Medical Device Alert

Action update

Ref: MDA/2010/054 Issued: 28 June 2010 at 15:30

Device

Fetal monitor/cardiotocograph (CTG).

This replaces MDA SN 2002(23) issued August 2002.

Problem

Adverse outcomes are still being reported in the presence of CTG traces that appear normal.

For example, the display of double maternal heart rate (MHR x 2) can be falsely reassuring.

Action by

Midwives, obstetrics and gynaecology medical staff, all clinical users of these medical devices.

CAS deadlines

Action underway: 28 July 2010
Action complete: 28 September 2010

Action

Local procedures for maintaining expertise should ensure that relevant clinical staff:

- do not rely solely on the CTG trace for fetal wellbeing and are aware of limitations and artefacts, such as double maternal heart rate being displayed
- confirm fetal heart rate using independent means (Pinard or hand held Doppler) if there is any clinical uncertainly
- read the manufacturer's instructions for use
- are familiar with the NICE clinical guideline for intrapartum care.

Device

Cardiotocographs (CTGs) monitor the fetal heart rate with an ultrasound transducer and maternal contractions with a toco (strain gauge) transducer. During labour, they give an indication of how the fetal heart rate (FHR) is responding to the stress caused by maternal contractions.

Problem

Cardiotocographs assist in the management of labour, but should not be relied upon in isolation to monitor the condition of the fetus.

The NICE clinical guideline 55 'Intrapartum care' (chapter 1.12.2 Interpretation of FHR traces/cardiotocographs) classifies four FHR trace features: 'Baseline', 'Variability', 'Decelerations' and 'Accelerations'.
It also gives values for 'Reassuring', 'Non-reassuring' and 'Abnormal'.
It then uses these features to define 'Normal', 'Suspicious' and 'Pathological' FHR traces. See appendix for details.

These guidelines also recommend that the maternal pulse is palpated if a FHR abnormality is detected, in order to differentiate the two heart rates (sections 1.6.13 observations during first stage of labour and 1.7.6 second stage).

The problem is that adverse incident reports often state that the fetal heart rate was in the normal range and staff only suspect a FHR abnormality after the event. CTG users should be aware of the limitations and artefacts that can occur, which have important implications for interpretation.

Below are two examples of situations that have occurred in UK hospitals.

Example 1 In two recently reported incidents the CTG trace showed the FHR was around 160 bpm. The maternal pulse had been noted earlier at around 80 bpm. In one case the baby was stillborn. In the other the baby required extensive resuscitation. It was later suspected that in both cases the trace was showing double maternal rate and was falsely reassuring.
Explanation The fetus can move out of the ultrasound field or in extreme cases the fetal heart can stop beating. The ultrasound may then pick up the maternal pulse from the aorta, iliac or uterine artery. The FHR displayed will then actually be the maternal heart rate, MHR. **Sometimes the maternal artery movement is double counted so MHR x 2 is displayed. This can be within the same range as the expected FHR and can be more difficult to interpret.** The resulting trace shows reactivity and variability due to MHR changes and muscle contractions and can be difficult to distinguish from FHR.

Example 2 It has been observed that half the fetal heart rate (FHR ÷ 2) can be displayed.
Explanation This can be due to difficulty in extracting the weak fetal heartbeat Doppler ultrasound signal from the noisy maternal environment.

Action

Check the presence of a fetal heartbeat by independent means (e.g. Pinard stethoscope, hand-held Doppler)
a) before starting CTG monitoring.
b) after a period where the FHR trace is reassuring and then a change occurs.
c) after a period where the FHR trace is non-reassuring and then appears to recover.

Consider maternal ECG or pulse oximetry (SpO_2) monitoring when using CTG monitors incorporating cross correlation software. This can alert the user when the FHR is the same value as the MHR.
Although an alert may not be generated if the FHR trace is constantly showing MHR x2, the recording of maternal pulse makes it easier for the user to check whether the FHR display could be MHR x 2.

