Medical Product Safety Network (MedSun) Final Survey Report
Topic: Syringe Pump Survey
Year Conducted: 2015

Introduction

Syringe pumps are a type of infusion pump used to deliver fluids such as medications, nutritional liquids such as breast milk or formula, and blood/blood products to patients. They are used extensively in the care of children, infants and newborns in areas of the hospital such as Pediatric Intensive Care Units, Neonatal Intensive Care Units and Emergency Departments.

In 2015, in response to medical device adverse event reports received from hospitals and review of professional literature, FDA staff from the Center for Devices and Radiological Health wanted to learn about experience with syringe pumps from the perspective of hospital-based Pediatric Intensive Care Unit (PICU) and/or Neonatal Intensive Care Unit (NICU) nurses who use them extensively. This effort was a part of FDA's ongoing efforts to ensure the safety and effectiveness of medical devices.

FDA staff recruited PICU/NICU nurses to respond to a questionnaire concerning their use of syringe pumps and especially their experience, if any, related to problems with delay of therapy (such as for delivery of pain medication or blood pressure medication) when syringe pumps were used with low volumes of medications infused at low rates (defined as less than 1 or 2 mL of medication per hour). The questions covered the respondents' clinical background, the types of syringe pumps and accessories for those pumps (e.g., tubing and syringes) that were used recently by the respondents, how long they had used the pumps, training provided for use of the pumps especially with low volumes of medications, the accessibility and use of Instructions for Use/Quick Reference Guides for the pumps, preparatory steps taken for activities such as priming the tubing, whether they had experience with and/or knowledge about delay of therapy issues using syringe pumps at low volumes, and comments concerning syringe pump use.

Methodology

A small sample of hospitals that participate in FDA's Medical Product Safety Network (MedSun) was selected for survey recruitment based on their size, location and likelihood of using syringe pumps for the care of pediatric and/or newborn patients. From late June to late July 2015, 7 NICU nurses were interviewed, and 2 additional nurses responded in writing. Two of the nurses who responded indicated that they were considered PICU/NICU nurses because their work was with pediatric patients as well as with newborns. In total, 9 responses came from nurses in 8 hospitals across the U.S. Although one of the hospitals was a pediatric hospital, the other 7 were acute care hospitals that included Neonatal Intensive Care Units (whether or not they provided any other pediatric care). The sites included two university-based hospitals. The hospitals that responded all had at least 150 beds, with two being large (over 400 total beds); the hospitals had NICU units of approximately 20 to 75 patients each, and at least two hospitals had more than one NICU.

Overview of Responses:

Level of Clinical Experience of the Respondents:

The majority of respondents had at least 7 years of NICU-based clinical nursing experience, with at least two having over 30 years of NICU and/or combination NICU/PICU nursing experience. One respondent was a Clinical Educator for her hospital's NICU staff. In some cases, NICU managers and/or other nursing leaders participated in

the calls; these calls involved 2-4 hospital staff, and always included at least one NICU nurse as the primary respondent.

Syringe Pumps Used:

In most cases, the respondents indicated that their NICUs used either the Alaris 8110 syringe pump from CareFusion or the Medfusion 3500 syringe pump from Smiths Medical. In some cases, while the Alaris or Medfusion pumps were used for a wide variety of medications and other fluids (such as antibiotics, epinephrine, norepinephrine, normal saline, and blood products), other pumps were used for feeding (e.g., the ABC pump or the Medela pump). In one case the Alaris 8110 was used for NICU syringe pump use, whereas the Medfusion 3500 was used when the patient was being transported.

Two hospitals indicated that they used color coding systems to distinguish between their syringe pumps used for feeding and syringe pumps used for medications/blood/other non-feeding products in order to avoid dangerous misconnections (such as infusing breast milk into an IV line). Notably the color for the pumps/tubing/syringes for feeding was orange in one hospital and purple in another hospital that used the color coding, indicating that the color coding is not consistent across hospitals in the US. One hospital indicated that they have a standard practice of having the syringe pump used for feeding located at a certain end of the patient's bed, whereas the syringe pump for medication infusion is always supposed to be located at the other end of the bed.

One nurse interviewed said that she thought her hospital was going to switch from use of the Medfusion pumps to the Alaris pumps because of the high percentage of NICUs in the nation that use the Alaris pump, but they would research the pumps first.

One hospital's respondents indicated that they had moved away from the Alaris 8110 syringe pump to the Medfusion 3500 approximately 3 months before the interview due to problems they experienced with delay of therapy with low volumes of medication. They indicated that Alaris staff came on site for one week to troubleshoot the problem without success, and then the hospital made the decision not to use the Alaris syringe pumps in the Critical Care (including NICU), OR, or ED settings, although they are still using them in acute care areas of the hospital. The troubleshooting effort that Alaris staff worked on with the hospital staff involved investigating any problems with the manifolds, using different manifolds, removing the manifolds, using a different sensing disc, using catch up valves for vasoactive drugs, and using smaller syringes. This hospital had been using the priming feature on the pump (rather than priming manually as described by nurses in other hospitals).

