Safety Alert

CycloGEST – CytoTEC Errors in Pregnancy

Irish Medication Safety Network

Patient Safety First
Working together for quality services

Issue

- Sound-alike look-alike drug (SALAD) errors have occurred in maternity care with serious or extreme consequences. If a prostaglandin analogue e.g. misoprostol or dinoprostone, is used in error during pregnancy, serious patient harm including preterm delivery and foetal/neonatal death may occur.
- The following mix-ups have occurred:
  - Progesterone (**CycloGEST®**) and misoprostol (**CytoTEC®**)
  - **Progesterone** and **Prostin E2®** (dinoprostone)
- Such errors have been reported in Ireland and internationally in women receiving progesterone supplements to maintain a pregnancy in the context of recurrent miscarriage or preterm birth.
- These errors have occurred at various stages of the medication use process, e.g. inadvertently prescribing the wrong product or selecting the wrong product at the point of dispensing or administration.

Evidence of Harm [1,2]

- Recurrent cases have been reported where prescriptions for CycloGEST® 200 mg (progesterone) pessaries for recurrent miscarriage/threatened preterm delivery were dispensed as CytoTEC® 200 microgram (misoprostol) tablets in error resulting in patient harm.
- A woman was prescribed a progesterone pessary due to threatened preterm labour at 28 weeks' gestation. Prostin E2® (dinoprostone) was administered in error. Over the following hours the patient became increasingly unwell, complaining of back pain and abdominal cramping. A baby was delivered who required NICU admission.
- Two women, admitted for bedrest due to threatened preterm delivery, were administered Prostin E2® (dinoprostone) instead of progesterone. The first woman's twins died following delivery at 4 months' gestation. Several hours later the same error occurred again with the second woman: she subsequently delivered a baby at 28 weeks' gestation who suffered neurodevelopmental impairment.

How to Reduce the Risks

Short-Term Strategies

- Implement current IMSN recommendations to reduce the risk of SALAD errors[3]
- Provide induction training for new staff to highlight the risk of these SALAD errors
- Use tall man lettering to distinguish CycloGEST® from CytoTEC® in prescribing and dispensing systems
- Ensure that prescriptions are complete and legible, spelling 'microgram' in full
- Prescribe progesterone supplements both generically and by brand name, including an indication for use e.g. "For maintenance of pregnancy".
- Hospitals should review their processes for the storage and supply of prostaglandin analogues.
- Pharmacies and clinical areas should segregate prostaglandin analogues to reduce the risk of SALAD errors.
- Implement a robust checking process during the administration or dispensing of progesterone, misoprostol or other prostaglandin analogues. [4] If an independent second person check is not feasible, technical solutions such as barcode verification of the selected product should be considered.
- Health professionals must be aware of the indication for use of a prostaglandin analogue or progesterone supplement.
- Submit any near misses, medication errors or adverse drug reactions to local incident reporting systems, to the Health Products Regulatory Agency (www.hpra.ie) and the State Claims Agency.

Longer-Term Strategies

- Introduction of electronic health records across all 19 maternity hospitals in Ireland will enable printed inpatient and discharge prescriptions; however prescribers need to be aware of the risk of product selection errors in drop-down menus at the point of prescribing.
- Introduction of barcode scanning at the dispensing and administration stage of the medication use process would enable positive patient identification and ensure that product selection errors are detected.
- Electronic transmission of prescriptions would facilitate direct import into pharmacy dispensing systems, removing the risk of transcription errors.

References
1.Cohen MR, Smetzer JL. Varizig Dilution Issue Reported; Prostin E2 Suppository Confused with Progesterone; FIRST Brand Oral Vancomycin Needs Improved Labeling. Hospital Pharmacy. 2014;49(11):1001-8; **2**. Patel A. Tragic Medication Errors Result in Accidental Abortions and Premature Birth. ABC News URL:http://abcnews.go.com/Blotter/story?id=8383062. Accessed: 6th September 2016. (Archived by WebCite® at http://www.webcitation.org/6kJbAzZkO) 2009; **3** IMSN. Briefing Document on Sound-Alike Look-Alike Drugs (SALADs) 2010; **4** ISMP Independent Double Checks: Undervalued and Misused: Selective Use of This Strategy Can Play an Important Role in Medication Safety. URL:https://www.ismp.org/resources/independent-double-checks-undervalued-and-misused-selective-use-strategy-can-play. Accessed: 23rd January 2019. (Archived by WebCite® at http://www.webcitation.org/75eHDieHl)

Prepared by: Brian Cleary, Fergal O'Shaughnessy and Elmarie Cottrell on behalf of the Irish Medication Safety Network.