Safety Information 014/23

Issue date
30 November 2023

Distributed to:
- Chief Executives
- Directors of Clinical Governance
- Director, Regulation and Compliance Unit

Action required by:
- Chief Executives
- Directors of Clinical Governance

We recommend you also inform:
Directors, managers, and staff of:
- Maternity Services
- Emergency Departments

Expert Reference Group Content reviewed by:
Representatives from:
- Maternity and Neonatal Stream, Clinical Excellence Commission
- Health and Social Policy Branch – Ministry of Health
- State Preparedness and Response Unit – Ministry of Health

Clinical Excellence Commission
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Review
November 2024

Updated: Potential increased risk of perinatal mortality associated with home fetal heart rate monitors (fetal dopplers) and baby movement Apps

What is updated in the Safety Information from 007/22?
Updated to include advice on cancellation of some home fetal heart rate (FHR) monitors (fetal dopplers) from the Australian Register of Therapeutic Goods (ARTG) by the Therapeutic Goods Administration (TGA). Additional information on the risks associated with baby movement Apps has also been included.

Situation
Several stillbirths and neonatal deaths have occurred in Australia following expectant parents misinterpreting the sounds detected from home fetal heart rate monitors. Baby movement Apps may also result in false reassurance of fetal wellbeing. Recently during the post-market review, some fetal dopplers have been cancelled from the ARTG by the TGA.

Background
Home fetal heart rate monitors are widely available without prescription to the public. They provide a snapshot of the fetal heart rate, indicating that the fetus is alive but provides little information on the overall wellbeing of the fetus. In untrained hands, it is difficult to accurately interpret the fetal heart rate and rhythm and distinguish between the maternal and fetal heartbeats.

There are a range of Apps and other software products available for recording pregnancy milestones, or for monitoring fetal movements during pregnancy. These products are widely available and can be downloaded by expectant parents. Their use may also result in false reassurance of fetal wellbeing.

Australian peak maternity bodies[1], national regulatory organisations[2,3] and other professional organisations[4] have cautioned against the use of home fetal heart rate monitors. The TGA has undertaken a review of their safety and will continue to provide updates on the review[3].

Assessment
The use of home fetal heart rate monitors and baby movement Apps by expectant parents may lead to false reassurance of fetal wellbeing and delayed presentation to maternity services for assessment.

Additional stress and anxiety for expectant parents may occur when the fetal heartbeat cannot be located with a home fetal heart rate monitor.

Clinical Recommendations
- During the antenatal period all expectant parents must:
  - be cautioned about the potential risks of using home fetal heart rate monitors (fetal dopplers) and baby movement Apps.
  - be advised to contact their maternity service and present for review without delay if they are concerned about their baby's wellbeing. This message should be reinforced regardless of what is or isn't heard on a home fetal heart rate monitor, or what advice a baby movement App may provide.
  - be provided with verbal and written information about fetal movements prior to 28 weeks gestation. Resources on decreased fetal movements can be found on the CEC Safer Baby Bundle Website.

- At every clinical encounter from 28 weeks gestation, clinicians must emphasise the importance of maternal awareness of fetal movements.
- When pregnant women report concerns about fetal movements, the NSW Health Guideline Care *Pathway for Women Concerned about Fetal Movements* (GL2021_019) must be followed.

Required actions for the Local Health Districts/Networks

1. Distribute this Safety Information to all relevant maternity clinicians including maternity managers, heads of department, childbirth educators, antenatal clinics, maternity day assessment units, birth units and inpatient wards, as well as emergency departments.
2. Include this Safety Information in relevant clinical handovers and safety huddles.
3. Report any adverse incidents associated with home fetal heart rate monitors or baby movement Apps via ims+ and to the TGA.

References

1. Royal Australian and New Zealand College of Obstetrics and Gynaecology (2009), Position Statement on Home Fetal Heart Monitoring. Available at: https://ranzcog.edu.au/wp-content/uploads/2022/05/Home-Fetal-Heart-Monitoring.pdf
2. Australian Government Therapeutic Goods Administration (2022) Use of fetal dopplers (heartbeat monitor) [Website]. https://www.tga.gov.au/monitoring-communication/home-use-fetal-dopplers-heartbeat-monitor.
3. Australian Government Therapeutic Goods Administration (2023). Post-market review of home use foetal dopplers [Website]. https://www.tga.gov.au/how-we-regulate/supply-therapeutic-good/supply-medical-device/medical-device-post-market-reviews/post-market-review-home-use-foetal-dopplers.
4. Stillbirth Centre of Research Excellence (2023), Warning: use of home fetal Doppler devices during pregnancy. Available at: https://learn.stillbirthcre.org.au/wp-content/uploads/2023/08/CRE_Home-Doppler-statement.pdf