NICE advice

Novii Wireless Patch System for maternal and fetal monitoring

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Summary

- The **technology** described in this briefing is Novii Wireless Patch System. It is used for maternal and fetal monitoring.
- The **innovative aspects** are the technology is wireless and does not need to be adjusted by the midwife when the baby or transducer moves.
- The intended **place in therapy** would be as an alternative to standard cardiotocography (CTG) monitoring using a wired transducer and belt for women who need monitoring during labour.
- The **main points from the evidence** summarised in this briefing are from 6 studies (1 randomised controlled trial, 2 secondary analyses, 2 observational studies and 1 equivalence study) including a total of 487 women in late pregnancy (n=228) and labour (n=259). They show that Novii is as effective as standard monitoring, is likely to be more effective in people with a high body mass index and may reduce maternal heart rate and fetal heart rate confusion during second stage labour.

- **Key uncertainties** around the evidence or technology are that half of the studies have been published on a previous version of the technology. In the studies using the previous version of the technology most of the women were not in labour.
- The **cost** of the Novii system is £4,995 and the Novii Wireless Patch System is about £35 per person (excluding VAT). The Novii system can only be used with the GE Corometrics 259cx Maternal Fetal Monitor (£6,600). The Novii system can be cost saving if the NHS trust already has a GE Corometrics 259cx Monitor. The cost of standard care (CTG monitoring) would be about £7,000 for the maternal fetal monitor depending on different options and about £30 per person for the belt, gel and fetal scalp electrode.

The technology

Novii Wireless Patch System (GE Healthcare) is a fetal and maternal monitor used to measure the heart rates of fetus and mother, and the activity of the uterus. It is used in labour when cardiotocography (CTG) monitoring of heart rates and uterus activity is needed. Novii Wireless Patch System is attached to the lower abdomen with multiple adhesive patches and connects wirelessly to the monitoring unit. Novii Wireless Patch System integrates with the Corometrics CTG monitor (GE healthcare), where clinical data are displayed, printed and available for transfer to the hospitals central perinatal surveillance system.

Innovations

The company claims that the wireless capability of Novii allows the wearer to move around during monitoring. It also claims that Novii's abdominal fetal electrocardiography (fECG) technology means once it acquires a signal, it does not need to be readjusted as the baby moves or if the transducer changes position away from the baby's heart. Also, a benefit of the multiple patches with ECG electrode areas is their ability to automatically detect and change to the strongest signal produced during monitoring, particularly when the woman or baby moves. The company claims that the Novii system can measure uterine contractions by detecting the electrical signal from the uterine muscle and processing it into a contraction pattern. This can be interpreted in the same way as a tocodynamometer (Toco), a device that monitors and records uterine contractions. It also claims that the Novii system provides a better performance than Toco, which indirectly measures the surface tension changes on the surface of the abdomen. The company claims that in

people with a high body mass index (BMI), Novii is more effective than wired monitoring with a transducer and belt. Novii may also reduce the need to apply an electrode to the baby's head. The company states that maternal heart rates (MHR) and fetal heart rates (FHR) are simultaneously monitored through 1 patch. The maternal ECG has a bigger amplitude and different morphological shape than the fetal ECG. The maternal ECG can be detected and separated from the fetal ECG. This helps to avoid the MHR and FHR being confused.

Current care pathway

CTG monitoring in the NHS is done predominantly through wired transducers. An ultrasound transducer is directed towards the baby's heart to monitor FHR and a separate Toco transducer monitors the abdominal surface tension changes caused by uterine contractions. Both transducers need specialist placement for good quality signals. The transducers are held in place by an elastic belt attached by wires to a static monitor, and the belt must be readjusted as the baby moves. MHR is not monitored by default, although some monitors can do this.

Monitoring FHR, uterine contractions and the baby's position is more difficult in women who are obese. These women are likely to have more complications. Also, growth restriction is more likely to have been missed from earlier scans, making accurate fetal monitoring particularly important in the intrapartum period. Fetal monitoring for women with a BMI over 30 kg/m^2 is based on the woman's preference and obstetric indications.

The following NICE Pathways have been identified as relevant to this care pathway:

- preterm labour and birth
- intrapartum care
- intrapartum care for women with obstetric complications
- induction of labour
- intrapartum care for women with existing medical conditions.

Population, setting and intended user

Novii Wireless Patch System is indicated for women who are at more than 36 completed

weeks (37.0), in labour, with singleton pregnancies. CTG should be offered when there are risk factors present during late pregnancy and labour. These include maternal pulse over 120 beats per minute, high blood pressure, protein in urine, high maternal temperature, vaginal blood loss, premature rupture of membranes, presence of significant meconium, unusual pain, abnormal positioning of the baby or umbilical cord, fetal growth restriction, low FHR or reduced movement of the baby.