Availability and Use of Instructions for Use (IFU) and Quick Reference Guides:

Although many of the nurses indicated that there were Instructions for Use and/or a Quick Reference Guide available in their NICU, generally they did not read them or refer to them. One nurse indicated that the new nurses use these materials until they become experienced, while another nurse indicated that once their NICU staff learn to use the pumps, they do not use these materials. In some interviews, the nurses indicated that they did not have Instructions for Use or Quick Reference Guides available.

Training concerning Use of Syringe Pumps with Low Volumes of Medications:

The respondents were asked to describe the types of training they had received for use of the syringe pumps. The training may have been provided by manufacturer representatives, hospital staff or both. The respondents described the types of training provided by manufacturers or by hospital "superusers" when the pumps were purchased. Staff who joined the NICU staff several years after the purchase indicated that they received less training or no training from the manufacturers or from hospital clinical educators.

One hospital that had experienced significant problems with using the Alaris 8110 said that they had received "little information" from CareFusion about infusion at low rates, and that their representatives had "trouble defining low rates," using less than 3 mL/hour in some cases and less than 1 mL in other cases (with similar discrepancies in some of their written materials according to this hospital).

Generally the respondents who used the Medfusion pumps indicated that they had received some training concerning use of that syringe pump with low volumes of medications, and they described what that training included (e.g., checklists, information about using the smallest syringe size that can be used when infusing low volumes, reducing the tubing length and diameter to accommodate low volume infusions, and information about priming on the pump).

Preparation Steps/Set-up Procedures:

Most of the nurses included in the survey indicated that they prefer to prime the tubing for the fluids to be infused using a manual procedure rather than use what they consider to be a more time-consuming process of priming the tubing using the syringe pump priming feature. They said they found the manual priming to be very quick (taking only seconds) and some nurses indicated they had more confidence in the priming if they had done it themselves.

Several nurses described the practice of two pumps running simultaneously in preparation for changeover of the patient's tubing to avoid problems with delay of therapy. One nurse indicated that this had been a very common practice by their NICU nurses, some of whom had first-hand experience with problems of delay in therapy, when they used the Alaris 8110 syringe pump but that the practice had been used less often since they changed to the Medfusion 3500 pump and "staff had more confidence" in the timing for the delivery of the low-volume medications. (They still use the two pumps for very critically ill patients who cannot tolerate a delay.) Note that a NICU nurse with over 30 years of experience who worked at another hospital that uses the Medfusion pump said that she used the 2-pump method frequently to ensure smooth transitions when tubing was being changed. Other nurses pointed out workarounds to avoid problems when tubing is not vertically aligned and the need to "prop up" pump tubing with gauze in some cases.

The nurses described steps they used to minimize the chances of delay in therapy. These steps included using syringes that are as small as possible to optimize medication delivery (coordinating with Pharmacy to provide a smaller pre-filled syringe as needed), making sure that they are using the right size of tubing for the situation, minimizing the distance between the pump and the patient, and using the 2-pump system described above when needed to prepare for periodic changeover of the patient's tubing.

Two hospitals described detailed charts that the nurses received to determine the proper doses for the weight of the patient that had been developed for their hospitals. In one case, the nurse provided examples of these charts, which had been developed by an interdisciplinary team of healthcare professionals specifically for their hospital, to FDA staff.

Experience With/Knowledge of Possible Delay in Therapy with Low Volume Medication Infusions:

Three of the nurses interviewed said they had experienced or seen first-hand a problem with delay in therapy when low volumes of medications were being infused using syringe pumps. Of the remaining respondents, approximately one-half had not experienced cases of delay in therapy but had heard/read something about the problem, and the other half said they did not know about the potential for delay in therapy with low volumes of medications.

Lengths of Tubing Used/Sizes of Tubing Used and Types and Sizes of Syringes Used:

Generally the respondents said that they used tubing that was either 59 inches long or 60 inches long, although other lengths were available as needed. Although the questions did not ask about specific diameters for the tubing, at least one hospital volunteered that they used microbore tubing with their syringe pumps. Another nurse provided the following specifics concerning tubing that her hospital used:

> (We use) 0.28 mL tubing for intermittent medications, (and) 0.8mL tubing with stopcock for continuous medication drips used on syringe pumps - both of these with a filter. Blood products use 2mL tubing with no filter.

Respondents said they used several sizes of syringes depending on the specific needs (generally sizes 1, 3, 5, or 10 mL for specific medication/feeding uses, and larger sizes such as 20 and 30 mL for use with blood/blood products). The BD ((Becton, Dickenson and Company) 1 mL syringes presented problems when used with the pumps at certain sites, as shown below:

> We have (experienced delay of therapy) a few times …with our BD 1mL syringes for IV that do not work well on the (Medfusion) pump. They alarm frequently "not reading"; many times we push the medication and put a flush …Other issues we have had were with our continuous sedation drips. If a slow rate was used, which is usual, we have had the fluid back up in the line and see blood backing up. The pump was infusing at 0.15 -0.5mL per hour. We have since changed to different filters (and) that should help.

