



# KidNet Roundtable

October 15, 2007

# KidNet most frequently reported devices by device type

- Report received from MedSun KidNet sites with patient ages listed as <21 years

6-1-2007 to 9-25-2007:

- |                     |      |
|---------------------|------|
|                     | n=42 |
| • IV Products       | n=17 |
| • Surgical Products | n=11 |
| • CV Products       | n=10 |
| • All others        | n= 4 |

# KidNet most frequently reported devices by device type

- IV Products n=17
  - IV tubing, filters 6
  - IV pumps (large volume, syringe) 5
  - IV catheters (short term) 3
  - CVCs, PICCs and Ports 3

# KidNet most frequently reported devices by device type

- Surgical Devices n=11
  - Orthopedic screw 2
  - Spinal system hardware 1
  - Intraventricular shunt 1
  - Laryngoscope handle 1
  - OR table 1
  - Surgical blade 1
  - Hydrosurgery handpiece 1
  - Dissecting forceps 1
  - Microscope, ENT 1
  - Guidewire, biliary 1

# KidNet most frequently reported devices by device type

- Cardiovascular Devices n=10
  - Pediatric ECG electrode 6
  - ECMO pump 2
  - Septal Occluder 1
  - Pulmonary valved graft conduit 1

# KidNet most frequently reported devices by device type

- All others n=4
  - Nebulizer 2
  - Crib 1
  - Echocardiography-Ultrasound 1

# KidNet - top 2 reported devices

- A note about our the types of reported problems for IV products and pediatric electrodes

# IV Products

- Reported catheter and port problems include cracks in hubs, disconnection of filters, cracks or disconnections in ports, bent needles, and a PICC line severing below the stabilizing wings.
- Reported IV tubing problems— disconnections, leaks (at the hub), fluid delivery issues (fluid backing up into the primary bag), and packaging (one set had no tubing in it when opened).
- Recent reported problems with pumps include fluids being infused too rapidly or not at the programmed rate, or the pump spontaneously shutting-down.

# IV Products – Recent Successful follow-up

## Syringe Infusion Pump

- A report described a pump failure whereby the motor shut down when the patient was walking outdoors in the sunlight under nursing supervision. The reporting hospital indicated the pump manufacturer had identified a defect causing the motor to shut down in extreme sunlight, which could be corrected by installation of a shield over the motor case. FDA follow-up with the manufacturer resulted in the manufacturer sending a letter to all customers asking them to obtain an update kit with a shield or to return these pumps to the manufacturer for retro-fitting.

# IV Products – Recent Successful follow-up

## Syringe Pump

- A pediatric patient was found holding a syringe of medication, while standing in the patient's crib. The syringe of medication had been properly placed in the syringe pump, even though the patient was able to pull on the tubing, reaching the syringe and removing it from the pump. Follow up with the manufacturer indicated that although the event was the only reported issue of this type at the time; a lock box was being created to prevent this issue from reoccurring.
- Before the manufacturer was able to get the lock box mechanism out again, another report of the same thing happening was received from a KidNet hospital this past summer. Our follow-up with the manufacturer was that the manufacturer had been working on it, but the new lock box wasn't complete yet. But by getting the second report on this pediatric syringe pump with the same problem, with a different patient, the manufacturer is now moving forward more quickly.

# Pediatric ECG Electrodes

- *It was reported to MedSun:*
- During a routine assessment it was noted the electrodes were sliding off. Upon removal of the electrodes, small bumps were found on the chest and stomach where the electrodes had been placed. The chest bumps were reddened and one was blistered. The stomach bumps resembled pimples. 6 reports of this problem were reported from a single facility.

# Pediatric ECG Electrodes

- Follow-up with the manufacturer indicates they have had other similar reports. In those cases, the person who attached the electrodes had lotion or an emollient on their hands that had gotten trapped between the electrode and the infant's skin and caused a chemical reaction. In this case, they have been analyzing the electrodes and, so far, have not found anything unusual, but they are continuing their evaluation and analysis.
- The manufacturer has told us that an update will be sent on their progress.

# Recently Received Medical Device Adverse Events

- Ventilator water trap
- Infant warmer mattress

# Ventilator Humidifier Water Trap

- *As reported to MedSun:*

Prior to this incident, the ventilator circuitry had just been changed. The sterile water bag had just been spiked to fill the heater/humidifier water chamber. The float in the water, which controls the water level was stuck. This caused the water to fill the water chamber and flow up into the circuit to the patient, causing a 51 day old patient to de-saturate, and become bradycardiac and cyanotic. The patient was immediately taken off the ventilator and manually ventilated until full recovery, and the water chamber was replaced. According to the hospital's respiratory therapy department, this type of failure is not easily identifiable until the sterile water is added to the circuits, which generally occurs after the patient is on the ventilator. Additionally, depending upon the speed and nature of the defect, it may take anywhere from seconds to hours for the water to fill the heater chamber to a level that will direct water toward the patient.