Novii Wireless Patch is not suitable for multiple pregnancies and does not transmit a signal while immersed in a birthing pool, although the company states it can be used in the shower.

The technology will be used by midwives. Obstetricians will also be involved in the interpretation of the clinical data. Training to use Novii Wireless Patch System is needed and provided onsite by the company after purchase of the equipment. The training is included in the cost of the device. Training materials and training videos are also available.

Costs

Technology costs

The company states that Novii Wireless Patch System consists of the following components:

- GE Novii system: £4,995
- GE Novii Patch: £35 per person
- GE Corometrics 259cx Maternal Fetal Monitor: £6,600. Only needed if the NHS trust does not have a GE Corometrics monitor.

There are also costs for temperature monitoring, blood pressure cuffs and, if needed, fetal scalp monitoring (see cost of standard care for details).

Costs of standard care

The company states that the costs for using CTG in labour and birth is around £7,000, depending on different options. Aside from the fetal monitor, options include a cart, temperature monitoring, external display and other accessories such as blood pressure

cuffs and additional transducers.

- Belt: £2 to £5 per person.
- Gel: approximately £1 per person.
- Fetal scalp electrode: £12 (excluding gloves, attachment pad). Multiple electrodes may be needed.
- Ultrasound transducer: approximately £300 (reusable).
- Toco transducer: approximately £300 (reusable).

Resource consequences

The company states that the technology is currently only used in Barnsley Hospital NHS trust.

The company states that although Novii Wireless Patch System is more expensive than CTG, the technology is expected to be resource releasing. This is because less midwife time will be needed as the monitor does not need to be readjusted. The technology can also be used in people with a high BMI, which may reduce the need for more invasive monitoring techniques such as applying electrodes to the baby's scalp. Novii Wireless Patch System displays MHR and FHR separately, so there is less chance of MHR and FHR confusion. As Novii Wireless Patch System allows the wearer to move around it is likely to lead to less stress for the woman, and research shows increased maternal movement results in reduced pain, shorter duration of labour and fewer caesarean sections.

Better monitoring may also reduce costs in the long term, through reduced cerebral palsy and clinical negligence cases for NHS trusts.

Regulatory information

Novii Wireless Patch System is a CE-marked class IIb in vitro diagnostic.

The following manufacturer field safety notices or medical device alerts for this technology have been identified:

Monica Healthcare: Monica Novii Wireless Patch System, Medicines and Healthcare products Regulatory Agency field safety notice (May 2017). A potential safety issue was identified when leaving the Novii Wireless Patch System plugged in and charging, unattended and not in clinical use, for days or weeks. The issue was resolved by releasing a software update and confirming all affected units in the field were upgraded free of charge.

Monica Healthcare: Monica Novii Wireless Patch System, Medicines and Healthcare products Regulatory Agency field safety notice (December 2017). A potential safety issue was identified that can happen if the interface cables of Novii Wireless Patch System are removed, and then incorrectly reconnected. The instructions and labelling describe the correct procedure for connecting the 3 interface cables to the Novii Interface System. This issue was resolved by providing screws and instructions that replace the user-accessible thumb screw hardware, with hardware that needs a screwdriver to apply and remove.

Equality considerations

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

Novii Wireless Patch System is intended for pregnant women during labour, including women with a high body mass index. Sex, physical disability and pregnancy are protected characteristics under the Equality Act 2010.

Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the interim process and methods statement. This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting mibs@nice.org.uk.

Published evidence

Six studies are summarised in this briefing, including a total of 487 people.

Three studies used the Novii Wireless Patch System and 3 studies used the AN24 device by Monica Healthcare. The Novii Wireless Patch System is a different product to AN24 but is based on the same technology and uses the same number and positioning of electrodes. Novii Wireless Patch System has an improved design that makes it easier to use, wireless and more comfortable, and gives greater control over electrode positioning. The Novii Wireless Patch System also features additional monitoring channels and improved monitoring of fetal heart rate (FHR), maternal heart rate (MHR) and uterine contractions.

