Safety Notice 012/18

Rupture of membranes testing in maternity settings

20 August 2018

Distributed to:

- Chief Executives
- Directors of Clinical Governance
- Director Regulation & Compliance Unit

Action required by:

- Chief Executives
- Directors of Clinical Governance

We recommend you also inform:

- Directors of Obstetrics
- Midwifery managers
- Obstetric Medical staff
- Midwives
- Directors of Medical Services
- Directors of Nursing/Midwifery

Expert Reference Group

Content reviewed by:

- Senior Clinical Advisor Obstetrics
- Maternity Risk Network
- Office of the Chief Health Officer
- Director Patient Safety

Clinical Excellence Commission

Tel. 02 9269 5500
Fax. 02 9269 5599

Email:
CEC-Quality@health.nsw.gov.au

Internet Website:
http://www.health.nsw.gov.au/sabs

Intranet Website
http://internal.health.nsw.gov.au/quality/sabs/

Review date

August 2019

Background

There have been several clinical incidents recently reported, including one SAC 1 incident, where rupture of membrane (ROM) test results have been used to make a definitive diagnosis in place of history and clinical examination findings. These incidents have resulted in prelabour rupture of membranes (PROM) not being diagnosed and managed appropriately, with subsequent poor outcomes for the neonates.

Delayed diagnosis of PROM can potentially result in significant maternal and neonatal morbidity, in particular sepsis.

There are a number of ROM testing kits available which are 'non-invasive' and purport that they can be used in place of a speculum examination. This is not consistent with best practice guidelines. Clinicians need to be aware of the limitations of these tests:

- 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 blocks the further passage of liquor.
- 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 test.
- The test may not be accurate if sample collection and testing occurs after the timeframe recommended by the manufacturer.

The United States Food and Drug Administration (FDA) have recently published a News Release to alert healthcare providers and women with the risks associated with improper use of rupture of membranes tests.

Best Practice Guidelines

RANZCOG guidelines state that where there is diagnostic uncertainty, a sterile speculum examination should be performed, and pH based tests (e.g. Nitrazine) or those that test for the presence of amniotic fluid proteins in vaginal fluid (e.g. Amnisure, Actim PROM, ROM Plus) may be used.

ROM tests are an adjunct to the clinical assessment.

In the event of suspected PROM:

1. Undertake a detailed clinical history
2. Perform a thorough clinical assessment, including a sterile speculum examination
3. Determine the need for rupture of membranes testing

The FDA recall on AmniSure ROM does not include products in Australia, it is only applicable to kits sold in the United Stated and Canada.

Suggested actions by Local Health Districts/Networks

1. Forward information to appropriate areas for action.

2. Report problems related to ROM testing kits to the TGA at: https://www.tga.gov.au/reporting-problems and via the Incident Information Management System (IIMS).

3. Document actions taken.