Operationalizing Post Market Surveillance

CASE STUDY ONE

MedCon 2014
May 7, 2014

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Case Study 1 – "Sweet Dreams Anesthesia Device"

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The Operating Room Nurse stated that as they were beginning to induce a child using the firm's "Sweet Dreams anesthesia machine" the clinician went to press "Start Case button" and accidently pressed the "Checkout button" putting the anesthesia machine in a system checkout mode. Once the machine started the system checkout cycle, the clinician was not able to exit the cycle to begin ventilating the patient they had begun inducing.

The clinician observed the patient desaturating down to 70% so she began mouth to mouth breathing while they set up an ambu bag to manually ventilate the patient. They successfully stabilized the patient.

After 10 minutes, the anesthesia machine completed its checkout cycle, and they were able to ventilate the patient normally using the anesthesia machine.

Case Study 1 – "Sweet Dreams Anesthesia Device" Cont'd

Both the Hospital and the Firm's Biomedical Engineers tested the device and found the device operated normally and that there was no system malfunction.

As part of the firm's investigation, a complaint review identified two similar events. In one of these events, the patient expired. The firm's investigation of this previous event was unable to conclude whether the interruption of ventilation caused the patient death.

Questions:

1. Was there a serious injury?
2. If there was a serious injury, did the device cause or contribute to the patient injury?
3. Is the event reportable as an MDR?
4. What other actions should the firm take?

Case Study 1 – "Sweet Dreams Anesthesia Device" Discussion

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- *Clinician went to press "Start Case button" and accidently pressed the "Checkout button".*
- *Could not exit checkout cycle delaying patient ventilation.*
- *Required medical intervention to preclude serious injury*
- *Device operated normally; no system malfunction.*
- *Two previous complaints. One was a death event; firm unable to determine if interruption of ventilation caused the patient death.*

Questions

1. Was there a serious injury?

Yes, medical intervention to preclude a serious injury

2. If there was a serious injury, did the device cause or contribute to the patient injury?

Device did not cause (e.g. system malfunction), however, it contributed to the serious injury.

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3. Is the event reportable as an MDR?

Yes, although the serious injury was attributable to user error, this event is reportable as a MDR.

4. What other actions should the firm take?

- Utilize risk assessments for determination of whether the hazardous situation has been reduced to As Low as Reasonably Practicable.
  - Labeling alone or relying on training may be inadequate for this device and intended use.
  - Investigate adequacy of the design to prevent user error.

- Does the firm have a potential recall?