Two studies were reported in abstract format only and so are limited in detail. One study is a randomised controlled trial (RCT) comparing Novii with doppler standard external monitoring (SEM), with 2 secondary analyses after this RCT. Two studies are non-comparative single arm studies and 1 study compared AN24 with a diffuse electrode array. Three of the studies included women with body mass indexes (BMIs) over 30 kg/m^2 and the results support the company's claim that the technology is effective in these women. There are further studies not summarised here: 3 published studies and 2 conference abstracts on AN24 (Cohen et al. 2012; Hayes-Gill et al. 2012; Hayes-Gill et al. 2019; Durosier et al. 2013; Geraldes et al. 2015). One study concluded that electrohysterographic technique (AN24) was more reliable and similar in accuracy to tocodynamometry in detecting intrapartum uterine contractions (Hayes-Gill et al. 2012).

The clinical evidence and its strengths and limitations is summarised in the overall assessment of the evidence.

Overall assessment of the evidence

The evidence for the technology is of low to moderate methodological quality, and most of the studies are small in terms of patient numbers. One study was partially done in the UK, but it is not clear if it was an NHS setting. The comparators chosen for the studies represent standard care in the NHS. The evidence shows that the technology is at least equivalent to standard care, is more effective in people with high BMIs (over 30 kg/m^2) and reduces MHR and FHR confusion during second stage labour.

Monson et al. (2020a)

Study size, design and location

RCT of 218 women in labour in the US.

Intervention and comparator

Novii Wireless Patch System compared with FHR SEM.

Key outcomes

Device setup failure occurred more often in the fetal electrocardiography (fECG) group (8 of 107 [7.5%] compared with 0 of 109 [0%] for SEM). There was no difference in the percentage of interpretable tracing between the 2 groups. However, fECG produced more interpretable FHR tracing in subjects with a BMI of 30 kg/m^2 or more. When considering the percentage of interpretable minutes of FHR tracing while on study device only, fECG outperformed SEM for all subjects, regardless of maternal BMI. Maternal demographics and clinical outcomes were similar between arms. In the fECG group, there were more device changes compared with SEM (51% compared with 39%), but there were fewer nursing device adjustments (2.9 compared with 6.2 mean adjustments intrapartum; $p<0.01$). There were no differences in physician device satisfaction scores between groups, but fECG generated higher patient satisfaction scores.

Strengths and limitations

This study adds to the very limited data available on comparing new FHR monitoring to SEM using a RCT design. It shows that fECG performed similarly to SEM, generated higher patient satisfaction rates and may be particularly useful in patients with a BMI over 30 kg/m^2. Obvious differences in the devices' appearances limited blinding, which may have led to provider, nurse and patient bias.

Monson et al. (2020b)

Study size, design and location

Secondary analysis of RCT data of 218 women in labour in the US.

Intervention and comparator

Novii Wireless Patch System compared with standard external FHR monitoring.

Key outcomes

A regression model Akaike information criteria (AIC) plot identified 31 kg/m^2 as the ideal BMI cut-off point for fECG device performance. At this point, fECG gave consistently more interpretable 10-minute FHR tracing segments compared with SEM. For the 1-minute FHR tracing analysis, an even lower BMI cut-off point of 25 kg/m^2 was identified based on AIC estimates. At a BMI of 25 kg/m^2, fECG gave a higher proportion of interpretable minutes of FHR tracing compared with SEM.

Strengths and limitations

This study shows that fECG consistently generated more interpretable 10-minute and 1-minute FHR tracing segments compared with SEM in women with BMIs over 31 kg/m^2 and 25 kg/m^2, respectively. Women with BMIs over 31 kg/m^2 may benefit from fECG device in labour. This study is based on the same group of patients included in Monson et al. (2020a). This study is reported in abstract form only and therefore is limited in detail.

Monson et al. (2020c)

Study size, design and location

A secondary analysis of RCT data from 117 women in the US assigned to either fECG or SEM who remained on their study device into the second stage of labour.

Intervention and comparator

Novii Wireless Patch System compared with SEM.

Key outcomes

Maternal demographics and clinical outcomes were similar between arms. fECG generated significantly more interpretable 10-minute segment FHR data in the second stage of labour. fECG use resulted in almost double the amount of interpretable 10-minute FHR tracing segments compared with SEM. Similar findings were noted in the 1-minute

segment FHR tracing analysis.

Strengths and limitations

This study highlights the clinical utility of fECG, particularly during the second stage of labour, when FHR tracing signal quality is often compromised. This study is based on the same group of women included in Monson et al. (2020a). This study is reported in abstract form only and so is limited in detail.

Graatsma et al. (2010)

Study size, design and location

An observational study of 204 pregnant women in the Netherlands.

Intervention and comparator

AN24 (Monica Healthcare).

