Information for General Practitioners Update - Home fetal heart monitors (dopplers)

Introduction

Important information for General Practitioners who care for pregnant women.

Situation

- In 2022, Queensland Health raised concerns about the use of home fetal heart monitors (dopplers) with the Therapeutic Goods Administration (TGA).
- This was in response to a retrospective audit in 2021-2022 conducted by the Queensland Maternal
 and Perinatal Quality Council, which uncovered potential risks associated with the use of home fetal
 heart monitors in pregnancy.
- The audit identified four clinical incidents involving the use of fetal dopplers at home, which saw women, concerned about a lack of fetal movement, being falsely reassured about their baby's heart rate.
- The four clinical incidents included three stillbirths and one baby dying shortly after birth.

Background

- In response to the reports, the TGA undertook a post-market review of all home use dopplers included in the Australian Register of Therapeutic Goods (ARTG). The purpose was to determine whether the risk of using these devices outweighed the potential benefit.
- On September 4, 2024, the TGA published the findings of their review. They announced: "All homeuse fetal dopplers that were intended to be used without the supervision of a healthcare professional have been removed from the ARTG." The cancellation means **home-use devices will no longer be available for purchase.**
- The TGA also considers Baby Movement Apps to be medical devices and must be included in the ARTG. These digital products may deter people from seeking medical attention if they are concerned about their baby's well-being.

How can the GP assist with this issue?

- Caution expectant parents about the potential risks of using home fetal dopplers or Baby Movement Apps.
- Advise expectant parents to contact their midwife or doctor and present to a maternity facility for timely review if they are concerned about their baby's well-being.
- Include the risks of home fetal doppler/Baby Movement App use in messaging around decreased fetal
 movements during antenatal appointments and when clinicians are in contact with concerned
 expectant parents.

More information

References

- Australian Government Therapeutic Goods Association (2024) <u>Post-market review of home-use fetal</u> dopplers
- 2. Royal Australian and New Zealand College of Obstetrics and Gynaecology (2009) <u>Position Statement on Home Fetal Heart Monitoring</u>