# Ventilator Humidifier Water Trap

- ***MedSun follow-up with the site reporter indicates:***
- The manufacturer's quality team has received the hospital's report.
- It took less than 5 minutes for the water to fill the heater chamber in the reported incident.
- This exact problem seems to happen once a year or once every other year. As a new risk manager, not sure why this hasn't been reported previously.
- The hospital doesn't think the ventilator circuitry is defective and there are no alarms/alerts to notify staff if the heater overfills – heaters don't have that as an option. There is a high pressure alarm.
- Have you seen this, or a similar problem?

# Infant Warmer Mattress

- Extremely low birthweight infant, born by vaginal delivery with Apgars of 5 at one minute 8 at 5 minutes was delivered and placed on a seated transport Isolette on a infant warmer mattress infant transport mattress, shown to the mom, and wheeled down the hall to the NICU for admission. At that time, the patient was hypothermic with a temperature of 35°C. The infant warmer mattress from the delivery room was placed under the infant when the infant was moved from the transport Isolette to the radiant warmer. The infant was on the radiant warmer for approximately 3 hours following admission. Subsequently, the patient was moved from the radiant warmer to an Isolette without the infant warmer mattress. At the change of shift, nursing staff noted what was thought to be an abrasion on the infant's lower back. Later, the area became more clearly demarcated as a 5 1/2 cm x 3 cm reddened area with a small open area in the lower aspect. It was diagnosed as a 2nd degree burn. A physician assessed the burn and prescribed Bactroban ointment 3 times a day. The burn completely healed without any escalation of care and no skin grafts were required.

# Infant Warmer Mattress

- ***Additional information about the event from the reporting hospital:***
- The event was reported voluntarily because no one at the reporting hospital has ever observed any issues with this product, which is used extensively for neonate after delivery for transport purposes.
- The manufacturer's instructions are that this device will warm to 40°C once the Silver disk is compressed. The unit manager re-created the scenario after the event. She was able to obtain temperature ranges between 40.2°C and 40.6°C taken with the temperature probe beneath the infant warmer gel pad and the mattress, and also on top of the infant warmer mattress patient side surface and the radiant warmer head. It took about five minutes for the device to reach the range of temperatures listed. The patient was placed correctly on the infant warmer mattress patient side surface.

# Infant Warmer Mattress

- Labeling review for the device found the peak temperature of the pad is dependent on the starting temperature of the pad itself.
- Have you seen or experienced this, or a similar problem?
- *A comment forwarded from a MedSun site was then shared about transport isolettes with battery packs not holding their charges. All of the isolettes needed to have the packs replaced.*
- *A MedSun Representative (a clinical engineer) from a pediatric hospital offered to be a resource to others having this difficulty. Those who are interested in the battery issue should contact [tpowell@s-3.com](mailto:tpowell@s-3.com) for more information about how to reach this MedSun Representative.*

# Peds ICU Monitor

- ***A device safety issue recently called in to us by a MedSun hospital:***
- Problems with being “unable to zero- unstable signal” with monitors in a Peds ICU. During the set up procedure using a MMS (multi-measurement server) but not using an invasive blood pressure module, the monitors experience an alarm/alert message “unable to zero - unstable signal. The staff believes that this condition should not be occurring during a procedure set up. The manufacturer has been out to the facility on more than one occasion and has witnessed this happening.
- Do you think this is an equipment (materials, or sensitivity to readings), a procedural issue (zeroing technique), or a patient issue (related to patient movement or size)?
- Have you seen or experienced this, or a similar problem?

*Cont'd on next slide*

# Peds ICU Monitor

- Discussion about specific human factors concerns with the display on specific patient monitors indicated that extensive staff re-training was needed. The MedSun Representative from the pediatric hospital bringing this safety issue to the Roundtable (a clinical engineer) offered to be a resource to others having this difficulty.
- Those who are interested in the further discussion on this hospital's actions taken to resolve the problems related to zero-ing ICU monitors on set-up should contact [tpowell@s-3.com](mailto:tpowell@s-3.com) for more information about how to reach this MedSun Representative.