NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology guidance scope

Novii Wireless Patch system for maternal and fetal monitoring

1 Technology

1.1 Description of the technology

Novii Wireless Patch System (GE Healthcare) is a fetal and maternal monitor used to measure the heart rates of mother and baby as well as the activity of the uterus. It is used in labour when cardiotocography monitoring of heart rates and uterus activity is needed. Novii Wireless Patch System comprises multiple adhesive patches which are attached to the lower abdomen and a remote monitoring unit which receives data from the patches. Novii measures the fetal heart rate tracing from abdominal surface electrodes that pick up the fetal electrocardiogram (ECG) signal. Using the same surface electrodes, the system also measures uterine activity tracing from the uterine electromyography signal and the maternal heart rate tracing from the maternal ECG signal. Novii Wireless Patch System integrates with the Corometrics CTG monitor (GE Healthcare) in which clinical data are displayed, printed and made available for transfer to the hospital central perinatal surveillance system.

The innovative aspects of the technology are that it is wireless and therefore allows the wearer to move around during monitoring. The company also claims that once Novii acquires a signal, it does not need to be readjusted when the woman or baby moves. 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.

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1.2 Relevant conditions

Novii Wireless Patch System is indicated for women in labour with a singleton pregnancy who are at least 37 weeks of gestation. Cardiotocography should be offered when risk factors (in line with NICE intrapartum care guidance) for poor maternal and fetal outcome are identified during late pregnancy and labour. These factors include a 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 fetal heart rate, reduced movement of the baby, any risk factors recorded in the woman's notes that indicate the need for obstetric led care, induction of labour (use of oxytocin) or use of regional analgesia.

There were 603,766 deliveries in NHS hospitals during 2018-19. This is a decrease of 3.6% from 2017-18. In 2018-19, 26% of labours and deliveries were complicated by fetal stress [distress] and the use of cardiotocography would have been recommended.

1.3 Current management

Current management for maternal and fetal monitoring include continuous monitoring (cardiotocography).

Cardiotocography monitoring is done in the NHS predominantly through wired transducers. An ultrasound transducer is directed towards the baby's heart to monitor fetal heart rate and a separate tocodynamometer 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. Maternal heart rate is not monitored by default, although some monitors can do this.

If the cardiotocography trace is of poor quality or if there is concern about loss of contact between the machine and the ability to detect the fetal heart rate through the maternal abdomen, then placement of a fetal scalp electrode

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should be considered to monitor the fetal heart rate. The fetal scalp electrode is attached directly to the baby's head during a vaginal examination. BNF states that when labour is induced with oxytocin careful monitoring of fetal heart rate and uterine motility is essential for dose titration.

1.4 Regulatory status

The Novii Wireless Patch System received a CE mark in November 2019 as a class IIb device for fetal monitoring devices.

1.5 Claimed benefits

The benefits to patients claimed by the company are:

- Better birthing experience through increased comfort during monitoring because of the beltless and wireless design.
- Increased maternal freedom of movement can help to reduce levels of pain, length of labour and number of caesarean sections.

The benefits to the healthcare system claimed by the company are:

- Increased accuracy and reliability monitoring fetal and maternal heart rate and in detecting intrapartum uterine contractions compared with standard of care.
- Reduction in midwife time (no need to reposition the patches once a good connection has been established).
- An alternative to invasive monitoring such as fetal scalp electrodes when the ultrasound and tocodynamometer are not detecting the contractions or fetal heart rate, especially for women who might be contraindicated for invasive monitoring.
- Effective in women with high BMI, which potentially leads to a reduction in invasive interventions, complicated births, or caesarean sections.
- Includes both fetal and maternal heart rate monitoring. However, there is a minimal rate of maternal / fetal heart rate confusion because the maternal ECG has a bigger amplitude and morphological shape and can be detected and separated from the fetal ECG, avoiding misdiagnosis.
- Cost savings as a result of reduced need for interventions.