Distribution

This MDA has been distributed to:

- NHS trusts in England (Chief Executives)
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Chief Executives)
- NHS boards and trusts in Wales (Chief Executives)
- Primary care trusts in England (Chief Executives)

Onward distribution

Please bring this notice to the attention of all who need to know or be aware of it. This may include distribution by:

Trusts to:

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- Anaesthetists
- Clinical governance leads
- Medical director
- Midwifery staff
- Nursing executive directors
- Obstetricians
- Risk managers

Care Quality Commission (CQC) (England only) to:

The MHRA considers this information to be important to:

- Hospitals in the independent sector
- Private medical practitioners

Primary care trusts to:

CAS liaison officers for onward distribution to all relevant staff including:

- Community midwives

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2010/054 or file number 2010/002/005/291/001**.

Technical aspects

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Clinical aspects

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How to report adverse incidents

Please report via our website http://www.mhra.gov.uk

Further information about **CAS** can be found at https://www.cas.dh.gov.uk/Home.aspx

Northern Ireland

Alerts in Northern Ireland will continue to be distributed via the NI SABS system.

Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)
Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast BT16 1US

Tel: 02890 523 704
Fax: 02890 523 900
Email: NIAIC@dhsspsni.gov.uk

http://www.dhsspsni.gov.uk/index/hea/niaic.htm

SAN2002(23) was published in Northern Ireland under SN(NI)2002/28.

How to report adverse incidents in Northern Ireland

Please report directly to NIAIC, further information can be found on our website http://www.dhsspsni.gov.uk/niaic

Further information about **SABS** can be found at http://sabs.dhsspsni.gov.uk/

Scotland

Enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre
Health Facilities Scotland
NHS National Services Scotland
Gyle Square
1 South Gyle Crescent
Edinburgh EH12 9EB

Tel: 0131 275 7575
Fax: 0131 314 0722
Email: nss.iric@nhs.net

http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-iric/

This MDA supersedes SAN(SC)02/31 in Scotland, issued 12/09/2002.

Wales

Enquiries in Wales should be addressed to:

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Appendix

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Interpretation of FHR traces/cardiotocographs

1.12.2 The recommended definitions and classifications of the FHR trace/cardiotocograph produced during EFM are shown in tables 5 and 6.

Table 5 Definition of normal, suspicious and pathological FHR traces

Category	Definition
Normal	An FHR trace in which all four features are classified as reassuring
Suspicious	An FHR trace with one feature classified as non-reassuring and the remaining features classified as reassuring
Pathological	An FHR trace with two or more features classified as non-reassuring or one or more classified as abnormal

Table 6 Classification of FHR trace features

Feature	Baseline (bpm)	Variability (bpm)	Decelerations	Accelerations
Reassuring	110–160	≥ 5	None	Present
Non-reassuring	100–109 161–180	< 5 for 40–90 minutes	Typical variable decelerations with over 50% of contractions, occurring for over 90 minutes Single prolonged deceleration for up to 3 minutes	The absence of accelerations with otherwise normal trace is of uncertain significance
Abnormal	< 100 > 180 Sinusoidal pattern ≥ 10 minutes	< 5 for 90 minutes	Either atypical variable decelerations with over 50% of contractions or late decelerations, both for over 30 minutes Single prolonged deceleration for more than 3 minutes	

Further information about classifying FHR traces is given below.

- If repeated accelerations are present with reduced variability, the FHR trace should be regarded as reassuring.
- True early uniform decelerations are rare and benign, and therefore they are not significant.
- Most decelerations in labour are variable.
- If a bradycardia occurs in the baby for more than 3 minutes, urgent medical aid should be sought and preparations should be made to urgently expedite the birth of the baby, classified as a category 1 birth. This could include moving the woman to theatre if the fetal heart has not recovered by 9 minutes. If the fetal heart recovers within 9 minutes the decision to deliver should be reconsidered in conjunction with the woman if reasonable.
- A tachycardia in the baby of 160–180 bpm, where accelerations are present and no other adverse features appear, should not be regarded as suspicious. However, an increase in the baseline heart rate, even within the normal range, with other non-reassuring or abnormal features should increase concern.