms Kate Evans, nominated/ratified by the Royal College of Nursing Midwives – clinical expert
- Dr Devender Roberts, nominated/ratified by the Royal College of Obstetrics and Gynaecology – clinical expert

About this guidance

This guidance was developed using the NICE medical technologies guidance process.

It has been incorporated into the NICE pathways on antenatal care (in women with unexplained vaginal wetness in pregnancy in the overview path) and intrapartum care (in suspected or certain prelabour rupture of the membranes at term in the prelabour rupture of the membranes at term path), along with other related guidance and products.

We have produced a summary of this guidance for the public. Tools to help you put the guidance into practice and information about the evidence it is based on are also available.

Related NICE guidance

For related NICE guidance, please see the NICE website.

Your responsibility

This guidance represents the views of NICE and was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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