

Technology and Risk **Implanted Pain Pumps**

An Oregon hospital has reported to the Patient Safety Commission that it has had an incident involving an implanted pain control device. The patient suffered no permanent harm, but the reporting hospital believes underscoring the risk involved in refilling the device is important to prevent future occurrences.



Why we are sharing this information: While this incident was associated with a procedure that is uncommon, the associated risks are very high. Implanted pumps are used to deliver medication into the intrathecal space to treat pain, spasticity, and cancer. Because the pump is inserted below the skin, the port used to refill the pump is not visible and is identified using a template provided by the manufacturer. The pump does not have an internal sensor to indicate the level of fluid in the reservoir, so does not provide feedback. The identified risk is that medication could be instilled into surrounding tissue if the port is not accessed.

What happened: A regular patient at this facility came in for refill of his pain pump as he had monthly for over a year. In performing the procedure, the RN had some difficulty in accessing the port; however she aspirated the expected amount of fluid to indicate the port had been successfully accessed. While the medication was being instilled, the patient noted some stinging and felt that “this isn’t right” but did not say anything. The medication, instead of going into the reservoir, apparently went into the surrounding tissue. The patient then went to physical therapy where he soon became symptomatic. He was taken to the ED where he was treated and admitted. He was discharged without permanent harm.

Findings (based on work done by the reporting hospital):

- ◆ The RN had prior experience in the procedure and had been trained, but did not perform the procedure frequently.
- ◆ There was no staff with more experience in the procedure available at the time to assist.
- ◆ Access of the port was difficult due to the depth and position of the device.
- ◆ The device does not have an internal sensor alert to indicate level of fluid in the pump.

Additional Information:

We contacted several infusion services and the [Infusion Nursing Society](#) as well as the manufacturer in order to understand this event and its implications for patients. This is a high risk, low volume procedure preferentially performed in pain clinics with a large patient caseload. The manufacturer trains nurses to use the device and is available for updating competencies. They also have DVDs and other training materials available for on-site resources. We have no information from the manufacturer regarding any next generation devices that would signal the provider if the reservoir was not filling. The manufacturer encourages comments and provides a website for questions, suggestions or requests at <http://www.medtronic.com/corporate/contact.jsp>

Nurses performing the procedure need to be specifically trained in the complexities of the device and the refilling procedures. No standards currently exist for maintaining competency in the procedure; (opinions expressed ranged from 7-12 procedures/year needed to maintain competency). The nurse experts we spoke with offered opinions and recommendations which we share below:

Recommendations:

- ◆ Only specially-trained nurses should perform the procedure and do so with enough frequency to maintain skills.
- ◆ When access is difficult, or a new patient is admitted to the service, two nurses should be present, allowing for a double check for port access.
- ◆ A longer needle is available from the company in addition to the standard length needle and should be used if there is any concern or question regarding the depth of the port.
- ◆ If concern over access remains, do not infuse and consider fluoroscopy if available, or refer to more experienced provider, either physician or trained RN.
- ◆ Include patient in the procedure and encourage comments regarding any symptoms experienced. Ask patient if experiencing any tingling or other unusual sensation during the infusion.
- ◆ Contact the manufacturer to encourage development of a pump which provides feedback indicating the fluid level in the reservoir.

Contact us!

If your hospital has observations, or lessons learned that can improve patient safety, please call Leslie Ray at 503.224.9227. In addition, we can connect you to other experts willing to analyze your particular situation. All information will be kept confidential.