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2 Decision problem

Population	Women in labour with a singleton pregnancy who are at least 37 weeks gestation and in whom there are risk factors for poor maternal or fetal outcome present during late pregnancy and labour. Indication for continuous intrapartum CTG monitoring in line with NICE intrapartum care guidance.
Intervention	• Novii Wireless Patch System • AN24 maternal and fetal heart rate monitor (previous version)
Comparator(s)	• Continuous cardiotocography with an ultrasound and tocodynamometer transducer using a wired belt
Outcomes	The outcome measures to consider include: • Percentage of interpretable tracing minutes (fetal heart rate) • Overall success rate for fetal heart rate monitoring (maintaining signal) • Device set up failure and the need to use an alternative method of cardiotocography including fetal scalp electrodes • Nurse / midwife time and device adjustments (e.g. number of adjustments per hour) • Patient satisfaction • Maternal/fetal heart rate confusion and misdiagnosis • Reliability and accuracy of uterine activity / contraction monitoring • Midwife satisfaction • Other complications of delivery / assisted births • Levels of pain and duration of labour • Perinatal mortality (still birth rate) • Morbidity (including hypoxic injuries) • Baby resuscitation rates • Apgar scores • Operative birth incidence (includes assisted vaginal birth and caesarean birth) • Device-related adverse events.
Cost analysis	Costs will be considered from an NHS and personal social services perspective. The time horizon for the cost analysis will be long enough to reflect differences in costs and consequences between the technologies being compared. Sensitivity analysis will be undertaken to address uncertainties in the model parameters, which will include scenarios in which different numbers and combinations of devices are needed.
Subgroups to be considered	• Women with high BMI • Women in whom there is a contraindication for invasive monitoring
Special considerations,	Novii Wireless Patch System is intended for pregnant women during labour, including women with a high body mass index.

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including those related to equality	Obesity is more common among people from deprived areas, older age groups, some black and minority ethnic groups and people with disabilities. Invasive fetal monitoring may be unsuitable for some women due to existing medical conditions that are considered disabilities. Sex, disability, race, age, and pregnancy and maternity are protected characteristics.	
Special considerations, specifically related to equality	Are there any people with a protected characteristic for whom this device has a particularly disadvantageous impact or for whom this device will have a disproportionate impact on daily living, compared with people without that protected characteristic?	No
	Are there any changes that need to be considered in the scope to eliminate unlawful discrimination and to promote equality?	No
	Is there anything specific that needs to be done now to ensure the Medical Technologies Advisory Committee will have relevant information to consider equality issues when developing guidance?	No
Any other special considerations	Not applicable.	

3 Related NICE guidance

Published

- Caesarean section (2011; updated 2019) NICE guideline CG132
- Intrapartum care for healthy women and babies (2014; updated 2017) NICE guideline CG190
- Preterm labour and birth (2015; updated 2019) NICE guideline NG25
- Intrapartum care for women with existing medical conditions or obstetric complications and their babies (2019) NICE guideline NG121
- Hypertension in pregnancy: diagnosis and management (2019) NICE guideline NG133

In development

NICE is developing the following guidance:

- Caesarean section (update) NICE guideline. Publication expected March 2021.

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4 External organisations

4.1 Professional

The following organisations have been asked to comment on the draft scope:

- Association for the Study of Obesity
- British Association for Nursing Cardiovascular Care
- British Association of Perinatal Medicine
- British Heart Foundation
- British Hypertension Society
- British Maternal and Foetal Medicine Society
- British Society for Gynaecological Surgery
- Cochrane Pregnancy & Childbirth Group (Co-ordinating Editors Professors Jim Neilson & Zarko Alfirevic)
- Nurses Hypertension Association
- Queen's Nursing Institute
- Royal College of Midwives
- Royal College of Nursing
- Royal College of Obstetricians and Gynaecologists
- Society for Cardiological Science and Technology

4.2 Patient

NICE's Public Involvement Programme contacted the following organisations for patient commentary and asked them to comment on the draft scope:

- Ante-natal Results and Choices (ARC)
- Association for Improvements in the Maternity Services
- Baby Lifeline
- Birth Trauma Association
- Bliss
- Little Heartbeats
- Tommy's - The Baby Charity
- Wellbeing of Women

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