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PATIENT SAFETY NETWORK

The Unfamiliar Catheter

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The Case

A 28-year-old woman, 20 months post–bilateral lung transplant, presented to the emergency department with sudden onset of severe shortness of breath and was admitted to the hospital. Diagnostic studies revealed that she was producing donor-specific antibodies. A large bore central line, similar to a hemodialysis catheter, was placed in her right chest, and daily bedside plasmapheresis therapy was initiated as treatment for humeral rejection.

A registered nurse (RN) received orders to draw the patient's morning labs. Although she had worked with many other types of catheters, the RN asked the charge nurse for instructions because she had no previous experience with this type of catheter. The charge nurse provided the RN with the following basic verbal instructions: waste 3 cc, draw labs, flush with saline, HEP-LOCK. The RN felt confident that the verbal instructions were sufficient.

The patient was awake and in no apparent distress when the RN entered her room. The two chatted as the RN drew the patient's labs. After all the tubes had been filled the patient sat upright and said, "Something isn't right." As the RN reached around the bedside table to grab the saline flush, the patient began to convulse. The RN called for help as the patient lost consciousness and fell, bleeding from her catheter, to the floor. The patient spent the next 3 days in the intensive care unit (ICU). She was conscious yet unable to respond for the first 24 hours. Testing revealed a cerebral air embolism, and the medical opinion was that damage was likely to be temporary.

The nurse manager conducted an immediate and thorough incident review, which revealed that the RN had failed to clamp the catheter prior to removing the syringe, thus allowing air to enter the catheter and obstruct the patient's circulatory system. The devastated RN requested a temporary leave of absence, but never returned to work. The hospital enacted a policy allowing only trained RNs to access the catheters and requiring all RNs to receive mandatory education.

The Commentary

This case demonstrates that misuse of an unfamiliar medical device can lead to potentially devastating patient injury and secondary emotional trauma for the involved health care professional. The nurse's lack of familiarity with the specific type of central venous catheter (CVC) and improper technique for obtaining samples from the CVC (failing to clamp catheter before removing the syringe) caused the patient to have an air embolism.

Central venous catheters are placed directly into the central veins, usually the subclavian, internal jugular, and common femoral vein. The many varieties and brands of CVCs include disposable single-, double-, triple-, and quad-lumen catheters, and they come in different colors, sizes, and tube lengths. Each lumen of a multi-lumen catheter is used for a different purpose, such as sampling, total parenteral nutrition, medication, and blood administration. Several types of needleless access devices, such as, negative-, positive-, or neutral-displacement connectors are available to connect at the end of each lumen. The main purpose of these connectors is to prevent reflux of blood or fluids into the CVC lumen after flushing or drawing labs. They contain a mechanical valve that controls the flow of fluid in both directions for infusion and aspiration. Negative fluid displacement connectors allow blood to be pulled back into the catheter lumen as the syringe is withdrawn. Positive fluid displacement connectors allow fluid to be pushed out to the catheter lumen to overcome the reflux of blood that has occurred. Neutral fluid displacement connectors prevent blood reflux on connection and disconnection. Techniques for accessing a CVC vary based on the type of connector used. For example, negative displacement connectors must be clamped *before* disconnecting the syringe and positive connectors clamped *after* disconnecting the syringe. The clamping sequence does not matter for neutral displacement catheters, although clamping these catheters is recommended to enhance patient safety.(1-4) The hospital's review of this incident suggests that a negative displacement connector may have been connected to the CVC lumen and that the nurse failed to clamp the catheter prior to removing the syringe from the connector.

Performing clinical tasks related to the use of medical devices without previously demonstrating competency puts patients at risk and may also expose the clinician to liability. The Joint Commission requires that hospitals use the following standards for staff competencies, including competency in medical device use:

- The hospital defines the competencies it requires of its staff who provide patient care, treatment, or services.
- The hospital uses assessment methods to determine the individual's competence in the skills being assessed. Methods may include test taking, return demonstration, or the use of simulation.
- An individual with the educational background, experience, or knowledge related to the skills being reviewed assesses competence. When a suitable individual cannot be found to assess staff competence, the hospital can utilize an outside individual for this task. Alternatively, the hospital may consult the competency guidelines from an appropriate professional organization to make its assessment.
- Staff competence is initially assessed and documented as part of orientation.
- Staff competence is assessed and documented once every 3 years, or more frequently as required by hospital policy or in accordance with law and regulation.
- The hospital takes action when a staff member's competence does not meet expectations.(5)

If a clinician is not competent in the use of a device, he or she should seek assistance from someone who is competent.(6) In this case, the nurse did seek help, which is praiseworthy. However, the verbal instructions she received were scanty, and specifically did not address clamping the catheter prior to removing the syringe. A more thorough assessment of the nurse's competency in the skill and review of the protocol were indicated, perhaps by having the nurse repeat back the instructions in her own words. Moreover, the nurse should have been supervised by an experienced mentor in the first use of the unfamiliar device.

