IV Bags Contaminated with Serratia Marcescens
Alabama
March, 2011

With the aid of the State Health Department and the Centers for Disease Control and Prevention (CDC), six hospitals have traced back recent patient infections to contamination in total parenteral nutrition (TPN) delivered via intravenous (IV) bags. Although the first infection occurred in January, 2011, a pattern was not established until March, 2011, after nineteen patients were infected with serratia marcescens bacteria. Patient infection is an impact to the patient safety goal.

The infections occurred as a result of the patients being given contaminated product, in this case the IV bags. The bags were recalled, and are no longer in production. Ten of the patients died. Investigators have said they won’t be able to determine whether caused the deaths because he patients were already very ill (TNP is used for patients who are too ill to eat on their own), caused the deaths.

The IV bags were compounded at a local pharmacy. There was a potential for contamination in the raw material used for compounding, during the compounding at the pharmacy, or at the hospital. Because six different hospitals experienced the same rare bacterial contamination, it is unlikely that the contamination occurred at the hospital. According to Dr. Alexander J. Kallen, a medical officer with the Centers for Disease Control and Prevention, “Historically, what we’ve seen is a breakdown in the manufacturing process.” The investigation to determine if it was in fact an issue with the manufacturing process, an issue with the sterility of equipment, or a contamination of the raw material. As the investigation continues, even more detail can be added to the Cause Map. As with any investigation the level of detail in the analysis is based on the impact of the incident on the applicable goals.

While investigating an issue, it can also be helpful to look at the process for identifying and isolating issues, and implementing improvements. In this case, after patients receive or use products, they are monitored for certain reactions. If those reactions occur (such as those that indicate a bacterial infection), they are reported to the State Health Department, then the CDC. The CDC investigates to determine the source of the infection, then pulls the affected products off the market. Currently, the CDC has identified the product that is contaminated, though not the source of the contamination. The investigation is continuing.