

Virtual Case for IMDRF Adverse Event Terminology Training

Case serial: SCH-2023-01-05

Title: Tubing line for dialyzer

Patient Condition

- A 54-year-old female patient on standby for regular hemodialysis for end-stage renal disease.
- Nurse was setting up a tubing line and a dialyzer on the Hemodialysis system.

Events

- There was an alarm for error in pressure and connection from the Hemodialysis system, when started to prime the Hemodialysis system.

Select the most appropriate IMDRF code for the above description.	
Annex A. Medical Device Problem	Annex G. Medical Device Component

Post-event management & Health effects

- The problem was resolved by changing the tubing line and the dialyzer to a new product from a different lot.
- No significant health complications occurred, but the patient complained about the delay.

Select the most appropriate IMDRF code for the above description.	
Annex E. Clinical Signs and Symptoms	Annex F. Health Impact

2023 SCH Medical Device CoE Training

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Investigation (Cause, Improvements)

- The investigator examined the tubing lines from the same lot and found micro-holes from the tubing line, which may have occurred due to abnormalities in the mold during the manufacturing process.
- Recall all tubing lines of the same lot, check the manufacturing process, take corrective actions and preventive actions.

Select the most appropriate IMDRF code for the above description.		
Annex B. Type of Investigation	Annex C. Investigation Findings	Annex D. Investigation Conclusion