The potential for device misuse errors is high because medical device technology continually evolves and because nurses move from one unit or hospital to another, where devices may be similar in design but have significant differences for safe use.(7) Regardless of the nurse's area of practice, every nurse who cares for patients with a CVC should be familiar with their organization's policies and procedures and use best practices when managing a patient with a CVC.(8) This may not always occur. In one hospital, direct observation of 50 nurses flushing a CVC with a positive pressure adapter revealed that 56% of them incorrectly performed the clamping and syringe attachment/removal sequence. Following education, 100% of the nurses were aware of the correct clamping sequence, and 80% performed the procedure correctly.(3) It is critical that the clinician know which of the displacement connectors requires clamping and in what sequence during the CVC access procedure. Step-by-step instructions on how to obtain a blood specimen from a CVC, including withdrawing the syringe and clamping the catheter if indicated, are available for instruction and reference.(9)

Quality control initiatives that align with nursing practice and patient safety can help mitigate the high level of medical error risk presented by devices.(10) In this case, it appears that an institutional policy for care and maintenance of CVCs was not developed and implemented until after the tragic event. A detailed discussion of the intended use, how to operate the device, the actual or potential risks associated with the device, and knowledge of how users may make mistakes (i.e., forgetting to clamp the catheter when certain adapters are used) is important in promoting safe use of medical devices.(6,7,11) It should be expected that nurses perform only the aspects of care and maintenance for CVCs for which they have been trained and obtained experience.(7,8,12) Such training might include competency training, simulation testing, mentoring programs, and lectures on patient safety and medical errors.(3,8,12,13)

Nurse-led vascular access teams, with backgrounds in critical care and with peripheral venous and arterial cannulation skills, have been shown to improve patient outcomes.(14) In addition, health professionals from a variety of disciplines may pursue vascular access certification to improve research and evidence-based practice, professionalism, and safe and responsible practice.(15) Vascular Access Certification Corporation (VACC) and Certified PICC Ultrasound Insertion (CPUI) are two such certification programs.(15,16)

Can we design devices to be more resistant to user error? Understanding the complexity of medical devices and the problems users may have in following the correct procedures and steps can help decrease risks to patients. The mission of the FDA's Center for Devices and Radiological Health (CDRH), the Office of Surveillance and Biometrics (OSB), and the CDRH Human Factors Premarket Review Team (HFRT) is to promote the safe use of medical devices. HFRT provides human factors review and guidance on medical device applications submitted by manufacturers prior to going to market and specifically promotes good human factors manufacturing techniques and validation of device usability to aid in avoiding user error with

medical devices. In 2011, the FDA developed guidance to assist the medical device industry in conducting human factors testing. The guidance is intended to improve the usability of medical devices to reduce user error, injuries from medical devices, and product recalls. The user's physical, perceptual, and cognitive abilities; the clinical environment; interactions with the device knobs, dials, switches, buttons, and connections; and the device's visual, auditory, and tactile outputs are considered in HFRT's review process.(17) Although it is difficult to anticipate all hazards, the team applies multiple analytical techniques to identify risks associated with device use when the device is still in the development stage. In addition, the FDA Quality System Regulation for medical device design requirements includes "needs of the user and patient" and discusses performance criteria, defined user needs and intended uses, testing of production units under actual or simulated use conditions, software validation, and risk analysis.(18)

Finally, the patient was not the only one harmed in this adverse event. The nurse was the second victim. A second victim (19) is a health care provider involved in an adverse event or medical error who becomes traumatized by it. Second victims often "feel personally responsible for the unexpected outcomes and feel as though they had failed their patients, second-guessing their clinical skills and knowledge base."(20,21) We don't know the full impact of user error on the nurse in this case study, nor do we know what, if any, counseling intervention she received. What we do know is that she took a temporary leave of absence and never returned to the hospital. Better training, credentialing, and oversight might have prevented harm befalling two people in this case: the patient and the nurse herself.

Take-Home Points

- Unfamiliarity with a CVC can lead to a serious patient injury and have a profound effect on the clinician involved.
- Nurses have a responsibility for maintaining competency and should only use devices for which they have received comprehensive education and training.
- Health care institutions must provide adequate training and should have in place robust quality control programs to promote patient safety when using CVCs.
- Medical device related deaths and injuries should be reported to the FDA.
- Post-incident activities should include a thorough incident review and a positive intervention to help the clinician(s) involved in device errors.

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