**Fentanyl Patches: Analysis of International Medication Incidents**

Authors: Roger Cheng, BScPhm., PharmD., Carol Samples, BGS., Carol Lee, CPhT, CCHRA(A)., David U, BScPhm., MScPhm., Sylvia Hyland, BScPhm., MHS(C) (Bioethics), Sibylle von Gussenberg, Certina Ho, BScPhm., MSt., MEd.

**BACKGROUND**

- Medication incidents reported around the world with fentanyl transdermal systems (fentanyl patches)
- Many of these incidents have resulted in patient harm and in some cases, even death

**OBJECTIVES**

- To gain an in-depth understanding of fentanyl patch incidents through the following:
  - an aggregate analysis of fentanyl patch incidents
  - a review of relevant medical literature
- To present recommendations for medication systems enhancements to ensure the safe use of fentanyl patches

**METHODOLOGY**

**DATA COLLECTION**

fentanyl patch incident data received from the participating medication and patient safety centers in the UK, US, Canada and Ireland

**QUANTITATIVE ANALYSIS**

- Incidents classified according to:
  - Severity / outcome (Figure 1)
  - Type of incident (Figure 2)
  - Medication system stages involved (Figure 3)

**QUALITATIVE ANALYSIS**

- Incidents with narrative data fields available
- Incidents reviewed by two analysts to identify main themes
- Further categorization within each main theme to achieve homogeneous clusters
- Clusters studied to identify potential contributing factors

**RESULTS**

**QUANTITATIVE ANALYSIS**

- From patients’ perspective:
  - 4 main themes identified:
    - Too much, too soon: dose or frequency too high
    - Too little, too late: dose or frequency too low
    - That’s my (shouldn’t get) inappropriate patient
    - Other
  - 21 potential contributing factors identified within each of the main themes

- From health system perspective:
  - 21 potential contributing factors re-grouped to 6 areas of medication systems improvement:
    - Critical information (e.g., inadequate knowledge on the part of health care practitioners)
    - Patient education
    - Complexities of administration
    - Communication (ordering and transcription)
    - Product design
    - Interfaces of care (e.g., fentanyl patches not recognized at interfaces of care)

**Example of potential contributing factors**

- Patient education not provided
  - “...a patient’s caregiver placed the fentanyl patch on the patient’s bicep, which was the site of her pain. When the patient went to bed, she also used a heating pad at the same place. The patient was discovered dead two days later...”
  - The prescribing physician had counselled her on how to use the patch properly, and they hadn’t told her to avoid applying heat over the patch.

- Patients with reduced functional status:
  - “A physician gave a 78 year old patient with chronic pain a prescription for fentanyl patch, with directions to apply on the buttock. The patient was confused and put the patches “wherever it hurt.” She applied 6 patches in all...”

- Lack of awareness of indication:
  - “A 14 year old boy was prescribed dextropropoxyphene 25 for throat pain due to infectious mononucleosis. He was found in a respiratory arrest 14 hours after the first and only patch was applied. Reassessment of errors were unsuccessful.”

**CONCLUSIONS**

- Multi-centered analysis conducted to gain an in-depth understanding of fentanyl patch-related incidents
- 6 areas of medication system improvement identified (21 potential contributing factors)
- Recommendations: Ensure practitioner knowledge and patient education
- Continued efforts are necessary for the further development of effective systems based solutions targeting the various areas of improvements identified in this analysis

Acknowledgements: Canadian Medication Incident Reporting and Prevention System (CMIRS), ISMP (US), National Patient Safety Agency (NPSA), U.K.; and Adelaide and Meath Hospital, Dublin, Ireland