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Patient Safety Alert: Wireless Oesophageal pH Capsule Monitoring

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Summary

- NHS England have recently communicated with the British Society of Gastroenterology (8/4/25) that recent cases of retained wireless oesophageal pH monitoring capsules have resulted in serious harm, including:
    - Oesophageal perforation requiring stapling
    - Deep neck space abscesses
    - Cardiac arrest
- Current patient information appears to provide inadequate details regarding the warning signs of retention.
- Follow-up procedures to confirm passage vary significantly between institutions, with some patients experiencing significant delays between symptom onset and diagnosis of retention.

Action

All healthcare professionals who perform or manage wireless oesophageal pH capsule monitoring should:

Appropriate Use of Wireless pH Monitoring

- Ensure adherence to previous BSG guidelines for oesophageal manometry and oesophageal reflux monitoring (esophageal Manometry and Reflux Monitoring Guidelines | BSG) to enhance patient selection.

Pre-Procedure patient information

- Provide all patients with standardised written information that:
    - Explains the expected timeframe for natural passage (typically 5-7 days)
    - Clearly states that patients should actively confirm passage
    - Lists specific symptoms that might indicate retention:
        - *Persistent or worsening chest pain*
        - *Neck discomfort or pain*

- *Difficulty swallowing (dysphagia)*
- *Pain on swallowing (odynophagia)*
- *Unexplained cough*
- *Sensation of something stuck in the throat/chest*
- *Fever or signs of infection*

Verification of capsule passage

- Provide patients with practical guidance for confirming capsule passage following insertion.
  - Include information about the size, shape and colour of the capsule.
  - Give clear instructions for checking stools for 7-10 days post-procedure.
  - Establish a mechanism for patients to call back relevant departments if they have not confirmed passage within 10 days.

Follow-up protocol

- Consider a structured follow-up process:
  - For example, schedule telephone follow-up 7-10 days post-procedure
  - Document whether capsule passage has been confirmed
- For patients who have not confirmed passage, but are asymptomatic:
  - Suggest extending the monitoring period for an additional 7 days
  - Consider chest and abdominal X-ray if passage is still not confirmed after 14 days
- For patients reporting potentially concerning symptoms:
  - Arrange urgent clinical review
  - Consider imaging (X-ray or CT scan) without delay
  - Have a clear pathway for escalation if retention is confirmed

MRI safety

- Emphasise that MRI imaging is contraindicated for 30 days after the wireless oesophageal capsule placement, unless there is confirmed passage of the wireless oesophageal capsule.
- For patients who have not confirmed passage of the capsule by 30 days, an X-ray is recommended for verification before any MRI scan is performed.

Reporting requirements

- Any suspected retention of a wireless oesophageal capsule causing harm should be:
  - Reported through local incident reporting systems
  - Reported to the MHRA via the Yellow Card scheme
  - Reported to the manufacturer as per vigilance requirements

Signatories on behalf of the BSG		
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