Key outcomes

Participants' BMI ranged from 16.0 kg/m^2 to 50.7 kg/m^2 (median 26.9 kg/m^2). The correlation coefficient between BMI and recording quality was -0.35 (95% confidence interval [CI] -0.60 to -0.03) for the gestational age group 20 weeks to 25 weeks plus 6 days, -0.08 (95% CI -0.28 to 0.13) for the 26 weeks to 33 weeks plus 6 days group, and -0.20 (95% CI -0.40 to 0.03) for the 34 weeks or more group. Median recording quality in participants with BMIs of 30 kg/m^2 or more in each gestational age group was 97.4%, 98.9%, and 100%, respectively. BMI has no clinically significant influence on FHR recording quality using fECG. It can therefore be considered a good method for monitoring the condition of the baby in pregnancies of women who are obese.

Strengths and limitations

AN24 is a previous version of Novii Wireless Patch System. This study shows that AN24 is effective for monitoring in pregnant women with a range of BMIs, including those with a BMI of 30 kg/m^2 and over who would be classified as obese or severely obese. The evidence is based on pregnant women who were not in labour. The results should be

interpreted with caution and further research is needed to determine the effect on women in labour.

Hill et al. (2014)

Study size, design and location

An equivalence study of 24 pregnant women in the UK and US.

Intervention and comparator

AN24 (Monica Healthcare) and a diffuse electrode array.

Key outcomes

Success rates for AN24 and the comparator were nearly identical (98.5% plus or minus 1.9% compared with 98.4% plus or minus 1.9%, respectively; p=0.879). The overall positive percent agreement of AN24 and the comparator was 94.7% plus or minus 3.8%. AN24 was as accurate as the comparator. The overall root-mean-square error of the Bland-Altman regression line was 5.5 beats per minute (bpm) plus or minus 2.4 bpm. Mean overall bias was near 0 (-0.004 bpm plus or minus 0.416 bpm). No measurements were affected by labour stage or BMI.

Strengths and limitations

AN24 is a previous version of the Novii Wireless Patch System. Part of the study was done in the UK so the setting may be more representative of NHS practice. This study shows that the AN24 is equivalent to a diffuse electrode array. One of the authors of the study is an employee of Monica Healthcare.

Stampalija et al. (2012)

Study size, design and location

A prospective longitudinal study of 41 women in labour in Italy.

Intervention and comparator

AN24 (Monica Healthcare) and doppler telemetry.

Key outcomes

The overall success rate for FHR monitoring was similar between trans-abdominal ECG and doppler telemetry (88.5% plus or minus 16.7% compared with 89.4% plus or minus 7.6%), except for the second stage of labour. A significantly higher rate of FHR and MHR confusion ($p<0.001$) was found for doppler telemetry (4.5% plus or minus 4.5%) compared with trans-abdominal ECG (1.3% plus or minus 1.9%), especially in the second stage of labour and during maternal movements.

Strengths and limitations

AN24 is a previous version of Novii Wireless Patch System. This study shows that trans-abdominal ECG monitoring is feasible, with comparable success rate to traditional doppler telemetry, without interfering with maternal mobility or requiring midwife intervention. Furthermore, the reduction in MHR and FHR confusion from trans-abdominal ECG could reduce obstetric interpretation errors.

Recent and ongoing studies

- Performance of the Monica Novii Wireless Patch System in pre-term labor. ClinicalTrials.gov identifier: NCT03057275. Status: completed, no results published. Indication: pre-term labour. Devices: Novii Wireless Patch System, doppler FHR, TOCO UC and photo plethysmograph MHR Predicate. Completion date: September 2019. Country: US.
- Performance of the Monica Novii Wireless Patch System in threatened and actual pre-term labour. ClinicalTrials.gov identifier: NCT03223324. Status: completed, no results published. Indication: pre-term labour. Devices: Novii Wireless Patch System. Completion date: May 2017. Country: Italy.

- Accuracy and reliability of Novii: fetal heart rate (FHR), maternal heart rate (MHR) and uterine contraction (UA) compared with doppler, scalp fetal scalp electrode (FSE), tocodynamometer (TOCO) and intra uterine pressure catheter (IUPC). ClinicalTrials.gov identifier: NCT03409146. Status: completed, no results published. Indication: term labour. Devices: Novii Wireless Patch System. Completion date: February 2017. Country: US.

Expert comments

Comments on this technology were invited from clinical experts working in the field and relevant patient organisations. The comments received are individual opinions and do not represent NICE's view.

All experts were familiar with the device but only 1 expert had used this device before.

