Risks Associated with Use of Rupture of Membranes Tests - Letter to Health Care Providers

[Posted 08/08/2018]

AUDIENCE: OBGYN, Risk Manager, Health Professional

ISSUE: The FDA is reminding health care providers that tests to detect rupture of the amniotic membranes should not be used without other clinical assessments to make critical patient management decisions. Health care providers using rupture of membranes (ROM) tests should be aware of test limitations listed within manufacturer instructions. The following limitations are typically stated in ROM device labeling:

- A negative result does not assure the absence of membrane rupture.
- False negatives may result if the amniotic sac has resealed or the position of the fetus has obstructed the rupture.
- The presence of blood, meconium, anti-fungal creams or suppositories, baby powder, baby oil, or the use of lubricant with a vaginal exam may interfere with the device.
- The test may not be accurate if sample collection and testing occurs after the timeframe recommended by the manufacturer.

BACKGROUND: The FDA is aware of adverse events related to the use of ROM tests, including 15 fetal deaths and multiple reports of health complications in pregnant women. In addition, the FDA has received information which indicates that health care providers may be over-relying on ROM test results when making critical patient management decisions, despite labeling instructions warning against this practice.

RECOMMENDATION: To help protect patients and reduce the chance of adverse events, ROM tests should be part of an overall clinical assessment, which may include physical examination of the patient and testing to detect leaking amniotic fluid.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: **www.fda.gov/MedWatch/report (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home)**
- **Download form (/Safety/MedWatch/HowToReport/DownloadForms/ucm2007307.htm)** or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

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