Infusion Pump Safety Model
Definition of Use
Adapted from Document Provided by the FDA

Overview

For logistic and support reasons, most hospitals select a type and model of infusion pump and then use it in several different applications. Pumps are used for infusing blood products, medication, and simple hydration. The most demanding use of the devices appears to be in the Intensive Care Unit (ICU) of the hospital. In that unit, patients will typically require several infusion lines, and the caregiver will be monitoring and controlling the various infusions in real time to control the patient's vital signs.

Description of Use

The use begins when a patient arrives at the ICU. That patient may already have several IV lines already started and may be receiving several drugs. The attending physician will identify additional medication and direct that one or more additional lines be established. At the hospitals studied, a multi-channel (3) pump will be set up to infuse the additional medications. An ICU nurse, trained in the use of the pump, will set up the pump and will implement the physicians order. For a typical ICU patient, there may be as many as four (4) multi-channel pumps connected at one time.

Once the IV's are started, the ICU caregiver will monitor the patient's vital signs and then adjust the medication dosage rates by controlling the settings on the pumps. Settings may be modified several times during a use. Once the patient is stabilized, the pump will be de-activated one channel at a time.

There are several aspects of this "use" that influence the overall safety of the infusion systems. First, there is a sense of urgency surrounding the care of the patient. There is a temptation to set the parameters of the pump and then operate without any check by an independent observer or by the physician that ordered the medication. Because of the urgency, the desired settings may be transmitted verbally from the physician with no written order as a check on correctness. Second, there is the complexity of the infusion setups themselves. There may be as many as (4) multi-channel pumps connected to the same patient. This could total 12 separate fluids being infused simultaneously. This presents the opportunity that someone could perform the adjustments on the wrong pump, or on the wrong channel of the correct pump. Errors of this type are typically mitigated by good training, good ICU procedure, and the highly responsible work ethic of the ICU personnel.

During a single use of the pump, several people may adjust its parameters. One caregiver may not fully understand all that has happened previously, and may take actions based on faulty assumptions. Again, training and proper procedure mitigate errors of this type.

Mechanical considerations

During the "Setup" of the pump, the nurse will obtain the requested medications, prepare 1,2, or 3 administrative sets, hang the pump on an appropriate support pole and plug the unit into an electric outlet. She may then run the "self-test" feature on the pump if such a feature is available. If satisfied that the pump is functioning properly prior to treating the patient, she will proceed with the infusion setup. Each channel of the pump will be set up sequentially.

The medication that is to be delivered through the first channel (called channel 1 for the purposes of this discussion) will be hung in a convenient location. The nurse will then set the pump parameters for that channel which may include a "start of treatment time", an infusion rate, and possibly a bolus amount or a total amount to be infused. An administrative set will be connected to the medication container. Air will be purged from the lines and the administrative set will be connected into the patient's infusion port. The line will be locked into the pump channel and the pump will remain inactive until started by the operator. The nurse would then set up the second and third channels of the pump in a similar fashion.

Once all of the pump channels are set and the medication is connected in, the nurse will recheck the settings and then press the "confirm settings" key to lock those settings into the unit. Pressing the start button then activates the pump and infusion begins. Infusion will continue until the pump is turned off, the fluid is totally expended, an error condition is recognized, or the "end-of-treatment-time" set into the pump is reached.

During infusion, several external actions may affect the operation of the pump.

1. An infusion line may become pinched causing the flow to be blocked. This will; be recognized by the pump as an occlusion and will cause the pump to alarm.
    a. The mitigation is to straighten the line and re-start the pump.
    b. Care giver may silence the alarm during the procedure
2. The infusion line may become plugged. The pump will recognize an occlusion and alarm.
    a. The mitigation is to clear the infusion lines and re start the pump.
    b. Caregiver may silence the alarm during the procedure
3. Electrical failure may occur causing the pump to switch to battery operation.
    a. Pump will switch over to battery power and notify the caregiver visually.
    b. Caregiver may or may not notice the power source change.
    c. Switch may not occur if the battery is not properly charged.
4. The patient may alter the pump settings either intentionally, or inadvertently.
    a. Mitigation is that the caregiver monitors the pump setting on a regular basis
    b. Caregiver can minimize the chances of patient modification by locking the pump settings
    c. Locking pump settings is rare in a ICU environment
5. Another doctor may modify pump settings without notifying the primary caregiver

a. Mitigation is through practiced teamwork among the ICU team