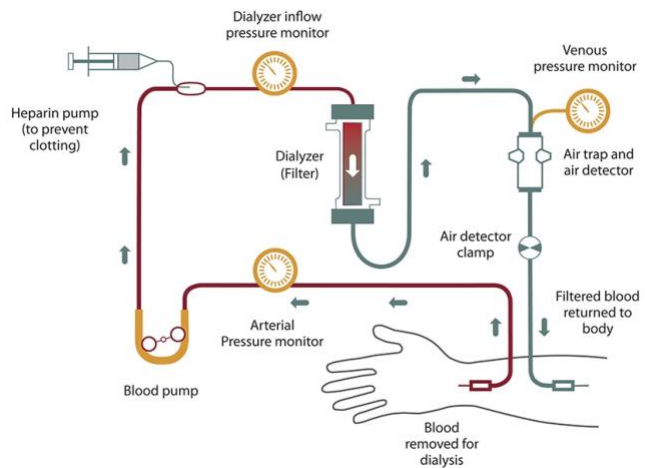


Venous Needle Dislodgement: A Risk Which Can Be Managed for Kidney Patients

Your kidneys filter your blood by removing waste and extra water to make urine. An estimated 37 million adults in the United States have chronic kidney disease (also known as CKD) and for nearly 800,000 adults in the U.S., kidney diseases progress to kidney failure (also known as end stage renal disease or ESRD), a life-threatening condition which requires management by a kidney transplant or dialysis.

Kidney diseases are most common in those over the age of 65 and among those with Medicare. The National Health and Nutrition Examination Survey (NHANES) data (2015-2018) show Black Americans are the most heavily impacted (43.3 percent), followed by Hispanic Americans (37.2 percent) and White Americans (37.1 percent).



Dialysis, the most common therapy to manage kidney failure, mimics some functions of the kidney, keeping the body in balance by 1) removing waste, salt and extra water to prevent them from building up in the body, 2) keeping a safe level of certain chemicals in your blood, such as potassium, sodium and bicarbonate, and 3) helping to control blood pressure.

Dialysis works by pumping the blood of a person with kidney failure through a specialized filter and back into the patient's body. While kidneys filter the blood continuously, dialysis is commonly performed in a 3–5-hour session 3-4 times per week. In order to obtain an appropriate level of filtration, the entire blood supply of a person receiving dialysis is passed through a dialysis machine every 10 minutes, meaning dislodgment of the venous needle that connects a person's body to the dialysis machine can have deadly consequences very quickly.

Venous Needle Dislodgement (VND)

VND is one of the most challenging safety monitoring problems for hemodialysis patients. Venous pressures typically exhibit minimal changes with disconnection, and life-threatening blood loss can happen fast, often within a few minutes. Research has indicated that three (3) people in the United States die every week due to VND, and an additional three (3) people experience serious bleeding issues every day during dialysis. However, there is no requirement to report VND incidents, thus reliable data is limited.

This risk is higher for those who dialyze at home who may be alone or sleeping during treatments. The costs associated with this preventable complication are often significant, requiring emergency interventions, as a patient can quickly lose 40 percent of their blood in approximately 4 minutes if not quickly detected. Treating the most significant hemorrhagic shock often requires multiple days in and out of the intensive care unit and the cost can easily exceed more than \$100,000 per episode.

Current Risk Mitigation

- Keep the vascular access site and bloodline connections visible at all times (blanket and clothing off of the vascular access site)
- Proper needle, catheter and bloodline securement (tape technique)
- Technicians and nurses monitor all individuals during their 3-4 hour dialysis session
- Current FDA cleared hemodialysis machines are equipped with standard arterial and venous pressure alarms but may not detect all VND or ABLs.
- Use of an FDA cleared device to detect blood loss from venous needle and catheter bloodline disconnection. The system consists of a patented fiber optic sensor, designed for either venous needle or central venous catheter, which is connected to an alarm unit.

If you would like to know more about VND and the risks for kidney patients, please contact the following:

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