Level of innovation

Four experts agreed that Novii is an innovative technology, while 2 experts said that it is a variation of standard care. All experts agreed that apart from standard care practice, no other similar technologies are currently available to the NHS. This device is novel because it is wireless and therefore does not need to be adjusted when moving, increasing mobility and comfort and the device is attached to the abdomen and not the baby's scalp.

Potential patient impact

All clinical experts noted that using Novii can allow increased mobility. The experts also noted that Novii is more comfortable and less invasive than applying electrodes to the baby's scalp. Also, it can be used in early labour before membrane rupture and fetal heart rate can still be monitored while the woman is positioned for epidural. Overall, experts noted that Novii is unlikely to change the current pathway or improve clinical outcomes, but it can potentially lead to a better birth experience.

Four experts noted that Novii would be of benefit to people who need continuous fetal monitoring but wish to remain mobile during labour. Five experts agreed that people with a high body mass index would benefit, however 1 expert noted that the evidence for this is currently limited.

Potential system impact

Two experts noted that Novii could lead to a reduction in more invasive methods of fetal heart rate monitoring, with 1 expert noting a potential reduction in time and cost compared with fitting more invasive methods. One expert noted better quality monitoring. One expert said that Novii can potentially increase patient safety if there are fewer episodes of signal loss. Another expert said that using this technology may lead to better outcomes for labour and potentially reduce the demand for pain relief.

Six experts noted that Novii is likely to cost more than standard care, and 1 expert felt unable to comment on the costs. One expert noted that Novii is perhaps not appropriate during advanced labour and may need to be used in addition to the current doppler technology.

Three experts mentioned Novii potentially having a positive impact on midwife time as there is no need to readjust the belt. However, 1 expert noted that there is no evidence to support this and another expert clarified that midwives are attending people in labour for other reasons apart from cardiotocography (CTG) monitoring. Other experts expected little resource impact and 1 expert noted that the main resource impact would be the purchase of the device. One expert noted that currently only GE monitors are compatible with Novii and that resources are needed to ensure existing monitors can accept input from Novii.

Five experts expressed the need for training midwives on how to use Novii.

None of the experts were aware of any safety issues surrounding this technology.

General comments

Five experts agreed that it has the potential to eventually replace standard care, and 1 expert said that it is in addition to standard care. One expert said that sometimes there is unexplained loss of signal during the second stage of labour. Another expert noted that currently it cannot replace doppler monitoring, which is needed to fill in any gaps in monitoring during the second stage of labour. This potentially puts babies at risk as it takes time to switch monitors. Experts raised other issues with the usability of the technology including the inability to use Novii in multiple pregnancies and whether the patches would be affected by sweat and other bodily fluids.

One expert said that there is other wireless monitoring technology available but that this

technology is particularly effective for women with a high body mass index. Two experts said that it cannot be used in a birth pool, unlike the Philips wireless system.

Experts noted that the main barriers to adoption in organisations or the NHS would be the additional costs, the need for specific fetal monitors and whether Novii can be integrated into existing infrastructures (for example, CTG outputs available on screens in the midwives' station).

One expert noted that evidence on the signal quality using the Novii system for uterine contractions is far less convincing than that for the fetal heart rate signal. All experts agreed that further research would be useful to address the uncertainty in the evidence base.

Expert commentators

The following clinicians contributed to this briefing:

- Dr Paul Ayuk, consultant obstetrician, Newcastle upon Tyne Hospitals NHS trust. Did not declare any interests.
- Dr Amarnath Bhide, consultant in obstetrics and fetal medicine, Fetal Medicine Unit, St George's Hospital. Did not declare any interests.
- Dr Latha Vinayakarao, consultant obstetrician and clinical lead for labour ward, Poole Hospital NHS trust. Did not declare any interests.
- Dr Allison Farnworth, senior research midwife and senior research methodologist, Newcastle University. Did not declare any interests.
- Miss Louise M Page, President, British Intrapartum Care Society, consultant obstetrician and gynaecologist, Chelsea and Westminster Hospital NHS Foundation trust. Did not declare any interests.
- Mr Austin Ugwumadu, consultant and clinical director, Women's Health Services, St George's University Hospitals NHS trust. Has received payment from Neoventa to lecture on fetal monitoring training courses and has received payment to undertake training for intrapartum care and fetal monitoring for maternity staff in the UK and overseas. Runs an annual training course for fetal monitoring at St George's University Hospitals NHS.

- Ms Bronwyn Godwin, midwife, Barnsley Birthing Centre. Did not declare any interests.

Development of this briefing

This briefing was developed by NICE. The interim process and methods statement sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

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