Pharmaceutical Failure Mode and Effects Analysis
Alpha₁-Proteinase Inhibitor – Human (Prolastin®)

· Step 1:

Describe how the intended product will be procured and used, from acquisition through administration.

Who will prescribe the drug and for what type of patient?
A physician will prescribe α₁-proteinase inhibitors for patients with low levels of α₁-antitrypsin levels (<130 mg/dL) using the approved treatment algorithm.

Where will the drug be stored?
The drug will be stored in the pharmacy storeroom until ordered by the Pulmonary clinic.

Who will prepare and dispense it?
The drug will be prepared by the storeroom technicians and dispensed by a central pharmacist.

How will it be administered?
The medication is administered by IV route at a rate not to exceed 0.08 mL/kg/min. The recommended dosage of 60 mg/kg takes approximately 30 minutes to infuse.

· Step 2:

Identify potential failure modes (how and where systems and processes may fail) while considering how the product will be used.

Could the drug be mistaken for another similarly packaged product?
No – the drug is packaged in a box with 2 vials (medication and diluent).

Does the label clearly express the strength or concentration?
Yes

Does the name sound or look like another drug on the formulary?
No

Are dosing parameters complex?
No

Is the administration process error prone?
Prolastin must be administered within 3 hours after preparation.
· Step 3:

Once failure modes have been identified, determine the likelihood of making a mistake and the potential consequences of an error.

What would happen to the patient if the drug were given in the wrong dose, at the wrong time, to the wrong patient, by the wrong route, at the wrong rate? Deviating from the recommended 60 mg/kg/week regimen may result in serum alpha1-antitrypsin levels less than the protective 80 mg/dL.

· Step 4:

Identify any preexisting processes in place that could help detect the error before it reaches the patient, and evaluate their effectiveness based upon knowledge of human factors.

Medication orders and administration timing are charted in the patient’s medical record.

· Step 5:

If failure modes could cause errors with significant consequences, what actions could be taken to prevent the error, detect it before it reaches the patient, or minimize its consequences? (A few examples include: using an alternative product; preparing the drug in the pharmacy; standardizing drug concentrations, order communication and dosing methods; using auxiliary warning labels or computer alerts; and requiring entry of specific data into computer systems before processing orders).

Administration Information:

What are the most common side effects that Nursing should be aware of to ensure proper monitoring?

The most severe side effect is anaphylaxis or severe anaphylactoid reactions. Should these events occur, the infusion must be discontinued immediately. Epinephrine and other appropriate supportive care should be on hand in case of anaphylactoid emergency. The most common symptoms were pharyngitis, headache, and increased cough.

Is there any associated laboratory monitoring that Nursing should be aware of to ensure proper patient care?

None