

IV Tubing Management System

Problem Description

Children admitted to the neonatal intensive care unit (NICU) are often placed on several lines of intravenous (IV) drug delivery. The number of IV lines can range from 3-10 per patient. These lines must be managed carefully to prevent disconnection from the patient or disruption to the liquid flow within the tubing. When NICU patients are sent for magnetic resonance imaging (MRI), the nurses and staff must complete the imaging procedure while ensuring that the patients maintain a connection to their IV lines. Safety restrictions for metal materials in the MRI room prohibit the medicine pumps from moving past the safety doors in the control room. For this reason, patients undergoing MR imaging must be attached to long IV lines (25 feet) [1] to avoid magnetization of the equipment. The patients must be attached to the long IV tubing before the nurses maneuver them from a hospital bed to the MRI bed. Following the procedure, the patient must be maneuvered back to the hospital bed and returned to their room all while maintaining a connection to the fluids.

During this process, the long IV tubes can be difficult to manage, and the tubing often becomes entangled. This tangling increases the occurrence of occlusions, preventing patients from receiving their intended fluid therapy until the occlusion is found. Disconnecting the tubing for de-tangling can expose the lines and the patients to bacteria from the environment, increasing the risk of infections. IV-line entanglement also disrupts the clinical workflow of the nurses, who spend considerable time and effort to free the lines from tangles. Nurses can spend up to an hour untangling lines after the MRI is complete [1].

If two NICU MRIs were done a day, nurses then spend 730 hours each year untangling IV lines. In the United States the average annual salary for nurses is \$73,550 which is an average of \$35.36 an hour [2]. Based on the average annual salary of nurses in the United States, this results in an approximate total of \$25,812.80 spent untangling lines each year at a single hospital. As of 2013 there were 983 hospitals with NICUs with a comprised total of 21,854 beds [3]. The number of beds increased 46% since the year 2000 with a growth rate of 2.4% per year.

Pathway to Implementation

This device has been developed and guided by following the FDA Medical design controls. Based on information from the client and clinical observations, the user needs were thoroughly understood. Requirements were developed based on the needs that were determined. The design of the prototype went through a rapid prototyping process. The next steps require evaluations of the design by conducting verification testing to ensure that the design meets these requirements. Part of these tests will include getting the device in the hands of nurses to provide feedback on usability to determine if the optimal prototype has been reached.

After verification, the team will begin validation testing. The testing will be completed with nurses to ensure that the design meets the end user's needs. The nurses will help the team deliver a useful and effective product. After validation testing, the team will determine freedom to operate with such a device system as well as patentability. The device is a class I medical device, and is 510(k) exempt. The fabrication process will be changed from 3D printing and modified to fit to a process that is easily mass produced by a manufacturer. Once the device is ready to mass produce the product can be licensed, sold, and used in NICUs around the country.

References

1. Kaseman, Sheila. Tangle Free MRI Medication Extension Tubing. [PowerPoint Presentation.]
2. RN-Salary - How Much Do Registered Nurses Make 2019. (n.d.). Retrieved November 13, 2019, from <https://nursesalaryguide.net/registered-nurse-rn-salary/>.
3. Munz, M. (2015, November 29). More Babies Are Going to the NICU and More than Half are Underweight Study Finds. Retrieved February 16, 2019, from https://www.stltoday.com/lifestyles/health-med-fit/health/more-babies-going-to-the-nicu-and-more-than-half/article_03b339e0-0be1-5d99-ad38-9a17f54311e5.html