There were consequences for the baby when this happened, as shown below:

> This baby did not receive his/her medication as it was backing up blood in the tubing. The baby was agitated, with higher pain scores. Sometimes we have to elevate our tubing with blankets (or) gauze, if they are running at low rates of infusion, as the (parenteral nutrition) or large volume fluids will back up in our IV tubing of our syringe pump fluid.

The nurses interviewed indicated that they generally used BD syringes with their syringe pumps, again in various sizes, and generally used a standard size syringe for drips (which differed among the hospitals in the survey). Some sites used Monoject syringes on their NICU feeding pumps and BD syringes for syringe pumps used in patient transport. The choice for the specific tubing and other accessories often depended on the hospitals' purchasing policies for such products, as well as compatibility with the pump.

Although one hospital indicated that their NICU staff sometimes transferred fluids such as medications into smaller syringes in the NICU as needed, most of the nurses interviewed indicated that if they needed a change to a different size of syringe (e.g., smaller syringe), their Pharmacy staff would provide it. One nurse indicated that they have a Pharmacy representative located in and assigned to the NICU. Another site indicated that their NICU nurses (rather than Pharmacy, as was generally the case) sometimes transferred fluids from larger syringes to smaller syringes in the Unit.

Other Comments:

One hospital that had experienced problems with the Alaris pump mentioned that they had received a Product Information Safety Sheet from CareFusion that they will forward to FDA, and an article about the pulsating action of various brands of syringe pumps that they will also send.

Several of the NICU nurses indicated how much they liked using syringe pumps with their patients, and the significant advantages they found with some of the pump features such as Guardrails (i.e., drug library dose error reduction software) and settings for NICU use.

One NICU nurse mentioned the difference in the number of decimal places for settings on the Medfusion 3500 pump (display shows to one-thousandth or 0.00x mL/hour) vs. the Alaris 8110 (display shows to one one-hundredth mL/hour or 0.0x).

Summary

The respondents to this survey provided a great deal of detailed information for FDA's research into the use of syringe pumps at low rates. Generally the NICU nurses that we spoke with did not make use of the Instructions for Use or Quick Reference Guides except perhaps in the early weeks of learning to use a new syringe pump or for troubleshooting purposes. They indicated that for some pumps, they received relatively little formal training but instead depended on their own experience and the experienced nurses in their units to help them address problems that came up with the use of syringe pumps.

Providing information about the possible problems with syringe pumps when they are identified emerged as an issue that needs to be addressed. A hospital that had experienced significant problems with the Alaris 8110 pump expressed concern about other hospitals serving pediatric patients that used that pump not knowing about the possible problems such as delay of therapy with low volume infusions. In contrast, sites that had not directly experienced problems with delay of therapy related to low volume medications delivered through syringe pumps indicated that the nurses who saw those problems "may not be priming the tubing correctly" or otherwise may be making errors in their set up or operations of the pumps. Some of these hospitals reported that they practiced the dual pump method when changing out medications for hemodynamically unstable patients.

The survey provides information that may lead to further data collection regarding problems with specific syringe pumps and the steps that hospital staff take to avoid them or address them if they occur.

Survey Limitations

Although the findings add to FDA's knowledge of hospitals' purchases and uses of syringe pumps, there are several limitations to the survey methodology. These include the small convenience sample of respondents and the challenge with obtaining specific product information from hospitals. In view of these limitations, the respondents' perspectives may not represent the perspectives of all device users.

Therefore, these findings represent only one piece of information. No conclusions can be made based on this report alone. Instead, the report should be considered along with other information that may include adverse event reports, scientific publications, clinical trials, enforcement/compliance information, and other data sources that are part of FDA's monitoring of device performance.

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Surveying device users is one of many tools the FDA uses to evaluate the public health impact of potential problems associated with the use of medical devices. Typically, small sample surveys are used to collect qualitative information on post-market experiences of clinicians or facilities with medical device performance or use. The FDA selects survey respondents based on their experience with the topic or device, their availability, and their willingness to participate.

The FDA makes our scientific, medical, nursing, and engineering staff aware of the survey results as needed. If the FDA believes there is a significant risk of adverse events as noted from the survey, we will combine those results with data gained from other sources. The FDA will work with the manufacturers and health care provider organizations to make important information known to the clinical community. Additionally, the FDA continues to work with manufacturers to ensure the development, testing, and promulgation of methods for reducing the risk associated with these devices and to minimize the complications from adverse events that may occur in the course of normal usage. If the results of any survey raise serious concerns about the safety of these devices, the FDA may convene a group of clinical, scientific, and regulatory experts to discuss any necessary action.